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

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2022.

OR

□ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For transition period from ____ to ____.

Commission File Number 001-41463

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

Delaware	**46-5211056**
(State or Other Jurisdiction of Incorporation)	(I.R.S. Employer Identification No.)
22211 W Interstate 10 Suite 1206 San Antonio, Texas	**78257**
(Address of Principal Executive Offices)	(Zip Code)

(210) 698-5334
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.007 per share	BIAF	The Nasdaq Stock Market LLC
Tradeable Warrants to purchase Common Stock	BIAFW	The Nasdaq Stock Market LLC

Securities registered pursuant to section 12(g) of the Act: **None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes □ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes □ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No □

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. □

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. □

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes □ No ☒

The registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and, therefore, cannot calculate the aggregate market value of the voting and non-voting common equity held by non-affiliates as of such date.

The number of shares outstanding of the issuer's common stock, $0.007 par value, is 8,462,953 as of March 20, 2023.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to the 2023 annual meeting of stockholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. Such definitive proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended December 31, 2022.

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Throughout this Annual Report on Form 10-K (the "Annual Report"), the terms "bioAffinity," "bioAffinity Technologies," "we," "us," "our" or "Company" refer to bioAffinity Technologies, Inc., a Delaware corporation, and its wholly owned subsidiary, OncoSelect® Therapeutics, LLC, a Delaware limited liability company.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of the federal securities laws. Forward-looking statements are predictive in nature, depend on or refer to future events or conditions, and are sometimes identified by words such as "may," "could," "plan," "project," "predict," "pursue," "believe," "expect," "estimate," "anticipate," "intend," "target," "seek," "potentially," "will likely result," "outlook," "budget, "objective," "trend," or similar expressions of a forward-looking nature and the negative versions of such expressions. The forward-looking information contained in this report is generally located under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" but may be found in other locations as well. The forward-looking statements in this report generally relate to the plans and objectives for future operations of bioAffinity Technologies, Inc. and are based on our management's reasonable estimates of future results or trends. Although we believe these forward-looking statements are reasonable, all forward-looking statements are subject to various risks and uncertainties, and our projections and expectations may be incorrect. The factors that may affect our expectations regarding our operations include, among others, the following:

- our projected financial position and estimated cash burn rate;
- our estimates regarding expenses, future revenues, and capital requirements;
- the success, cost, and timing of our clinical trials;
- our ability to obtain funding for our operations necessary to complete further development and commercialization of our diagnostic tests or therapeutic product candidates;
- our dependence on third parties in the conduct of our clinical trials;
- our ability to obtain the necessary regulatory approvals to market and commercialize our diagnostic tests or therapeutic product candidates;
- the potential that the results of our pre-clinical and clinical trials indicate our current diagnostic tests or any future diagnostic tests or therapeutic product candidates we may seek to develop are unsafe or ineffective;
- the results of market research conducted by us or others;
- our ability to obtain and maintain intellectual property protection for our current diagnostic tests or future diagnostic and therapeutic product candidates;
- our ability to protect our IP rights and the potential for us to incur substantial costs from lawsuits to enforce or protect our IP rights;
- the possibility that a third party may claim we or our third-party licensors have infringed, misappropriated, or otherwise violated their IP rights and that we may incur substantial costs and be required to devote substantial time defending against such claims;
- our reliance on third parties;
- the success of competing therapies, diagnostic tests, and therapeutic products that are or will become available;
- our ability to expand our organization to accommodate potential growth and to retain and attract key personnel;

- our potential to incur substantial costs resulting from product liability lawsuits against us and the potential for such lawsuits to cause us to limit the commercialization of our diagnostic tests and therapeutic product candidates;

- market acceptance of our diagnostic tests and therapeutic product candidates, the size and growth of the potential markets for our current diagnostic tests and therapeutic product candidates, and any future diagnostic tests and therapeutic product candidates we may seek to develop, and our ability to serve those markets;

- the successful development of our commercialization capabilities, including sales and marketing capabilities;

- compliance with government regulations, including environmental, health, and safety regulations and liabilities thereunder;

- the ultimate impact of the 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;

- general instability of economic and political conditions in the United States, including inflationary pressures, increased interest rates, economic slowdown or recession, and escalating geopolitical tensions;

- compliance with government regulations, including environmental, health, and safety regulations and liabilities thereunder;

- our anticipated uses of net proceeds from our initial public offering ("the IPO");

- the increased expenses associated with being a public company; and

- other factors discussed elsewhere in this Annual Report.

Many of the foregoing risks and uncertainties, as well as risks and uncertainties that are currently unknown to us, are or may be exacerbated by factors such as the ongoing conflict between Ukraine and Russia, escalating tensions between China and Taiwan, increasing economic uncertainty and inflationary pressures, the evolving nature of the COVID-19 pandemic and the emergence of new viral variants, and any consequent worsening of the global business and economic environment. New factors emerge from time to time, and it is not possible for us to predict all such factors. Should one or more of the risks or uncertainties described in this Annual Report or any other filing with the Securities and Exchange Commission (the "SEC") occur, or should the assumptions underlying the forward-looking statements we make herein and therein prove incorrect, our actual results and plans could differ materially from those expressed in any forward-looking statements. We undertake no obligation to update publicly any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

You should read this Annual Report and the documents that we reference within it with the understanding that our actual future results, performance, and events and circumstances may be materially different from what we expect.

Website and Social Media Disclosure

We use our websites (www.bioaffinitytech.com and ir.bioaffinitytech.com) and at times our corporate Twitter account (@bioAffinity) and LinkedIn account (www.linkedin.com/company/bioaffinitytechnologies) to distribute company information. The information we post through these channels may be deemed material. Accordingly, investors should monitor these channels and review our press releases, filings with the SEC, and public conference calls and webcasts. In addition, investors and others can be automatically notified in real time when new information is posted on our websites by visiting the homepage of our Company website at www.bioaffinitytech.com and subscribing to "News from bioAffinity Technologies" or visiting the "Email Alerts" section of our investor relations website at ir.bioaffinitytech.com/news-events/email-alerts and enrolling an email address. Information contained on or that can be accessed through our websites and social media channels is not, however, incorporated by reference in this Annual Report. Investors should not consider any such information to be part of this Annual Report.

PART I

Item 1. Business.

Business Overview

bioAffinity Technologies, Inc. (the "Company," "we," or "our") develops noninvasive, early-stage diagnostics to detect and researches targeted therapies to detect and treat lung cancer and other diseases of the lung at the cellular level. Our Company also is conducting early-stage research focused on advancing therapeutic discoveries that could result in broad-spectrum cancer treatments. We develop proprietary noninvasive diagnostic tests and cancer therapeutics using technology that preferentially targets cancer cells and cell populations indicative of a diseased state.

The Company was formed as a Delaware corporation on March 26, 2014. On June 15, 2016, we formed OncoSelect® Therapeutics, LLC, a Delaware limited liability company and wholly owned subsidiary of the Company. Research and optimization of our platform technologies are conducted in our laboratories at The University of Texas at San Antonio.

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

Through our wholly owned subsidiary, OncoSelect® Therapeutics, LLC, our research has led to discoveries and advancement of novel cancer therapeutics that specifically and selectively target cancer cells. We are focused on expanding our broad-spectrum platform technologies to continue developing tests that detect and therapies that target various types of cancer and potentially other diseases.

Information regarding the general development of bioAffinity's business can be found in the "Business" section of our final IPO prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act") on September 2, 2022 (the "Final Prospectus") (see https://www.sec.gov/Archives/edgar/data/1712762/000149315222024949/form424b4.htm).

Our First Diagnostic Test – CyPath® Lung

Overview of the CyPath® Lung Methodology

Lung cancer is the leading cause of cancer-related death worldwide, claiming nearly 1.8 million lives annually.[1] Individuals at high risk for lung cancer are recommended for annual screening by low-dose computed tomography ("LDCT"). Apart from LDCT, there is currently no reliable noninvasive method that can detect lung cancer at an early stage. Our first diagnostic test, CyPath® Lung, is designed to be a cost-effective,[2] noninvasive, early-stage lung cancer diagnostic. Using CyPath® Lung in conjunction with LDCT is predicted to improve the positive predictive value (the proportion of true positive results) by a factor of five.[2] 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.[3]

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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 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 the Company's Final Prospectus filed with the SEC on September 2, 2022, pursuant to Rule 424(b)(4) under the Securities Act (see https://www.sec.gov/Archives/edgar/data/1712762/000149315222024949/form424b4.htm).

3 Ibid.

CyPath® Lung uses flow cytometry technology to detect and analyze cell populations in a person's sputum, or phlegm, to find characteristics indicative of lung cancer, including cancer and/or cancer-related cells that have shed from a lung tumor. The flow cytometer is a well-established instrument used in many commercial laboratories that records properties of labeled and unlabeled single cells. Sputum is an excellent sample for analysis because it is in direct contact with any malignancy in the lungs and can thus provide a snapshot of the tumor itself, its microenvironment, and its area of field cancerization. While studies have shown that expert cytological analysis of sputum can detect cancerous and pre-malignant cells,[4] the process of looking at microscopy slides is an extremely laborious approach and demands years of expertise. CyPath® Lung uses flow cytometry and automated data analysis developed by artificial intelligence (AI) that allows for an entire sample of sputum to be examined for cost-effective, large-scale screening or diagnosis.

In particular, CyPath® Lung uses a synthetic porphyrin called meso-tetra (4-carboxyphenyl) porphine ("TCPP"), which is a naturally highly fluorescent porphyrin that has an unusually high affinity for cancer and cancer-associated cells.[5] The uptake and retention of TCPP in cancerous tissue and its fluorescent properties make TCPP an excellent bio-label for cancer. 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 AI-developed automated analysis platform in the detection of lung cancer and other lung diseases using sputum as a sample.

We developed an algorithm using AI to distinguish samples from high-risk patients who had lung cancer from those who are cancer-free. Precision Pathology Services ("Precision Pathology") developed CyPath® Lung for sale as a Laboratory Developed Test (an "LDT") in accordance with the standards of the College of American Pathologists ("CAP") and the regulations and guidance of the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") program, which is administered by the Centers for Medicare and Medicaid Services ("CMS"). In developing the test as an LDT, Precision Pathology developed and integrated software into the test protocol, which generated high-throughput and user-friendly, standardized analysis of flow cytometric sample data. Our test can analyze an average sputum sample containing about 20 million cells 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 by AI captures complex interactions between lung cancer, the microenvironment, and areas of field cancerization that would be difficult if not impossible for individuals to predict or detect reliably by eye. For example, during test development, we discovered that viability staining density suggests a link with apoptosis, or cell death, that is linked to many cancers, including lung cancer. Our model also suggests that specific markers of immune cell populations may be informative as to the presence of cancer in the lung. These findings are the result of our AI approach to automated analysis.

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

Clinical Validation, Certification, and Classification of CyPath® Lung

A 19-month test validation clinical trial of CyPath® Lung[6] collected sputum noninvasively from people at high risk for lung cancer, including patients with the disease (N=28) and those cancer-free (N=122). Patients collected their sputum sample over three days at home before bringing their sample to the clinical collection site. Samples were shipped overnight to the laboratory for analysis. Study participants in the high-risk cohort had a CT to confirm they did not have lung cancer. Those in the cancer cohort had imaging and a biopsy that confirmed lung cancer. After providing a sputum sample, participants were released from the study after a physician either confirmed the individual was cancer-free by examination of CT imaging or confirmed the presence of lung cancer by biopsy. Flow cytometry and patient data used in analysis to produce the results included (1) the proportion of cells with a high ratio of high TCPP fluorescence intensity over cell size; (2) the proportion of cells with an intermediate ratio of fluorescence intensity caused by the viability dye (FVS510) over cell size; (3) the proportion of cells that were CD206 negative but positive for one or more of the following markers: CD66b (granulocytes), CD3 (T cells), and CD19 (B cells); and (4) patient age.

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

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

6 M.E. Lemieux, et al., Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning. Respir Res. 2023;24(1):23. doi: 10.1186/s12931-023-02327-3.

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 eight out of 10 (80%) of Stage I tumors were correctly identified. Sensitivity is the percentage of persons with the disease – in this case lung cancer – who are correctly identified by the test. Specificity is the percentage of persons without lung cancer who are correctly identified by the test. The cancer group included all lung cancer types, but mostly squamous cell carcinoma and adenocarcinoma lung cancer (in near equal numbers), showing that CyPath® Lung detects all types of lung cancer.

Following completion of the test validation trial, CyPath® Lung was evaluated independently by Precision Pathology, which developed the test for sale as an LDT in accordance with CAP/CLIA standards. 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, a CAP-accredited, CLIA-certified clinical pathology laboratory in San Antonio, Texas, pursuant to a joint development agreement with the Company. In third quarter 2022, Precision was inspected by CAP in accordance with CAP/CLIA regulatory standards and regulations resulting in continued accreditation for the laboratory and the CyPath® Lung test as an LDT.

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. Results of Precision Pathology's certification were comparable to those from the test validation trial and demonstrated that CyPath® Lung remains robust to differences in sample handling, processing, and the type of flow cytometer.

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 has designed its pivotal trial with guidance from its clinical research organization ("CRO"), Courante Oncology, and has prepared a pre-submission that will be submitted to the FDA for review and feedback. We anticipate a three-year diagnostic trial including an 18-month patient enrollment of approximately 1,800 patients, with participants followed for at least one year after enrollment to determine whether they have lung cancer. Similar to the test validation trial, the planned pivotal trial will analyze flow cytometry and patient data including (1) the proportion of cells with a high ratio of high TCPP fluorescence intensity over cell size; (2) the proportion of cells with an intermediate ratio of fluorescence intensity caused by the viability dye (FVS510) over cell size; (3) the proportion of cells that were CD206 negative but positive for one or more of the following markers: CD66b (granulocytes), CD3 (T cells), and CD19 (B cells); and (4) patient age. Patient enrollment is scheduled to begin in 2023 at up to 20 collection sites. Assuming the study is successful, we intend to submit a de novo classification request to the FDA within six months of study completion.

The Patient- and Physician-Friendly CyPath® Lung Process

CyPath® Lung is designed to be noninvasive and 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 indeterminate 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%.[7]

For the CyPath® Lung test, patients are given a small sample collection kit during an office visit with their physician. (See Figure 1 below.) From the privacy of the patient's home, the patient collects a sample of his or her sputum over three days using a hand-held assist device that comes in the collection kit called an acapella® Choice Blue made by Smiths Medical, which acts to break up mucus in the patient's lung and facilitates the patient's ability to cough up 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 are 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 the three-day sample of sputum is collected in the collection cup, the patient puts the collection cup into the kit and uses a pre-addressed envelope provided in the kit to overnight the sample to the laboratory.

[7] Gierada et al; https://pubmed.ncbi.nlm.nih.gov/25326638/.

At the laboratory, the sputum is processed by technicians into a single-cell suspension and labeled with TCPP, which 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. The sputum sample is analyzed using flow cytometry, which allows an average sputum sample containing about 20 million cells to be profiled in less than 20 minutes. A laboratory technician skilled in general laboratory techniques can accomplish sample processing, labeling, and data collection.

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

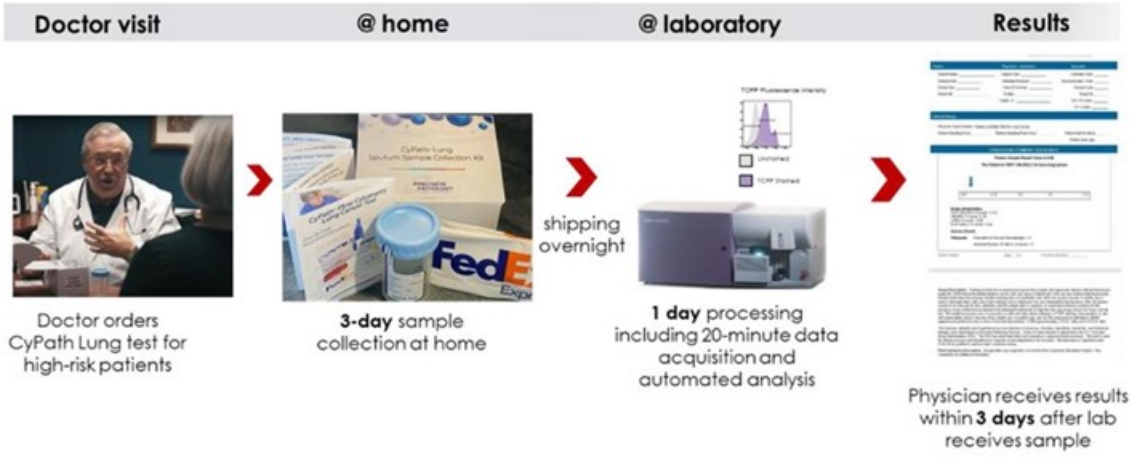

Figure 1. Patient- and Physician-Friendly CyPath® Lung Process.

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® Lung technology is based on this concept and scientific work originating at Los Alamos National Laboratory in collaboration with St. Mary's Hospital in Colorado. A blinded clinical trial[8] (Patriquin, et. al, 2015) of an earlier version of CyPath® Lung used a microscope to directly identify cells labeled with TCPP in one-third or less of the sputum sample. For each trial participant, researchers manually scanned 12 microscope slides labeled with TCPP for the presence of red fluorescing cells ("RFCs") displaying a spectral signature that indicated uptake of TCPP in the cell. In addition to measuring the spectral signature, the fluorescent intensity and cell size of RFCs were measured. The test data, including fluorescent intensity over cell size, was analyzed. The Patriquin trial was conducted over 24 months and resulted in 81% test accuracy, 77.9% sensitivity, and 65.7% specificity in the ability to correctly differentiate between samples from lung cancer patients and those at high risk who were cancer-free. The Patriquin trial required participants to provide a sputum sample and CT imaging of the lungs. Those in the cancer cohort underwent a biopsy to confirm lung cancer. High-risk patients displaying indeterminate nodules were followed for 18 months to confirm they were cancer-free. The Patriquin study concluded that optimizing the test to provide for analysis of the entire sputum sample would improve results.

8 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.

The Company continued development of its lung cancer diagnostic technology culminating in a flow cytometry-based CyPath® Lung test incorporating automated AI analysis that evaluates the entire sputum sample. A blinded diagnostic trial of the advanced test[9] (Lemieux, et al, 2023) 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 eight out of 10 (80%) of Stage I tumors were correctly identified. 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.

All 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. Uptake was determined by visual assessment. Cell lines were used. Researchers did not report the length of time taken to conduct this study, nor any follow-up.
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) that labeled sputum with TCPP resulted in 100% sensitivity and 100% specificity. Classification of cancer was made by subjective visual assessment of the presence and intensity of red fluorescing cells on slides. In this blinded study, one patient initially enrolled as a healthy subject was correctly diagnosed with cancer by the test. Length of study not reported. No patient follow-up was reported except for correct detection of cancer in patient initially enrolled as healthy.
Internal validation study with microscopy-based assay completed to optimize TCPP labeling of sputum containing cancer and cancer-related cells in lung cancer samples	In this research study lasting eight months, the florescence intensity of TCPP-labeled cells in sputum was measured by subjective visual assessment of microscope slides to distinguish samples from cancer and healthy cohorts. Researchers who were blinded to sample origin correctly identified samples from lung cancer patients (cancer N=15 / healthy N=12) resulting in 100% sensitivity and 100% specificity. Participants were not followed up after providing the sputum sample and CT scan or biopsy.

9 M.E. Lemieux, et al. Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning. Respir Res. 2023;24(1):23. doi: 10.1186/s12931-023-02327-3.

Early Detection of Lung Cancer with Meso-Tetra (4-Carboxyphenyl) Porphyrin-Labeled Sputum[10]	A 24-month clinical trial of 128 high-risk smokers and cancer patients used microscopy-based assay to identify TCPP-labeled cells in sputum (cancer N=26 / high risk N=102) that resulted in 81% accuracy, 77.9% sensitivity, 65.7% specificity. Slides were scanned. Fluorescent intensity and cell size of RFCs were objectively measured by software. High-risk participants who were cancer-free were followed for 18 months to confirm status.
Sputum analysis by flow cytometry; an effective platform to analyze the lung environment.[11]	Research reporting on the CyPath® Lung test's quality controls included manual analysis of cell population data acquired by flow cytometry analysis of sputum. This research evaluated flow cytometry data from 164 participants' sputum samples analyzed manually for differences in cell characteristics, cell population size, and cell fluorescence intensity.
Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning[12]	Test validation clinical trial using bioAffinity's automated flow cytometry CyPath® Lung test (cancer N=28 / high risk N=122) resulted in overall 82% sensitivity and 88% specificity for the test; CyPath® Lung sensitivity is 92% and specificity is 87% for patients with lung nodules smaller than 20 mm.
Porphyrin-modified beads for use as compensation controls in flow cytometry[13]	Reporting on the protocol for preparing porphyrin-labeled compensation beads invented by bioAffinity and used to optimize the results of CyPath® Lung test to detect early-stage lung cancer.

The Cancer Diagnostics Market and CyPath® Lung

The global cancer diagnostic market is projected to grow from an estimated $172.3 billion in 2022 to $293.5 billion in 2030, with a compound annual growth rate ("CAGR") of 6.8%.[14] The market worldwide for lung cancer diagnostic tests was estimated at $2.6 billion in 2022 and is projected to reach $4.7 billion by 2030, with a CAGR of 7.8% over 2022-2030.[15] bioAffinity Technologies has the potential to play a significant role in the cancer diagnostic market because our 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 the Company's Final Prospectus filed with the SEC on September 2, 2022, pursuant to Rule 424(b)(4) under the Securities Act) (see https://www.sec.gov/Archives/edgar/data/1712762/000149315222024949/form424b4.htm).

10 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.

11 Bederka, et al. Sputum analysis by flow cytometry; an effective platform to analyze the lung environment. PLoS One 2022;17(8). doi: 10.1371/journal.pone.0272069.

12 M.E. Lemieux, et al. Detection of Early-Stage Lung Cancer in Sputum using Automated Flow Cytometry and Machine Learning. Respir Res. 2023;24(1):23. doi: 10.1186/s12931-023-02327-3.

13 Bauta, et al., Porphyrin-modified beads for use as compensation controls in flow cytometry, Journal of Visualized Experiments (JoVE) 2023, CITATION

14 Research and Markets. Cancer Diagnostics Market Size, Share & Trends Analysis Report by Product (Consumables, Instruments), by Technology, by Screening Type, by Application, by End-user, by Region, and Segment Forecasts, 2022-2030. Oct. 2022. ResearchAndMarkets.com.

15 ReportLinker. Global Lung Cancer Diagnostics Industry. Jan. 2023. ReportLinker.com.

CyPath® Lung is currently utilized as a diagnostic tool for detecting early-stage lung cancer. bioAffinity is conducting research for the expansion of its flow cytometric platform technology to detect and monitor lung diseases, such as Chronic Obstructive Pulmonary Disease (COPD) and asthma, and other cancers.

The Company licensed CyPath® Lung to Precision Pathology, which began marketing CyPath® Lung in Texas as an LDT in accordance with CAP/CLIA regulations pursuant to the terms of the joint development agreement between the Company and Precision Pathology. Limited funds were available to market CyPath® Lung until the Company completed its IPO in September 2022. 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).

As a front-end diagnostic tool used in conjunction with LDCT, the Company's lung cancer test will help determine whether 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[16]	High risk	82%	88%	None
CyPath® Lung	High risk – nodules less than 20 mm	92%	87%	None
Low Dose CT screening[17]	High risk	93.80%	73.40%	Radiation exposure
FDG PET imaging[18]	Suspicious lung nodules	88%	75%	Radiation exposure
Bronchoscopy[19]	Suspicious lung nodules – central lesions	88%	47%	Invasive, risk of collapsed/bleeding lung infection
Fine Needle Biopsy[20]	Suspicious lung nodules	90.4%	75.4%	Invasive, risk of collapsed/bleeding lung infection
Core Needle Biopsy[21]	Suspicious lung nodules	89.1%	88.6%	Invasive, risk of collapsed/bleeding lung infection

16 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.

17 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.

18 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.

19 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

20 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.

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

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 an estimated 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

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 report. However, the timing, strategies, and stages of our Business Plan may evolve in light of new circumstances that cannot be predicted with certainty at this time. Our Business Plan envisions 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 followed by expansion into the Southwest market area. Limited marketing was undertaken prior to the IPO that provided funds necessary to begin our controlled market launch. In February 2023, the Company announced that the marketing and advertising firms of Havas Health & You and Trinity Life Sciences had been engaged to build the CyPath® Lung brand and position it for success in the cancer diagnostics sector. Havas Health & You, the world's largest global health network, is creating the branding and broader marketing strategy to align with the need for a patient-friendly diagnostic that gives physicians another tool to assess the potential or presence of lung cancer in their high-risk patients. Trinity Life Sciences is providing advisory services, insights, and analytics to bioAffinity Technologies' marketing strategy for CyPath® Lung. The Company expects to begin a staged nationwide expansion of sales and marketing following the successful completion of its controlled launch in 2023. Phase 2 of our Business Plan anticipates entering the EU market with CyPath® Lung as a CE-marked IVD test with sales in the Netherlands, followed by a staged EU expansion. Phase 3 of our Business Plan focuses on the marketing of an FDA-cleared CyPath® Lung test, beginning with a pivotal clinical trial in the U.S. Phase 4 of our Business Plan accelerates the market presence of CyPath® Lung in countries in Asia, Eastern Europe, and Australia after obtaining FDA marketing authorization 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 and sales tools, and will be used as references to support our product claims as well as sales and marketing efforts to physicians, reference laboratories, and patients. We will also work with lung cancer advocacy groups throughout all phases to support the message that routine screening can diagnose cancer at an early stage and save lives.

The Competition for CyPath® Lung

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 11 had conducted clinical studies in a manner and with results that could lead to further analysis. The majority of these 11 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 of the Company's Final Prospectus (see https://www.sec.gov/Archives/edgar/data/1712762/000149315222024949/form424b4.htm)).

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. The two remaining balanced tests are not on the market.

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® Lung platform technology is not a molecular test and does not collect genetic material that requires immediate processing. CyPath® Lung uses well-established flow cytometry techniques to investigate cells contained in the sputum for characteristics that indicate 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.

For a discussion of our competitors and competitive analysis, please see the "Business – The Competition for CyPath® Lung" section of our Final Prospectus (see https://www.sec.gov/Archives/edgar/data/1712762/000149315222024949/form424b4.htm).

Research and Development Activities

The Company is continuing its research and development activities pertaining to diagnostics that include multiple studies we believe will support FDA final approval of CyPath® Lung, which we will seek after the pivotal trial is complete. Our scientists also have begun preliminary studies toward the development of CyPath® Lung for detection of Chronic Obstructive Pulmonary Disease (COPD) and the assay's use with bronchoalveolar lavage fluid (BAL). With regard to therapeutic research, the Company continues its experiments focused on establishing proof-of-concept for our discovery that the silencing or knockdown of two genes that each encode a cell surface receptor results in cancer death without much harm to healthy cells with the intent of advancing toward animal studies.

Intellectual Property Portfolio

As of March 31, 2023, the Company and its subsidiary OncoSelect have a patent estate that includes 14 issued U.S. and foreign counterpart patents, including two U.S. patents and twelve foreign counterpart patents in Australia, Canada, China, France, Germany, Hong Kong, Italy, Mexico, Spain, Sweden, and the United Kingdom. One U.S. patent and nine counterpart foreign patents directed at diagnostic applications expire in 2030. Therapeutic patents registered in Australia, China Mexico and the U.S. expire in 2037.

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

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

Government Regulation

For a discussion of the extensive government regulation that the Company and our IVD medical device, CyPath® Lung, are subject to, please see the "Business – Government Regulation" section of our Final Prospectus (see https://www.sec.gov/Archives/edgar/data/1712762/000149315222024949/form424b4.htm).

Our Employees

The Company places significant emphasis on the recruitment, development, and retention of its employees who include award-winning scientists dedicated to advancing scientific discovery from bench to bedside. Of the Company's 14 employees, all of whom are employed full-time by the Company, one holds an MD and seven hold PhDs in biology or medicinal chemistry. Approximately nine employees are engaged in research and development and approximately five in sales or general administration.

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. Of those employees hired prior to 2022, most have been with the Company for more than five years of its nine-year history. Outside partnerships and collaborations that advance business and scientific research are encouraged, allowing the Company to multiply workforce efforts without expending significant capital.

Item 1A. Risk Factors.

As a smaller reporting company, we are not required to provide disclosure pursuant to this Item 1A. However, in addition to other information set forth in this Annual Report, you should carefully consider the "Risk Factors" discussed in our Final Prospectus filed with the SEC on September 2, 2022, pursuant to Rule 424(b)(4) under the Securities Act (see https://www.sec.gov/Archives/edgar/data/1712762/000149315222024949/form424b4.htm) and elsewhere in this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in this Annual Report. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition, and operating results.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

In June 2015, we were accepted into the "New Venture Incubator Program," which was established by The University of Texas at San Antonio ("UTSA") to foster research by assisting technology-based businesses and entrepreneurs. Pursuant to the terms of a license agreement, UTSA grants us a license for the temporary use of approximately 1,250 square feet of laboratory and office space in room SRL 1.424 inside the Science Research Laboratories on UTSA's campus. In exchange, we pay a licensing fee of $3,081 per month. The license agreement has a one-year term that we can extend by requesting a term extension from UTSA. Since 2016, UTSA has granted each of our annual requests for a license extension.

We rent additional corporate office space from Venture Point (formerly known as WorkHub Elite Business Center) pursuant to a membership agreement that is renewable on a monthly basis. Currently, we rent several office suites for a monthly fee of approximately $ 5, 000 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.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information.

Our common stock, par value $0.007 per share (the "Common Stock") trades under the symbol "BIAF." Our tradeable warrants, each to purchase one share of Common Stock (collectively, the "Tradeable Warrants"), trade under the symbol "BIAFW." Our Common Stock and Tradeable Warrants trade on The Nasdaq Capital Market.

Use of Proceeds from Initial Public Offering

On September 6, 2022, we completed our IPO of 1,282,600 Units at an Offering Price of $6.125 per Unit. Each Unit consisted of one share of Common Stock, one Tradeable Warrant exercisable for the purchase of one share of Common Stock at an exercise price of $7.35 per share, and one Non-tradeable Warrant exercisable for the purchase of one share of Common Stock at an exercise price of $7.656 per share. The total number of shares of Common Stock sold in the IPO does not include the Over-Allotment Option that we granted to the Underwriters to purchase additional shares of Common Stock, Tradeable Warrants, and/or Non-tradeable Warrants. The Underwriters exercised a portion of their Over-Allotment Option and purchased 110,167 Tradeable Warrants at a purchase price of $0.01 per warrant, and 110,167 Non-tradeable warrants at a purchase price of $0.01 per warrant. The shares of Common Stock and Tradeable Warrants underlying the Units offered in our IPO and the Over-Allotment Option were registered for sale pursuant to our Registration Statement on Form S-1, as amended (File No. 333-264463), filed with and declared effective by the SEC on August 29, 2022.

The aggregate offering price for the registered shares of Common Stock and Tradeable Warrants was approximately $7.9 million. We received net proceeds of approximately $6.0 million from the IPO, after deducting underwriting discounts and commissions of approximately $0.7 million and offering expenses of approximately $1.2 million. The representative of the Underwriters was WallachBeth Capital, LLC. No payments for the foregoing expenses were made by us to any of our officers, directors, or persons owning ten percent (10%) or more of our Common Stock, or to the associates of any of the foregoing, or to their affiliates, other than payments in the ordinary course of business to our officers for salaries, bonuses, and expense reimbursements.

There has been no material change in the planned use of proceeds as described in our Final Prospectus filed with the SEC on September 2, 2022 (see https://www.sec.gov/Archives/edgar/data/1712762/000149315222024949/form424b4.htm). The expected use of net proceeds from the IPO represents our intentions based upon our present plans and business conditions. We cannot predict with certainty all of the particular uses for the proceeds of the IPO or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have broad discretion in the application of the net proceeds we received from the IPO, and investors will be relying on the judgment of our management regarding the application of our net proceeds. While we expect to use the net proceeds for the purposes described above, the timing and amount of our actual expenditures will be based on many factors, including cash flows from operations, the anticipated growth of our business, and the availability and terms of alternative financing sources to fund our growth.

Holders of Record.

As of March 20, 2023, there were approximately 68 holders of record of shares of our Common Stock. This number does not reflect the beneficial holders of our common stock who hold shares in street name through brokerage accounts or other nominees.

Dividends.

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

Securities Authorized for Issuance Under Equity Compensation Plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	5,456,344	$ 5.88	237,160
Equity compensation plans not approved by security holders	—	—	—
Total	5,456,344	$ 5.88	237,160

Item 6. [Reserved.]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

This section presents management's perspective on our financial condition and results of operations. The following discussion and analysis (the "MD&A") is intended to highlight and supplement data and information presented elsewhere in this Annual Report on Form 10-K. The MD&A is also intended to provide you with information that will assist you in understanding our consolidated financial statements, the changes in key items in those consolidated financial statements from year to year, and the primary factors that accounted for those changes. To the extent that this discussion describes prior performance, the descriptions relate only to the periods listed, which may not be indicative of our future financial outcomes. In addition to historical information, this discussion contains forward-looking statements that involve risks, uncertainties, and assumptions that could cause the Company's financial results to differ materially from management's expectations. Factors that could cause such differences are discussed in the "Cautionary Note Regarding Forward-Looking Statements" section of this Quarterly Report and in the "Risk Factors" in our Annual Report on Form10-K.

Our MD&A is organized as follows:

- *Company Overview* – Discussion of our Business Plan and strategy to provide context for the remainder of the MD&A.
- *Results of Operations* – Analysis of our financial results comparing the year ended December 31, 2022, to the year ended December 31, 2021.
- *Liquidity and Capital Resources* – Analysis of changes in our cash flows, and discussion of our financial condition and potential sources of liquidity.
- *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.

Company Overview

Business

bioAffinity Technologies, Inc. (the "Company," "we," or "our") develops noninvasive, early-stage diagnostics to detect and researches targeted therapies to detect and treat lung cancer and other diseases of the lung at the cellular level. Our Company also is conducting early-stage research focused on advancing therapeutic discoveries that could result in broad-spectrum cancer treatments. We develop 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.

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

Through our wholly owned subsidiary, OncoSelect® Therapeutics, LLC, our research has led to discoveries and advancement of novel cancer therapeutics that specifically and selectively target cancer cells. We are focused on expanding our broad-spectrum platform technologies to continue developing tests that detect and therapies that target various types of cancer and potentially other diseases.

Recent Developments

- In the third quarter of 2022, the Company completed our initial public offering (IPO), with net proceeds of $6.0 million after deducting underwriting discounts, commissions and offering expenses. In connection with our IPO, the Company converted almost $11 million in debt and related accrued interest into shares of Common Stock.
- In the third quarter of 2022, the Company raised additional proceeds of $7.8 million from the sale of warrants and the exercise of options.
- In the second quarter of 2022, we recognized royalty revenue on sales of our CyPath® Lung test to physicians by Precision Pathology Services ("Precision Pathology"), a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee in San Antonio, Texas.

- We have determined we will need to enroll an estimated 1,800 participants in our pivotal clinical trial that is designed to confirm the sensitivity and specificity of CyPath® Lung in detecting lung cancer in persons at high risk for the disease, including patients who display indeterminate lung nodules between 6mm and 30 mm in size which often present a challenge in diagnosis.

- In the third quarter of 2022, the Company was awarded therapeutic patents in The People's Republic of China, Mexico, and Australia directed at compounds comprised of porphyrins conjugated to chemotherapeutic agents that can provide selective treatment for cancer.

- In the third quarter of 2022, Precision was inspected by the College of American Pathologists (CAP) including inspection of the CyPath® Lung test in accordance with CAP/CLIA regulatory standards and regulations. The inspection resulted in continued accreditation for the laboratory and the CyPath® Lung test as a Laboratory Developed Test (LDT).

- In the first quarter of 2023, the Company announced publication of "Detection of early-stage lung cancer in sputum using automated flow cytometry and machine learning" detailing results of the Company's validation clinical trial for its non-invasive diagnostic CyPath® Lung in Respiratory Research, which showed CyPath® Lung had 92% sensitivity and 87% specificity in high-risk patients who had nodules smaller than 20 millimeters or no nodules in the lung, with an area under the ROC curve of 94%. Overall, the test resulted in specificity of 88% and sensitivity of 82%. More than half of those in the cancer cohort had early Stage I or II lung cancer. CyPath® Lung detected multiple forms of cancer including adenocarcinoma, squamous cell carcinoma, and small cell lung cancer.

- In the first quarter of 2023, the Company announced publication in the peer-reviewed journal JoVE of "Porphyrin-modified beads for use as compensation controls in flow cytometry" that describes the beads engineered by the Company for use with its CyPath® Lung test.

- In the first quarter of 2023, the Company announced that the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for a therapeutic patent application directed at compounds comprised of porphyrins conjugated to chemotherapeutic agents that can provide selective treatment for cancer.

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 *in vitro* diagnostic (IVD) test in the EU;

- Initiate and complete a pivotal clinical trial proving the efficacy of CyPath® Lung;

- Submit to the U.S. Food and Drug Administration (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.

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 funded our operations principally through private sales of our equity or debt securities. From October 2021 through August 2022, the Company raised $2.7 million through the sale of Bridge Notes. In July 2022, all but six of the Bridge Notes with an aggregate principal amount of $325,000 were further amended to have a maturity date of October 31, 2022. As consideration for the maturity date extension, each noteholder received a warrant to purchase that number of shares of Common Stock equal to the quotient obtained by dividing the principal amount of such holder's note by 10.5 at an exercise price equal to $5.25 per share of Common Stock, representing 50% warrant coverage on the principal amount of the note. In connection with the sale of our convertible Bridge Notes, our Placement Agent was paid commissions of nine percent (9.0%) and was issued the Placement Agent's Warrant to purchase 54,464 shares of Common Stock. The Placement Agent's Warrants have substantially the same terms as the warrants issued to our noteholders and an exercise price of $7.35 per share.

In September 2022, we completed our IPO, with net proceeds of $6.0 million after underwriting discounts, commissions, and offering expenses, and received proceeds of approximately $7.8 million from the exercise of warrants and options. As of December 31, 2022, we had cash and cash equivalents of $11.5 million. We believe that our available cash will be sufficient to fund our planned operations for at least 12 months following the issuance date of this Annual Report.

In the second quarter of 2022, we started to recognize revenue from sales of the CyPath® Lung test by our licensee, Precision Pathology. We have never been profitable, and as of December 31, 2022, we had working capital of $10.8 million and an accumulated deficit of approximately $36.7 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue the development of our diagnostic tests and therapeutic products and advance our diagnostic tests through clinical trials. We intend to license our therapeutic products for clinical development should animal and pre-clinical studies prove successful.

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

Results of Operations

Year Ended December 31, 2022, Compared to the Year Ended December 31, 2021

Our results of operations have varied significantly from year to year and quarter to quarter and may vary significantly in the future. Net loss for the year ended December 31, 2022, was approximately $8.2 million, compared to a net loss of approximately $6.3 million for the year ended December 31, 2021, resulting from the operational activities described below.

Revenue

Our revenue is generated exclusively from royalties for our first diagnostic test, CyPath® Lung, from sales by Precision Pathology, a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee. Although Precision Pathology placed CyPath® Lung on its list of tests offered to physicians in second quarter 2022, there was limited marketing of the product until our IPO in September provided funds to assemble a marketing team of experts focused on demonstrating the clinical value of CyPath® Lung in the marketplace. The limited test market launch in the San Antonio area is designed to evaluate our marketing program and help us ensure each step in the care pathway is efficient and effective, from the initial order by physicians to patient sputum collection and processing, to generating and delivering the patient report. This limited test market approach allows us to refine future positioning and develop strategic insight for our CyPath® Lung test before expanding to a larger market. We had revenue of approximately $5,000 during the year ended December 31, 2022, from the sale of CyPath® Lung as an LDT, compared to no revenue in 2021.

We expect our revenue to continue to grow for CyPath® Lung as we add physicians prescribing our diagnostic test and expand our outreach to other geographic areas. Our revenues are affected by the test volume of our products, patient adherence rates, payer mix, the levels of reimbursement, and payment patterns of payers and patients.

Cost of Sales

Cost of sales is comprised primarily of costs related to inventory production and usage and shipment of collection kits to patients and healthcare providers. The increase in cost of sales for the year ended December 31, 2022, is primarily due to the launch of sales in the second quarter of 2022, compared to no sales in the prior year.

Operating Expenses

	Year Ended December 31,		Change in 2022 Versus 2021	
	2022	2021	$	%
	(amounts in thousands)		(amounts in thousands)	
Operating expenses:				
Research and development	$ 1,143	$ 1,008	$ 135	13%
Clinical development	146	130	16	12%
Selling, general and administrative	2,727	1,069	1,658	155%
Total operating expense	$ 4,016	$ 2,207	$ 1,809	82%

Operating expenses totaled $4.0 million and $2.2 million during 2022 and 2021, respectively. The increase 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 $1.1 million and $1.0 million during 2022 and 2021, respectively. The increase of approximately $135,000, or 13%, for 2022 compared to 2021 was primarily attributable to an increase in compensation costs and benefits as we added research personnel, partially offset by a decrease in the prior year due to several employees who were furloughed for several months and later returned to their positions with the Company. Additionally, costs related to lab supplies and reagents increased as employees returned to facilities after restrictions eased for COVID-19. These increases were partially offset by a decrease in stock compensation expense related to stock option and restricted share grants to employees and consultants in 2022 compared to 2021.

Clinical Development

Clinical development expenses totaled approximately $146,000 and $130,000 during 2022 and 2021, respectively. The increase of approximately $16,000, or 12%, for 2022, compared to 2021 was primarily attributable to an increase in professional fees, including consulting fees, and increases in clinical study activities related to site costs compared to 2021 as operations were still being affected by the global pandemic.

Selling, General and Administrative

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

Selling, general and administrative expenses totaled approximately $2.7 million and $1.1 million during 2022 and 2021, respectively. The increase of $1.7 million, or 155%, for 2022 compared to 2021 was primarily attributable to increases related to consulting, legal, and professional fees incurred in 2022 compared to 2021 as we prepared for our IPO and comply with the reporting requirements of a public company. Patent costs increased in the current year as we maintain and expand our patent portfolio to protect our diagnostic and therapeutic platforms. Additionally, the increase was due to an increase in stock-based compensation, as well as an increase in compensation and benefits as we increased personnel and support services to support the launch of sales of our diagnostic test, CyPath® Lung.

Other Income (Expense)

	Year Ended December 31,		Change in 2022 Versus 2021	
	2022	2021	$	%
	(amounts in thousands)		(amounts in thousands)	
Interest income (expense), net	$ (2,486)	$ (1,002)	$ (1,484)	148%
Gain on extinguishment of debt	212	239	(27)	-11%
Fair value of warrants	—	(4,080)	4,080	-100%
Loss on change in fair value of convertible notes	(1,867)	725	(2,592)	-358%
Total other income (expense)	$ (4,141)	$ (4,118)	$ (23)	1%

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

Interest income (expense)

We had net interest expense of approximately $2.5 million and $1.0 million for the years ended December 31, 2022 and 2021, respectively. The increase was due to additional convertible notes outstanding during the same period in the prior year. Additionally, in 2022 the Company recorded interest expense of approximately $2.1 million for the amortization of debt discount related to the issuance of Bridge Notes.

Gain on Extinguishment of Debt

In March 2021, the Company received a second draw $0.2 million Paycheck Protection Program Loan (the "PPP Loan") and received forgiveness from the Small Business Administration (SBA) in April 2022, recording a gain of $212,000 on the extinguishment of the PPP Loan. In April 2020, the Company received an initial $0.2 million PPP Loan and received forgiveness from the SBA in June 2021, recording a gain of $239,000 on the extinguishment of the PPP Loan.

Fair value of warrants

In 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 consolidated statement of operations.

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

The loss on the change in fair value of convertible notes totaled approximately $1.9 million during 2022 compared to a gain of $0.7 million during 2021, 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

To date, we have funded our operations primarily through our IPO, exercise of warrants and options, and the sale of our equity and debt securities, resulting in gross proceeds of approximately $34.3 million.

We have incurred losses since our inception in 2014 as a result of significant expenditures for operations and research and development and, prior to April 2022, the lack of any approved diagnostic tests or therapeutic products to generate revenue. We have an accumulated deficit of approximately $36.7 million as of December 31, 2022. We anticipate that we will continue to incur additional losses for the foreseeable future. Cash and cash equivalents were approximately $11.4 million as of December 31, 2022. Based on our current level of expected operating expenditures, we expect to be able to fund our operations for at least twelve (12) months following the date of this Annual Report.

In the fourth quarter of 2021 and the first quarter of 2022, the Company issued a total of $2.4 million in Bridge Notes. In August 2022, the Company issued an additional $0.3 million in Bridge Notes to related parties. The Bridge Notes were convertible into the Company's Common Stock at the time of an IPO or at the noteholder's option at $4.20 per share, adjusted to reflect any stock split, stock dividend, or other similar change in the Common Stock. The convertible Bridge Notes bore interest at six percent (6%) and, with one exception, were amended to have a maturity date of August 31, 2022. The maturity date of one convertible bridge note with a principal amount of $100,000 was not extended and was repaid in full.

In July 2022, all but six of the Bridge Notes with an aggregate principal amount of $325,000 were further amended to have a maturity date of October 31, 2022. As consideration for the maturity date extension, each noteholder received a warrant to purchase that number of shares of Common Stock equal to the quotient obtained by dividing the principal amount of such holder's note by 10.5 at an exercise price equal to $5.25 per share of Common Stock, representing 50% warrant coverage on the principal amount of the note. In connection with the sale of our convertible Bridge Notes, our Placement Agent was paid commissions of nine percent (9.0%) and was issued the Placement Agent's Warrant to purchase 54,464 shares of Common Stock. The Placement Agent's Warrants have substantially the same terms as the warrants issued to our noteholders and an exercise price of $7.35 per share. In the fourth quarter of 2022, the Company repaid $325,000 for those notes that were not converted at the time of the Company's IPO.

We continue to seek sources of financing 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.

Cash Flows

The following information reflects cash flows for the years presented:

	Year Ended December 31,	
	2022	**2021**
	(amounts in thousands)	
Cash and cash equivalents at beginning of year	$ 1,361	$ 83
Net cash used in operating activities	(4,071)	(2,049)
Net cash used in investing activities	(220)	—
Net cash provided by financing activities	14,344	3,327
Cash and cash equivalents at end of year	$ 11,414	$ 1,361

Net Cash Used in Operating Activities

Net cash used in operating activities was approximately $4.1 million and $2.0 million for the years ended December 31, 2022 and 2021, respectively. The increase of approximately $2.1 million in cash used by operations during the year ended December 31, 2022, compared to 2021, was primarily attributable to an increase of $1.8 million in our loss from operations as compared to the prior year as described above. These increases were partially offset by adjustments for the amortization of debt discount related to the issuance of Bridge Notes and non-cash charges related to stock-based compensation.

Net Cash Used in Investing Activities

The Company used approximately $0.2 million in investing activities in 2022, compared to no cash used for the year ended December 31, 2021. The increase in cash used in investing activities in 2022, compared to 2021, is attributable to the purchase of lab equipment in the fourth quarter of 2022.

Net Cash Provided by Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $14.3 million primarily due to net proceeds of approximately $6.0 million from issuance of Common Stock in our IPO, as well as proceeds of approximately $7.8 million from the exercise of warrants and options. Additionally, the increase is due to the issuance of $0.7 million of our Bridge Notes during the year, partially offset by debt issuance costs and the repayment of $425,000 of notes not converted as part of the IPO.

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

Critical Accounting Policies and Use of Estimates

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

Share-Based Compensation

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

Accounting for Income Taxes

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

Fair Value of Convertible Notes Payable

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

The Company elected to account for the convertible notes payable at fair value with any changes in fair value being recognized in the consolidated 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, or ii) conversion into the common share class. Given the issuance dates, a negotiation discount was calibrated and applied such that the probability weighting of the 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.

Emerging Growth Company (EGC) 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 the IPO, 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 would also cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Item 10 of Regulation S-K and are not required to provide the information otherwise required under this Item 7A.

Item 8. Financial Statements and Supplementary Data.

The information required by this item is presented at the end of this Annual Report on Form 10-K beginning on page F-1 and is incorporated herein by reference. An index of those financial statements is found in Part IV, Item 15, Exhibits, Financial Statement Schedules, of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

As of December 31, 2022, the end of the period covered by this Annual Report, our Chief Executive Officer and Chief Financial Officer evaluated the effectiveness of our "disclosure controls and procedures," as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Rules 13a-15(e)and 15d-15(e)). Based on that evaluation, management has concluded that due to limited resources and limited number of employees, its internal control over financial reporting was ineffective as of December 31, 2022, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. To mitigate the limited resources and employees, we rely heavily on direct management oversight of transactions, along with the use of legal and accounting professionals. As we grow, we expect to increase the number of employees, which we believe will enable us to implement adequate segregation of duties within the internal control framework.

Internal Control over Financial Reporting

Management's Annual Report on Internal Control over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the SEC for newly public companies.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of the Company's registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal controls (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) over financial reporting during the year ended December 31, 2022, covered by this Annual Report that could materially affect, or are reasonably likely to materially affect, our financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance.

The information required by this item of Form 10-K will be included under the caption "Directors, Executive Officers, and Corporate Governance" in our 2023 Proxy Statement, and is incorporated by reference herein.

Item 11. Executive Compensation.

The information required by this item of Form 10-K will be included under the caption "Executive and Director Compensation" in our 2023 Proxy Statement and is incorporated by reference herein.

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

The information required by this item of Form 10-K will be included in our 2023 Proxy Statement and is incorporated by reference herein.

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

The information required by this item of Form 10-K will be included under the captions "Certain Relationships and Related Party Transactions" and "Board of Directors and Corporate Governance – Director Independence" in our 2023 Proxy Statement and is incorporated by reference herein.

Item 14. Principal Accounting Fees and Services.

The information required by this item of Form 10-K will be included in our 2023 Proxy Statement and is incorporated by reference herein.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a) Financial Statements and Schedules.

See "Index to Consolidated Financial Statements" in Part II, Item 8 of this Annual Report on Form 10-K.

(b) Exhibits.

		Incorporated by Reference		
Exhibit No.	**Exhibit Title**	**Form**	**Filed Date**	**Exhibit No.**
3.1	Amended and Restated Certificate of Incorporation of Registrant, as currently in effect.	Form S-1/A	June 16, 2022	3.3
3.2	Bylaws of the Registrant, as currently in effect.	Form S-1/A	June 16, 2022	3.6
4.1	Form of Registrant's Common Stock Certificate.	Form S-1/A	June 16, 2022	4.1
4.2	Common Stock Purchase Warrant issued to San Antonio Economic Development Corporation dated March 17, 2017.	Form S-1/A	May 25, 2022	4.2
4.3	Form of Common Stock Purchase Warrant issued to Holders of the Registrant's Convertible Promissory Notes.	Form S-1/A	May 25, 2022	4.3
4.4	Form of Placement Agent's Warrant issued to WallachBeth Capital, LLC.	Form S-1/A	August 5, 2022	4.4
4.5	Form of Representative's Warrant issued to WallachBeth Capital, LLC.	Form S-1/A	July 28, 2022	4.5
4.6	Form of (Tradeable) Common Stock Purchase Warrant issued as part of the Units sold in the Registrant's IPO.	Form S-1/A	August 18, 2022	4.6
4.7	Form of Warrant Agent Agreement for the Warrants issued as part of the Units sold in the Registrant's IPO.	Form S-1/A	August 18, 2022	4.7
4.8	Form of (Non-tradeable) Common Stock Purchase Warrant issued as part of the Units sold in the Registrant's IPO.	Form S-1/A	August 18, 2022	4.15
10.1	2014 Equity Incentive Plan of Registrant, as amended.	Form S-1/A	May 25, 2022	10.1
10.2	Executive Chairman Employment Agreement dated January 1, 2020, by and between Registrant and Steven Girgenti, as amended.	Form S-1/A	May 25, 2022	10.2
10.3	Employment Agreement dated February 1, 2015, by and between Registrant and Maria Zannes.	Form S-1/A	May 25, 2022	10.3
10.4	Employment Agreement dated April 4, 2016, by and between Registrant and Vivienne Rebel, as amended.	Form S-1/A	May 25, 2022	10.4

Exhibit No.	Exhibit Title	Incorporated by Reference		
		Form	Filed Date	Exhibit No.
10.5	Employment Agreement dated February 1, 2015, by and between Registrant and Timothy Zannes.	Form S-1/A	May 25, 2022	10.5
10.6	Consulting Agreement dated May 25, 2017, by and between Registrant and Michael Edwards, as amended.	Form S-1/A	May 25, 2022	10.6
10.7	License Agreement to Participate in the UTSA New Venture Incubator Program dated June 15, 2015, by and between Registrant and the University of Texas at San Antonio.	Form S-1/A	May 25, 2022	10.7
10.8	Joint Development Agreement dated October 1, 2018, by and between the Registrant and Village Oaks Pathology Services, P.A. d/b/a Precision Pathology Services.	Form S-1/A	May 25, 2022	10.8
10.9	Agreement dated October 17, 2020, by and between Registrant and GO2 Partners.	Form S-1/A	May 25, 2022	10.9
14.1	Code of Business Conduct of the Registrant.	Form S-1/A	May 25, 2022	14.1
19.1	Insider Trading Policy of the Registrant.	Filed herewith		
21.1	List of Subsidiaries of the Registrant.	Form S-1/A	May 25, 2022	21.1
31.1	Certification of Chief Executive Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith		
31.2	Certification of Chief Financial Officer pursuant to Section 302 of Sarbanes-Oxley Act of 2002	Filed herewith		
32.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002	Furnished herewith		
101.INS	Inline XBRL Instance Document	Filed herewith		
101.SCH	Inline XBRL Taxonomy Extension Schema Document	Filed herewith		
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith		
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith		
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	Filed herewith		
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith		
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)	Filed herewith		

SIGNATURES.

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

bioAffinity Technologies, Inc.

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Maria Zannes Maria Zannes	President, Chief Executive Officer, and Director (Principal Executive Officer)	March 31, 2023
/s/ Michael Edwards Michael Edwards	Chief Financial Officer (Principal Financial and Accounting Officer)	March 31, 2023
/s/ Steven Girgenti Steven Girgenti	Executive Chairman and Director	March 31, 2023
/s/ Robert Anderson Robert Anderson	Director	March 31, 2023
/s/ Stuart Diamond Stuart Diamond	Director	March 31, 2023
/s/ Peter S. Knight Peter S. Knight	Director	March 31, 2023
/s/ Mohsin Meghji Mohsin Meghji	Director	March 31, 2023
/s/ Gary Rubin Gary Rubin	Director	March 31, 2023

bioAffinity Technologies, Inc.
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Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of bioAffinity Technologies, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, changes in convertible preferred stock and stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021 and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB 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 audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ WithumSmith+Brown, PC

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

New York, New York
March 31, 2023

PCAOB ID Number 100

BIOAFFINITY TECHNOLOGIES, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,413,759	$ 1,360,638
Accounts and other receivables, net	10,489	1,530
Inventory	5,540	—
Prepaid expenses and other current assets	531,899	76,065
Total current assets	11,961,687	1,438,233
Deferred offering costs	—	7,942
Property and equipment, net	214,438	4,633
Other assets	6,000	2,500
Total assets	$ 12,182,125	$ 1,453,308
LIABILITIES, CONVERTIBLE PREFERRED STOCK, AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 345,042	$ 230,407
Accrued expenses	541,894	483,501
Accrued interest	—	1,121,392
Current portion of Paycheck Protection Program loan	—	52,074
Loan payable	251,746	—
Convertible notes payable at fair value	—	11,152,151
Total current liabilities	1,138,682	13,039,525
Paycheck Protection Program loan, less current portion	—	160,184
Total liabilities	1,138,682	13,199,709
Commitments and contingencies (See Note 9)		
Convertible preferred stock, par value $0.001 per share; 20,000,000 shares authorized; 0 and 756,558 shares issued and outstanding, aggregate liquidation preference of $0 and $5,825,648 at December 31, 2022 and 2021, respectively	—	4,044,318
Stockholders' equity (deficit):		
Preferred stock, no shares issued or outstanding at December 31, 2022 and 2021, respectively	—	—
Common Stock, par value $0.007 per share; 14,285,714 shares authorized; 8,381,324 and 2,677,140 shares issued and outstanding as of December 31, 2022 and 2021, respectively	58,669	18,740
Additional paid-in capital	47,652,242	12,703,896
Accumulated deficit	(36,667,468)	(28,513,355)
Total stockholders' equity (deficit)	11,043,443	(15,790,719)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	$ 12,182,125	$ 1,453,308

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

bioAffinity Technologies, Inc.
consolidated Statements of Operations
For the Years Ended December 31, 2022 and 2021

	2022	2021
Revenue	$ 4,803	$ —
Cost of sales	467	—
Gross profit	4,336	—
Operating expenses:		
Research and development	1,142,777	1,007,476
Clinical development	145,546	130,475
Selling, general and administrative	2,727,071	1,068,871
Total operating expenses	4,015,394	2,206,822
Loss from operations	(4,011,058)	(2,206,822)
Other income (expense):		
Interest income	46,708	424
Interest expense	(2,532,640)	(1,001,854)
Gain on extinguishment of debt	212,258	239,200
Fair value of warrants issued	—	(4,080,339)
Fair value adjustments on convertible notes payable	(1,866,922)	724,928
Loss before income taxes	(8,151,654)	(6,324,463)
Income tax expense	(2,459)	(1,950)
Net loss	$ (8,154,113)	$ (6,326,413)
Net loss per common share, basic and diluted	$ (1.81)	$ (2.36)
Weighted average common shares outstanding	4,498,964	2,675,270

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' EQUITY (DEFICIT)
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	756,558	$ 4,044,318	2,674,860	$ 18,724	$ 7,095,355	$ (22,186,942)	$ (15,072,863)
Stock-based compensation expense	—	—	2,280	16	42,996	—	43,012
Fair value of warrants issued	—	—	—	—	4,080,339	—	4,080,339
Beneficial conversion feature for bridge notes	—	—	—	—	739,602	—	739,602
Debt discount for warrants issued	—	—	—	—	745,604	—	745,604
Net loss	—	—	—	—	—	(6,326,413)	(6,326,413)
Balance at December 31, 2021	756,558	$ 4,044,318	2,677,140	$ 18,740	$ 12,703,896	$ (28,513,355)	$ (15,790,719)
Stock-based compensation expense	—	—	29,728	208	248,384	—	248,592
Beneficial conversion feature for bridge notes	—	—	—	—	462,344	—	462,344
Return of capital from stock split	—	—	—	—	(185)	—	(185)
Debt discount for warrants issued	—	—	—	—	352,250	—	352,250
Common stock issued upon initial public offering, net of underwriters' commission and offering costs of $1.8 million	—	—	1,282,600	8,978	6,018,436	—	6,027,414
Common stock issued on conversion of convertible preferred stock	(756,558)	$ (4,044,318)	756,558	5,296	4,039,022	—	4,044,318
Common stock issued on conversion of notes payable	—	—	2,533,964	17,738	16,047,594	—	16,065,332
Exercise of warrants	—	—	1,036,486	7,255	7,706,055	—	7,713,310
Exercise of stock options	—	—	64,848	454	74,446	—	74,900
Net loss	—	—	—	—	—	(8,154,113)	(8,154,113)
Balance at December 31, 2022	—	$ —	8,381,324	$ 58,669	$ 47,652,242	$ (36,667,468)	$ 11,043,443

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

BIOAFFINITY TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021

	2022	2021
Cash flows from operating activities		
Net loss	$ (8,154,113)	$ (6,326,413)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	10,182	4,817
Accretion of debt issuance costs	2,055,627	480,574
Fair value adjustments on convertible notes payable	1,866,922	(724,928)
Stock-based compensation expense	248,592	43,012
Fair value of warrants issued	—	4,080,339
Gain on extinguishment of debt	(212,258)	(239,200)
Changes in operating assets and liabilities:		
Accounts and other receivables	(8,959)	—
Inventory	(5,540)	—
Prepaid expenses and other assets	(492,753)	(34,990)
Accounts payable	114,635	39,020
Accrued expenses	66,335	107,744
Accrued interest	440,485	521,047
Net cash used in operating activities	(4,070,845)	(2,048,978)
Cash flows from investing activities		
Purchase of property and equipment	(219,987)	—
Net cash used in investing activities	(219,987)	—
Cash flows from financing activities		
Proceeds from loan payable	555,148	212,258
Payment on loans payable	(269,983)	—
Proceeds from issuance of convertible notes payable	724,000	3,295,000
Repayment of convertible loan payable	(425,000)	—
Proceeds from issuance of common stock from the initial public offering, net of underwriting discounts, commissions and offering expenses of approximately $1.8 million	6,027,414	—
Exercise of warrants	7,713,310	—
Exercise of stock options	74,900	—
Return of capital from stock split	(185)	—
Payment of debt issuance costs	(55,651)	(180,750)
Net cash provided by financing activities	14,343,953	3,326,508
Net increase in cash and cash equivalents	10,053,121	1,277,530
Cash and cash equivalents at beginning of year	1,360,638	83,108
Cash and cash equivalents at end of year	$ 11,413,759	$ 1,360,638
Supplemental disclosures of cash flow information:		
Income taxes paid in cash	$ 2,459	$ 1,950
Interest paid	$ 30,637	—
Conversion of convertible preferred stock into common stock	$ 4,044,318	—
Conversion of convertible notes payable into common stock	$ 16,065,332	—
Fair value of warrants issued to placement agents	$ 352,250	$ 74,556
Beneficial conversion feature for bridge notes	$ 462,344	$ 739,602

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

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

Description of Business

bioAffinity Technologies, Inc., a Delaware corporation (the "Company," "we," or "our"), addresses the need for noninvasive diagnosis of early-stage cancer and diseases of the lung and for targeted cancer treatment. The Company develops proprietary noninvasive diagnostic tests and cancer therapeutics using technology that preferentially targets cancer cells and cell populations indicative of a diseased state. Our first diagnostic test, CyPath® Lung, is a noninvasive test for early detection of lung cancer, the leading cause of cancer-related deaths. Research and optimization of our proprietary platform for *in vitro* diagnostics and 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, monitor, and treat diseases of the lung and other cancers.

Organization and Initial Public Offering

The Company was formed on March 26, 2014, as a Delaware corporation with its corporate offices located in San Antonio, Texas. On June 15, 2016, the Company formed a wholly owned subsidiary, OncoSelect® Therapeutics, LLC, as a Delaware limited liability company.

On September 6, 2022, the Company completed its initial public offering (the "IPO") of 1,282,600 units (the "Units") at an offering price of $6.125 per Unit (the "Offering Price"). Each Unit consists of (i) one share of the Company's common stock, par value $0.007 per share ("Common Stock"), (ii) one tradeable warrant (a "Tradeable Warrant") exercisable for the purchase of one share of Common Stock at an exercise price of $7.35 per share, and (iii) one non-tradeable warrant (a "Non-tradeable Warrant") exercisable for the purchase of one share of Common Stock at an exercise price of $7.656 per share. The sale of Units in the IPO generated gross proceeds to the Company of approximately $7.8 million before deducting underwriting discounts, commissions, and other offering expenses. The Company intends to use the net proceeds from the Offering for working capital and for general corporate purposes, including product and test development, sales, general and administrative matters, and capital expenditures.

In connection with the closing of the IPO, the Company converted 5,296,044 shares of the convertible preferred stock into 756,558 shares of Common Stock. Additionally, the Company converted approximately $16.1 million in convertible notes, Bridge Notes, and related accrued interest into 2,533,964 Common Stock. See Note 8.

In June 2022, the Company completed a 1-for-7 reverse stock split of its Common Stock. All share and per share amounts have been adjusted on a retroactive basis in these consolidated financial statements to reflect the effect of the reverse stock split. In addition, the stock split resulted in the par value of the Company's Common Stock increasing to $0.007 per share.

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 $36.7 million at December 31, 2022. Our cash and cash equivalents at December 31, 2022 were approximately $11.4 million, representing 93% of our total assets. Based on our current expected level of operating expenditures, the Company believes its cash on hand at December 31, 2022, is sufficient 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. Thereafter, the Company may need to raise further capital through the sale of additional equity or debt securities or other debt instruments, strategic relationships or grants, or other arrangements to support its future operations. If such funding is not available or not available on terms acceptable to the Company, the Company's current development plan may be curtailed.

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 continues to monitor the situation closely.

Note 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

Principles of Consolidation

The accompanying consolidated financial statements include all of the accounts of the Company and its wholly owned subsidiary, Oncoselect Therapeutics, LLC. 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 has significant cash balances at financial institutions which throughout the year regularly exceed the federally insured limit of $250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flows.

Accounts and Other Receivables, Net

Accounts and other receivables, net consists of amounts invoiced to Precision Pathology Services ("Precision Pathology"), a CAP-accredited, CLIA-certified clinical pathology laboratory and our licensee for royalties from sales of our first diagnostic test, CyPath® Lung.

The allowance for doubtful accounts is based on forecasted losses and a review on a specific identification basis of the collectability of outstanding receivables. As of December 31, 2022 and 2021, there is no allowance for doubtful accounts.

Prepaid Expenses and Other Assets

Prepaid expenses 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 term of service.

Deferred Offering Costs

The Company capitalizes certain legal, accounting, and other third-party fees that are directly related to the Company's equity financings, including its IPO, until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the financing. The Company capitalized certain legal, accounting, and other third-party fees that were directly related to the Company's IPO. After the completion of the IPO in September 2022, total deferred offering costs of approximately $1.8 million were offset against the proceeds from the IPO and reclassified to additional paid-in capital in the accompanying consolidated balance sheets. At December 31, 2021, deferred offering costs totaling approximately $8,000 were included as non-current assets in the accompanying consolidated balance sheet.

Property and Equipment, Net

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, 2022 and 2021, respectively.

Patent Expenses

Costs related to filing and pursuing patent applications, as well as costs related to maintaining the Company's existing patent portfolio, are recorded as expenses 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.

Advertising expense

The Company expenses all advertising costs as incurred. Advertising expense was approximately $3,000 for the year ended December 31, 2022. There were no advertising expenses for the year ended December 31, 2021.

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

Revenue Recognition

Our revenue is generated exclusively from royalties for our first diagnostic test, CyPath® Lung, from sales by Precision Pathology that began a limited market launch in the second quarter of 2022 to pulmonologists in the San Antonio, Texas, area designed to refine future positioning and develop strategic insight for our CyPath® Lung test. The services are completed upon release of a patient's test result to the ordering healthcare provider.

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

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, 2022 and 2021, as they would be anti-dilutive:

	Year Ended December 31,	
	2022	2021
Convertible preferred stock	—	756,558
Shares underlying options outstanding	806,392	878,380
Shares underlying warrants outstanding	4,649,952	1,890,183
Shares underlying convertible notes outstanding	—	2,357,941
	5,456,344	5,883,062

Segment Information

The Company is organized as a single operating segment, whereby its chief operating decision maker assesses 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 consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

The three-tier fair value hierarchy for disclosure of fair value measurements is 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 $1.1 million and $1.0 million for the years ended December 31, 2022 and 2021, 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 ("FDA") and the Center for Medicare and Medicaid. The Company has not yet obtained marketing authorization from the FDA but is able to market its CyPath® Lung test as a Laboratory Developed test licensed to and sold by Precision Pathology Services, a CAP-accredited, CLIA-certified clinical pathology laboratory.

Reclassifications

Certain prior year balances have been reclassified to conform to current year presentation. The Company reclassified patent and annuity costs of approximately $236,000 and $188,000 from research and development to selling, general and administrative for the years ended December 31, 2022, and 2021, respectively.

Recently Issued Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12). ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistency in application. ASU 2019-12 will be effective for public entities for interim and annual periods beginning after December 15, 2020, with early adoption permitted. The Company adopted ASU 2019-12 and concluded there is no impact on the Company's consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity, which simplifies the accounting for convertible instruments by eliminating the requirement to separate embedded conversion features from the host contract when the conversion features are not required to be accounted for as derivatives under Topic 815, Derivatives and Hedging, or that do not result in substantial premiums accounted for as paid-in capital. By removing the separation model, a convertible debt instrument will be reported as a single liability instrument with no separate accounting for embedded conversion features. This new standard also removes certain settlement conditions that are required for contracts to qualify for equity classification and simplifies the diluted earnings per share calculations by requiring that an entity use the if-converted method and that the effect of potential share settlement be included in diluted earnings per share calculations. The new standard will be effective for fiscal years beginning after December 15, 2023, for smaller reporting companies. As the Company currently does not have debt with conversion and other options, the Company does not believe the adoption will have a material impact on our consolidated financial statements.

Note 3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets at December 31, 2022 and 2021, are summarized below:

	December 31, 2022	December 31, 2021
Prepaid insurance	$ 340,078	$ 16,765
Legal and professional	72,048	55,081
Other	119,773	4,219
Total prepaid expenses and other current assets	$ 531,899	$ 76,065

Note 4. PROPERTY AND EQUIPMENT, NET

Property and equipment at December 31, 2022 and 2021, are summarized below:

	December 31, 2022	December 31, 2021
Lab equipment	$ 462,155	$ 242,168
Computers and software	21,463	21,463
	483,618	263,631
Less: accumulated depreciation and amortization	(269,180)	(258,998)
Total property and equipment, net	$ 214,438	$ 4,633

Depreciation and amortization expense was $10,182 and $4,817 for the years ended December 31, 2022, and 2021, respectively.

Note 5. ACCRUED EXPENSES

Accrued expenses at December 31, 2022 and 2021, are summarized below:

	December 31, 2022	December 31, 2021
Compensation	$ 340,680	$ 277,185
Legal and professional	144,440	166,069
Clinical	50,922	39,481
Other	5,852	766
Total accrued expenses	$ 541,894	$ 483,501

Note 6. LOAN PAYABLE

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") provided 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 and recorded a gain of $212,000 on the extinguishment of debt in the accompanying consolidated statements of operations.

In September 2022, the Company obtained short-term financing of approximately $0.5 million with ten monthly payments of approximately $42,000 and interest at a 4.3% fixed annual rate for director and officer insurance policies.

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. There are no assets and liabilities that are measured at fair value at December 31, 2022. The table below summarizes the Company's assets and liabilities that are measured at fair value at December 31, 2021:

	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

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:

	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%

The Company transferred $325,000 of convertible notes payable from level 3 to level 2 during the year ended December 31, 2022, to account for notes that were not converted at the time of the Company's IPO. During the fourth quarter of 2022, these notes, together with the related accrued interest, were repaid in full. See Note 8. There were no transfers into or out of level 3 during the year ended December 31, 2021. The Company issued a total of $0.7 million and $3.3 million in convertible notes for the years ended December 31, 2022, and 2021, respectively, which are included in level 3 liabilities. The following table summarizes the fair values of convertible note payables and the change in fair value at each measurement date:

Fair value of convertible notes payable at December 31, 2020	$	9,767,461
Convertible notes payable issued		3,295,000
Debt discount for warrants issued		(1,665,956)
Accretion of debt issuance costs		480,574
Change in fair value of convertible notes payable		(724,928)
Fair value of convertible notes payable at December 31, 2021	$	11,152,151
Additional convertible notes payable issued		724,000
Repayment of convertible notes payable		(100,000)
Debt discount for warrants issued		(870,245)
Accretion of debt issuance costs		2,055,627
Change in fair value of convertible notes payable		1,866,922
Transfer from level 3 to level 2		(325,000)
Conversion of convertible notes payable into common stock		(14,503,455)
Fair value of convertible notes payable at December 31, 2022	$	—

Note 8. CONVERTIBLE NOTES PAYABLE

In September 2022, in connection with the closing of the IPO, the Company converted approximately $16.1 million consisting of approximately $9.1 million in convertible notes and Bridge Notes, related accrued interest of approximately $1.6 million, and approximately $5.4 million of fair value adjustments into 2,533,964 shares of Common Stock.

From August 2018 through July 2020, the Company 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 have elected to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of $6.62 per share. The convertible notes payable had a maturity date of December 31, 2020, bore interest at 8% annually, and were secured by the intellectual property of the Company. The Company obtained the necessary noteholder approvals to extend the maturity date of the notes in November 2021 to May 31, 2022, and in May 2022 to August 2022. In July 2022, the Company obtained approval from a majority of the noteholders to extend the maturity date from August 31, 2022, to October 31, 2022, for certain Bridge Notes in exchange for a Common Stock purchase warrant equal to the principal amount of each note divided by 10.5. As a result, the Company issued warrants to purchase 478,446 shares of Common Stock at a price of $5.25 per share. See Note 12 for additional disclosures related to warrants. Upon completion of the IPO, the notes automatically converted into shares of Common Stock. Conversion of the note at the IPO closing extinguished this security and resulted in the Company wholly owning all its intellectual property without a security interest.

From October 2020 through June 2021, the Company 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 have elected to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of $6.62 per share. The convertible notes payable bore interest at 8% annually and had a maturity date in October 2021. The Company obtained the necessary noteholder approvals to extend the maturity date of the notes in December 2021 to May 2022 and in May 2022 to August 2022. In July 2022, the Company obtained approval from a majority of the noteholders to extend the maturity date from August 31, 2022, to October 31, 2022, for certain Bridge Notes in exchange for a Common Stock purchase warrant equal to the principal amount of each note divided by 10.5. As a result, the Company issued warrants to purchase 79,795 shares of the Company's Common Stock at a price of $5.25 per share. See Note 12 for additional disclosures related to warrants. Upon completion of the IPO, the $0.9 million of the notes automatically converted into shares of Common Stock. In October 2022, the Company repaid $100,000 for the note that was not converted at the time of the Company's IPO.

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 was still outstanding, the noteholder could elect to convert the outstanding principal and accrued interest into shares of the Company's Common Stock at a price of $6.62 per share. As a result of the completion of a bridge financing sufficient to provide working capital to complete an IPO, the notes became convertible into the Company's equity securities on the same terms as the conversion feature established in the bridge financing. The convertible notes payable had a maturity date in December 2022 and bore interest at eight percent (8%) annually. Upon completion of the IPO, the notes automatically converted into shares of Common Stock.

Bridge Notes

In the fourth quarter of 2021 and until our IPO in the third quarter of 2022, the Company issued a total of $2.6 million in Bridge Notes, which were convertible into the Company's Common Stock, at the time of an IPO, or at the noteholder's option, at $4.20 per share, adjusted to reflect any stock split, stock dividend, or other similar change in the Common Stock. The Bridge Notes bore interest at 6% and had a maturity date of May 31, 2022. In May 2022, the Company obtained the necessary noteholder approvals to extend the maturity date of the notes to August 31, 2022. In July 2022, the Company obtained approval from a majority of the noteholders to extend the maturity date to October 31, 2022, for certain Bridge Notes in exchange for a Common Stock purchase warrant equal to the principal amount of the note divided by 10.5. As a result, the Company issued warrants to purchase 758,227 shares of the Company's Common Stock at a price of $5.25 per share. See Note 12 for additional disclosures related to warrants. Upon completion of the IPO, approximately $2.3 million of the notes automatically converted into shares of Common Stock. In the fourth quarter of 2022, the Company repaid $325,000 for those notes that were not converted at the time of the Company's IPO.

Additionally, each noteholder received a warrant to purchase one share of Common Stock based on the investor's bridge note principal balance investment. The warrants have a five-year term at an exercise price equal to $5.25 per share. In connection with the IPO, the Company paid commissions of nine percent (9%) and issued its placement agents warrants to purchase 54,464 shares of Common Stock. The warrants issued to the Company's placement agents have substantially the same terms as the warrants issued to our noteholders.

The Company elected to account for the convertible notes payable at fair value with any changes in fair value being recognized through the consolidated statements of operations until the convertible notes are settled. The fair value of the convertible notes was determined with the assistance of a third-party specialist, considering the value of the notes payable that would be received by converting into common stock in each scenario, plus a put option. In coordination with the Company's IPO, the notes were converted to Common Stock. Convertible notes payable consisted of the following:

	December 31, 2021
Secured convertible notes payable	$ 5,041,957
Unsecured convertible notes payable	3,740,000
Principal amount of convertible notes payable	8,781,957
Debt issuance costs	(1,185,382)
Fair value adjustments on convertible notes payable	3,555,576
Total convertible notes payable	$ 11,152,151

The Company elected to account for the convertible notes payable at fair value with any changes in fair value being recognized through the consolidated statements of operations until the convertible notes are settled. The fair value of the convertible notes was determined with the assistance of a third-party specialist, considering the value of the notes payable that would be received by converting into Common Stock in each scenario, plus a put option.

Note 9. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its corporate offices under a month-to-month agreement and lab space under an operating lease that is renewable annually and expires in February 2024. Rent expense for office and lab space amounted to approximately $65,000 and $52,000 for the years ended December 31, 2022 and 2021, respectively.

Legal Matters

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

Note 10. CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

In June 2022, the Company completed a 1-for-7 reverse stock split of its Common Stock. All share and per share amounts have been adjusted on a retroactive basis in these condensed consolidated financial statements to reflect the effect of the reverse stock split. The Company made a cash payment to stockholders for all fractional shares that it would otherwise be required to issue as a result of the stock split. In addition, the stock split resulted in the par value of the Company's Common Stock increasing to $0.007 per share.

Convertible Preferred Stock

The Company has authorized a total of 20,000,000 shares of $0.001 per share par value preferred stock. In July 2017, the Company completed a private placement of securities in which 0.2 million shares of Series A preferred stock were sold, resulting in net proceeds of $1.5 million. As part of the closing, the Company issued 0.6 million shares in exchange for $2.6 million of the Company's convertible notes payable and related accrued interest.

In accordance with the Certificate of Designation of the Series A preferred stock, all of the shares of Series A preferred stock that were issued and outstanding at the time of the IPO were automatically converted into 756,558 fully paid and nonassessable shares of Common Stock at a 1-for-7 conversion rate (as adjusted for the 1-for-7 reverse stock split). The shares of Series A preferred stock that were so converted ceased to be part of the Company's authorized stock and will never again be issued by the Company. As of December 31, 2022, no preferred stock is outstanding.

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 had various rights, preferences, and privileges as follows:

Voting Rights

Each share of Series A preferred stock was 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 were 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, were entitled to elect one director of the Company.

Dividends

The holders of shares of Series A preferred stock were 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 was not cumulative, and no right to such dividends would 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 was 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, each of the 756,558 shares of Series A preferred stock was convertible into one share of Common Stock. The respective applicable conversion prices for the Series A preferred stock were 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 converted 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 were entitled to receive an amount equal to $7.70 per share (subsequent to the reverse-stock-split calculation) plus an additional amount equal to any dividends declared or accrued but unpaid on each share. If, upon such liquidation event, the assets and funds distributed are insufficient to permit the payment to each holder of the Series A preferred stock of the full preferential amount, the entire assets and funds legally available for distribution to the holders of Series A preferred stock would have been 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 14,285,714 shares of $0.007 per share par value Common Stock. Holders of Common Stock are entitled to cast one vote for each share held of record on all matters presented to the stockholders and have no cumulative voting rights. As of December 31, 2022, the Company has issued 8,381,324 shares of Common Stock.

In November 2021, the Company received shareholder approval to increase the number of authorized shares from 7,142,857 to a total of 14,285,714 shares of $0.007 per share par value Common Stock.

Note 11. STOCK-BASED COMPENSATION

The Company grants options under its 2014 Equity Incentive Plan (the "Plan"). The Plan is authorized to grant Incentive Stock Options, Non-statutory Stock Options, or Restricted Stock for up to 1.1 million shares of Common Stock, or twenty percent (20%) of the total issued and outstanding Common Stock, whichever is greater. The Company has reserved 1.1 million shares to be under the plan. Options may be granted to employees, the Company's board of directors, and external consultants who provide service to the Company. The options 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 ceases to be employed or providing 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:

	2022	2021
Research and development	$ 7,832	$ 25,262
Selling, general and administrative	240,760	17,750
Total stock-based compensation expense	$ 248,592	$ 43,012

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, 2020	824,104	$ 4.10		
Granted	79,273	5.49		
Exercised	—	—		
Forfeited	(24,997)	7.70		
Outstanding at December 31, 2021	878,380	$ 4.12		
Granted	7,142	4.20		
Exercised	(64,848)	1.16		
Forfeited	(14,282)	5.95		
Outstanding at December 31, 2022	806,392	$ 4.33	4.0	$ 164,255
Vested and exercisable at December 31, 2022	800,838	$ 4.31	4.0	$ 164,255

As of December 31, 2022, there was no unrecognized compensation cost related to non-vested stock options.

During the year ended December 31, 2021, the Company issued options to purchase 79,273 shares of Common Stock to employees and non-employees. The per share weighted-average fair value of the options granted during 2021 was estimated at $2.23 on the date of grant. During the year ended December 31, 2021, no options were exercised.

During the year ended December 31, 2021, the Company issued restricted stock units (RSUs) for 7,856 shares of Common Stock to employees. The shares vest in equal monthly installments over terms of between one to three years, subject to the employee providing continuous service through the vesting date. The approximately 6,000 unissued shares vest over a weighted-average period of 1.7 years.

During the year ended December 31, 2022, the Company issued options to purchase 7,142 shares of Common Stock to employees. The per share weighted-average fair value of the options granted during 2022 was estimated at $2.84 on the date of grant. During the year ended December 31, 2022, 64,848 options were exercised into an equivalent number of common shares. The company received proceeds of approximately $75,000 from the exercise of the options.

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, 2022, and 2021, respectively:

	2022	2021
Fair value of Common Stock	$ 4.62	$ 3.79
Volatility	63.9%	72.8%
Expected term (years)	6.0	6.1
Risk-free interest rate	2.20%	1.14%
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—The fair value of stock option and restricted share grants are determined based on the closing price of our stock on the date of grant.

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 does not have sufficient 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 consolidated balance sheet at fair value, and changes in fair value during the periods presented in the consolidated statement of operations, which is revalued at each consolidated balance sheet date subsequent to the initial issuance of the stock warrant.

In September 2022, in connection with our IPO, we issued a total of 1,282,600 Tradeable Warrants, each exercisable for the purchase of one share of Common Stock at an exercise price of $7.35 per share, and 1,282,600 Non-tradeable Warrants, each exercisable for the purchaseof one share of Common Stock at an exercise price of $7.656 per share. The Common Stock and the Tradeable Warrants trade on The Nasdaq Capital Market under the symbols “BIAF’ and “BIAFW,” respectively.

Pursuant to the underwriting agreement dated August 31, 2022, (the “Underwriting Agreement”) between the Company and WallachBeth Capital, LLC, as representative of the underwriters (the “Underwriters”), and solely for purposes of covering any over-allotments made in connection with our IPO, we granted the Underwriters an option to purchase up to an additional 192,390 shares of Common Stock at the Offering Price per Unit less $0.02, and/or up to 192,390 Tradeable Warrants at $0.01 per Tradeable Warrant, and/or up to 192,390 Non-tradeable Warrants at $0.01 per Non-tradeable Warrant, or any combination of additional shares of Common Stock, Tradeable Warrants, and Non-tradeable Warrants representing in the aggregate up to 15% of the number of Units sold in the IPO (the “Over-Allotment Option”). The Over-Allotment Option was exercisable for a period of 45 days from the date of our Final Prospectus. The Underwriters exercised a portion of their overallotment option and purchased 110,167 Tradeable Warrants at a purchase price of $0.01 per warrant, and 110,167 non-tradable warrants at a purchase price of $0.01 per warrant.

In 2022, 1,036,486 warrants were exercised into an equivalent number of Common Shares for proceeds of approximately $7.7 million. During the year ended December 31, 2021, no warrants were exercised into an equivalent number of common shares.

In 2022, the Company issued an additional 226,842 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 $0.5 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, 2022, the Company recognized approximately $2.1 million in interest expense related to the amortization of the debt discount and issuance costs.

From October 2021 through August 2022, the Company issued approximately $2.7 million in convertible promissory notes ("Bridge Notes"), which accrued interest at a rate of 6% per year. Originally, all principal and unpaid interest on the Bridge Notes were due, if not settled prior, on May 31, 2022. See Note 8. Each Bridge Note was issued 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 $5.25 per share.

In 2021, the Company issued an aggregate of 464,272 equity-classified Common Stock warrants. Proceeds from the Bridge Notes were allocated to the notes and warrants on a relative fair value basis resulting in a 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 was being amortized over the life of the Bridge Notes using the effective interest method. For the year ended December 31, 2021, the Company recognized $0.5 million in interest expense including the amortization of the debt discount.

In connection with the issuance of the Bridge Notes, the Company amended the 2018 and 2020 Notes whereby upon completion of an IPO, all outstanding principal and interest will convert into shares of the Company's Common Stock and at $4.20 per share. As an inducement to amending the notes to extend the maturity dates until October 31, 2022, the Company issued 1,419,483 Common Stock warrants with the same terms and conditions as the warrants issued to the Bridge Note holders. The estimated fair value of the warrants was $4.1 million and immediately expensed within the accompanying statement of operations.

The following table summarizes the calculated aggregate fair values for the warrant derivative liability using the Black-Scholes method based on the following assumptions at December 31, 2022:

Exercise price per share of warrant	$	5.25
Fair market closing price per share of Common Stock	$	4.13
Volatility		107-121%
Expected term (years)		5.0
Risk-free interest rate		1.37-1.62%
Dividend yield		0%

In March 2017, the Company issued an aggregate of 6,428 Common Stock purchase warrants, which are classified as equity. The warrants were issued with an exercise price of $7.00 per share and expire on the tenth anniversary of the issuance date.

Note 13. INCOME TAXES

Deferred tax assets and valuation allowance

The Company had, subject to limitation, approximately $18.4 million of net operating loss carryforwards at December 31, 2022, of which approximately $6.0 million will begin expiring in 2034. The remaining balance of approximately $12.4 million will carry forward indefinitely. A 100% valuation allowance has been provided for the deferred tax benefits resulting from the net operating loss carryover due to a lack of earnings history. In addressing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences are deductible. The valuation allowance increased by approximately $0.8 million and $0.5 million for the years ended December 31, 2022, and 2021, respectively. Significant components of deferred tax assets are as follows:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryover	$ 3,871,192	$ 3,302,836
Stock compensation	477,055	434,645
Capitalized R&E costs	260,560	—
Depreciation and amortization	(7,337)	1,099
Other	5,708	3,974
Tax credits	443,867	484,778
Total deferred tax assets	5,051,045	4,227,332
Less: valuation allowance	(5,051,045)	(4,227,332)
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, 2022 and 2021, was as follows:

	Year Ended December 31,	
	2022	2021
Tax at federal statutory rate	(21.0)%	(21.0)%
Permanent differences	10.4	14.8
Research and development credits	2.2	(1.9)
Change in valuation allowance	10.1	8.1
Effective income tax rate	—%	—%

Unrecognized tax benefits

As of December 31, 2022 and 2021, the Company has unrecognized tax benefits related to tax credits of $190,229 and $49,646, respectively. None of the unrecognized tax benefits as of December 31, 2022, 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,	
	2022	2021
Beginning balance	$ 49,646	$ 70,893
Deductions based on tax positions related to the prior year	110,681	(21,247)
Additions based on tax positions related to the current year	29,902	—
Ending balance	$ 190,229	$ 49,646

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 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 bore interest at 8% per annum. The unpaid principal and accrued interest under the notes may be converted into shares of the Company's Common Stock at a conversion price of $4.20 per share. The notes automatically converted into shares of the Company's Common Stock upon the completion of our IPO.
In August 2022, Maria Zannes, the founder, President, Chief Executive Officer, and a director of the Company, purchased a Bridge Note in the principal amount of $99,000. Upon the IPO Closing, the Bridge Note automatically converted into 23,672 shares of Common Stock. In connection with her Bridge Note purchase, Ms. Zannes received a Bridge Warrant to purchase 23,571 shares of Common Stock at an exercise price of $5.25 per share.
In August 2022, Steven Girgenti, the Executive Chairman and a director of the Company, purchased a Bridge Note in the principal amount of $150,000. Upon the IPO closing, the Bridge Note automatically converted into 35,866 shares of Common Stock. In connection with his Bridge Note purchase, Mr. Girgenti received a Bridge Warrant to purchase 35,714 shares of Common Stock at an exercise price of $5.25 per share.

Note 15. SUBSEQUENT EVENTS

The Company evaluated all events or transactions that occurred after December 31, 2022, up through the date the consolidated financial statements were issued. 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, 2022.

EXHIBIT 19.1

BIOAFFINITY TECHNOLOGIES, INC.
INSIDER TRADING POLICY
and Guidelines with Respect to Certain Transactions in Company Securities
As Adopted by the Board of Directors on July 12, 2022

I. PURPOSE

It is illegal for any employee, officer or director of bioAffinity Technologies, Inc. or any subsidiary thereof (the "Company") to trade in the securities of the Company while in the possession of material nonpublic information about the Company. It is also illegal for any employee, officer or director of the Company to give material nonpublic information to others who may trade on the basis of that information.

In order to comply with U.S. securities laws governing (i) trading in Company securities while in the possession of material nonpublic information concerning the Company and (ii) tipping or disclosing material nonpublic information to outsiders, and in order to prevent the appearance of improper trading or tipping, the Company has adopted this policy for all of its employees, officers and directors.

II. SCOPE

A. This policy covers all employees, officers and directors of the Company. Employees, officers or directors are responsible for ensuring compliance by their immediate families and other members of their households.

B. This policy applies to any and all transactions in the Company's securities, including its shares of common stock and options to purchase shares of common stock (as described in more detail in Section V.E below), and any other type of securities that the Company may issue, such as preferred shares, convertible debentures, warrants and exchange-traded options or other derivative securities.

C. This policy will be delivered to all employees, officers or directors upon its adoption by the Company, and to all new employees, officers or directors at the start of their employment or relationship with the Company. Upon first receiving a copy of this policy or any revised versions, each employee, officer or director must sign a certification that he or she has received a copy and agrees to comply with the terms of this policy. This certification and agreement will constitute consent for the Company to impose sanctions for violation of this policy and to issue any necessary stop-transfer orders to the Company's transfer agent to enforce compliance with this policy. As discussed in Section VI.B, sanctions for individuals may include demotion or other disciplinary actions, up to and including termination of employment, if the Company has a reasonable basis to conclude that its policy has been violated.

D. This policy allows for trades by employees, officers and directors made in compliance with Rule 10b5-1 ("Rule 10b5-1") promulgated by the U.S. Securities and Exchange Commission under the Securities Exchange Act of 1934 (the "Exchange Act"), subject to the approval of the Insider Trading Compliance Officer (as defined in Section III below).

E. The Company may change these procedures or adopt such other procedures in the future as the Company considers appropriate in order to carry out the purposes of its policy.

III. INSIDER TRADING COMPLIANCE OFFICER

The Company has designated Timothy Zannes, the Company's Executive Vice President, Secretary and General Counsel (or his successor in that position), as its Insider Trading Compliance Officer (the "Compliance Officer") and in the event of the General Counsel's unavailability, Maria Zannes, the Company's President and Chief Executive Officer (or her successor in that position), shall be authorized to serve as Compliance Officer in the interim. The duties of the Compliance Officer will include the following:

A. Administering and interpreting this policy and monitoring and enforcing compliance with all policy provisions and procedures.

B. Responding to all inquiries relating to this policy and its procedures.

C. Designating and announcing special trading blackout periods during which no designated employees, officers or directors may trade in Company securities.

D. Providing copies of this policy and other appropriate materials to all current and new employees, officers and employees, and such other persons who the Compliance Officer determines may have access to material nonpublic information concerning the Company.

E. Administering, monitoring and enforcing compliance with all US insider trading laws and regulations, including without limitation the Exchange Act and the rules and regulations promulgated thereunder, the Securities Act of 1933, as amended (the "Securities Act"); and assisting in the preparation and filing of all required SEC reports relating to insider trading in Company securities.

F. Revising the policy as necessary to reflect changes in insider trading laws and regulations.

G. Maintaining as Company records originals or copies of all documents required by the provisions of this policy or the procedures set forth herein, and copies of all required SEC reports relating to insider trading.

The Compliance Officer may designate one or more individuals who may perform the Compliance Officer's duties in the event that the Compliance Officer is unable or unavailable to perform such duties.

IV. DEFINITION OF "MATERIAL NONPUBLIC INFORMATION"

A. "MATERIAL" INFORMATION

Information about the Company is "material" if it would be expected to affect the investment or voting decisions of a reasonable shareholder or investor, or if the disclosure of the information would be expected to alter significantly the total mix of the information in the marketplace about the Company. In simple terms, material information is any type of information that could reasonably be expected to affect the market price of the Company's securities. Both positive and negative information may be material. While it is not possible to identify all information that would be deemed "material," the following types of information ordinarily would be considered material:

i. Financial performance, especially quarterly and year-end earnings, and significant changes in financial performance or liquidity.

ii. Potential material mergers and acquisitions or material sales of Company assets or subsidiaries.

iii. Stock splits, public or private securities/debt offerings, or changes in Company dividend policies or amounts.

iv. Significant changes in senior management.

v. New major contracts or customers, or the loss of a major customer.

vi. Initiation of a significant lawsuit.

B. "NONPUBLIC" INFORMATION

Material information is "nonpublic" if it has not been widely disseminated to the public, for example, through major newswire services, national news services, Web casts or financial news services. For the purposes of this policy, information will be considered public, i.e., no longer "nonpublic," at the opening of trading on the third full trading day following the Company's widespread public release of the information.

C. CONSULT THE COMPLIANCE OFFICER FOR GUIDANCE

Employees, officers or directors who are unsure whether the information that they possess is material or nonpublic must consult the Compliance Officer for guidance before trading in any Company securities.

V. STATEMENT OF COMPANY POLICY AND PROCEDURES

A. PROHIBITED ACTIVITIES

i. No employee, officer or director may trade in Company securities while possessing material nonpublic information concerning the Company (except as permitted by Section V.C). It does not matter that there is an independent, justifiable reason for a purchase or sale, if the employee, officer or director has material nonpublic information, the prohibition still applies.

ii. No employee, officer or director may trade in Company securities outside of the applicable "trading windows" described in Section V.B below and no employee, officer or director may trade in the Company securities during any special trading blackout periods designated by the Compliance Officer that are applicable to such employee, officer or director (except as permitted by Section V.C).

iii. The Compliance Officer may not trade in Company securities unless the trade has been approved by the Company's General Counsel in accordance with the procedures set forth in Section V.D below (except as permitted by Section V.C).

iv. No employee, officer or director may disclose material nonpublic information concerning the Company to any outside person (including family members, analysts, individual investors and members of the investment community and news media), unless required as part of the regular duties of such employee, director or officer for the Company or authorized by the Compliance Officer. In any instance in which such information is disclosed to outsiders, the Company will take such steps as are necessary to preserve the confidentiality of the information, including requiring the outsider to agree in writing to comply with the terms of this policy and/or to sign a confidentiality agreement. All inquiries from outsiders regarding material nonpublic information about the Company must be forwarded to the Compliance Officer.

v. No employee, officer or director may give trading advice of any kind about the Company to anyone while possessing material nonpublic information about the Company, except that employees, officers or directors should advise others not to trade if doing so might violate the law or this policy. The Company strongly discourages all employees, officers or directors from giving trading advice concerning the Company to third parties even when the directors, officers and employees do not possess material nonpublic information about the Company.

vi. No employee, officer or director may trade in any interest or position relating to the future price of Company securities, such as a put, call or short sale (including a short sale "against the box").

vii. Except as permitted by Section V.C, no employee, officer or director may give or make any other transfer of securities without consideration during a period when that employee, officer or director is not permitted to trade.

viii. No director, officer or employee may participate, in any manner other than passive observation, in any of the investment or stock-related Internet "chat" rooms or message boards relating to the Company.

ix. No employee, officer or director may (a) trade in the securities of any other public company while possessing material nonpublic information concerning that company obtained in the course of service as an employee, officer or director, (b) "tip" or disclose such material nonpublic information concerning any other public company to anyone, or (c) give trading advice of any kind to anyone concerning any other public company while possessing such material nonpublic information about that company.

B. TRADING WINDOWS AND BLACKOUT PERIODS

i. *Trading Windows for Employees*. Employees may trade in Company securities only during the period beginning at the opening of trading on the third full trading day following the Company's widespread public release of quarterly or year-end operating results, and ending at the close of trading two weeks before the end of the then-current quarter, as long as they are not in possession of material nonpublic information or subject to any special trade blackout.

ii. *No Trading Even During Trading Windows While in the Possession of Material Nonpublic Information*. No employee, officer or director possessing material nonpublic information concerning the Company may trade in Company securities even during applicable trading windows. Persons possessing such information may trade during a trading window only after the opening of trading on the third full trading day following the Company's widespread public release of the information.

iii. *No Trading During Blackout Periods*. No director, officer or employee may trade in Company securities outside of the applicable trading windows or during any special blackout periods that the Compliance Officer may designate. No director, officer or employee may disclose to any outside third party that a special blackout period has been designated.

C. EXCEPTION FOR TRANSFERS PURSUANT TO RULE 10b5-1

The restrictions outlined in Sections V.A. i, ii, iii, iv and viii and V.B shall not prohibit transfers of Company securities made pursuant to a written contract, letter of instruction or plan that (a) complies with the requirements of Rule 10b5-1 (a "Rule 10b5-1 Plan"), (b) has been approved by the Compliance Officer in advance of the first trade thereunder and (c) with respect to which the Company's Compliance Officer has received the certification referred to in Section V.D.3. No such approval by the Compliance Officer shall be considered the Compliance Officer's or the Company's approval that the Rule 10b5-1 Plan satisfies the requirements of Rule 10b5-1. It shall be the sole responsibility of the person establishing the Rule 10b5-1 Plan to ensure that such plan complies with the requirements of Rule 10b5-1.

D. PROCEDURES FOR APPROVING TRADES UNDER RULE 10B5-1 PLANS.

No trades shall be treated as having been made pursuant to a Rule 10b5-1 Plan under this policy unless:

i. The Rule 10b5-1 Plan complies with the requirements of Rule 10b5-1;

ii. The Compliance Officer has approved the Rule 10b5-1 Plan, and has certified such approval in writing at least one month in advance of the first trade thereunder; and

iii. The person establishing the Rule 10b5-1 Plan has certified to the Compliance Officer in writing no earlier than two business days prior to the date that the Rule 10b5-1 Plan is formally established, that: (a) Such person is not in possession of material nonpublic information concerning the Company and all such trades to be made pursuant to Rule 10b5-1 Plan will be made in accordance with the Exchange Act and the Securities Act; and (b) The Rule 10b5-1 Plan complies with the requirements of Rule 10b5-1. The existence of the foregoing approval procedures does not in any way obligate the Compliance Officer to approve any Rule 10b5-1 Plan. The Compliance Officer may reject any trading requests or Rule 10b5-1 Plans at his or her sole reasonable discretion.

E. STOCK OPTION PLANS

The trading prohibitions and restrictions of this policy apply to all sales of securities acquired through the exercise of stock options granted by the Company, but not to the acquisition of securities through such exercises.

F. PRIORITY OF STATUTORY OR REGULATORY TRADING RESTRICTIONS

The trading prohibitions and restrictions set forth in this policy will be superseded by any greater prohibitions or restrictions prescribed by securities laws and regulations.

VI. POTENTIAL CIVIL, CRIMINAL AND DISCIPLINARY SANCTIONS

A. CIVIL AND CRIMINAL PENALTIES

The consequences of prohibited insider trading or tipping can be severe. Persons violating insider trading or tipping rules may be required to pay over to the Company the profit made or the loss avoided by trading, pay the loss suffered by the persons who purchased securities from or sold securities to the insider tippee, pay civil penalties up to three times the profit made or loss avoided, pay a criminal penalty of up to $1 million and serve a jail term of up to 10 years. The Company and/or the supervisors of the person violating the rules may also be required to pay major civil or criminal penalties and could under certain circumstances be subject to private lawsuits by contemporaneous traders for damages suffered as a result of illegal insider trading or tipping by persons under the Company's control.

B. COMPANY DISCIPLINE

Violation of this policy or federal or state insider trading or tipping laws by any employee, officer or director may subject a director to dismissal proceedings and an officer or employee to disciplinary action by the Company up to and including termination for cause. A violation of the Company's policy is not necessarily the same as a violation of law. In fact, for the reasons indicated above, the Company's policy is intended to be broader than the law. The Company reserves the right to determine, in its own discretion and on the basis of the information available to it, whether its policy has been violated. The Company may determine that specific conduct violates its policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

C. REPORTING OF VIOLATIONS

Any employee, officer or director who violates this policy or any federal or state laws governing insider trading or tipping, or knows of any such violation by any other employee, officer or director, must report the violation immediately to the Compliance Officer. Upon learning of any such violation, the Compliance Officer, in consultation with the Company's legal counsel, will determine whether the Company should release any material nonpublic information, or whether the Company should report the violation to the SEC or other appropriate governmental authority.

VII. INQUIRIES

Please direct all inquiries regarding any of the provisions or procedures of this policy to the Compliance Officer.

Acknowledgement

I have read the procedures outlined in this policy. I understand that while this is not an employment contract I am bound to abide by the policies set herein. I further understand that bioAffinity Technologies may modify, revise and update policy at any time. I am also aware that this updating may include additions or deletions. I also certify that I have had ample time to discuss this policy and its contents with a bioAffinity Technologies representative, and I fully understand the contents.

Employee signature _____

Employee name _____

Date _____

bioAffinity Technologies reserves the right to make changes to this policy for the purpose of modifying, revising and updating Company policy. Notice of changes will be provided to the employee electronically and become a part of this policy. Violation of any Company policy may result in immediate termination.

Exhibit 31.1

Certification
For the Year Ended December 31, 2022

I, Maria Zannes, certify that:

1. I have reviewed this report on Form 10-K of bioAffinity Technologies, Inc. ("registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) [intentionally omitted];

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2023

/s/ Maria Zannes
Maria Zannes
President and Chief Executive Officer

Exhibit 31.2

Certification
For the Year Ended December 31, 2022

I, Michael Edwards, certify that:

1. I have reviewed this report on Form 10-K of bioAffinity Technologies, Inc. ("registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    (b) [intentionally omitted];

    (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2023

/s/ Michael Edwards
Michael Edwards
Chief Financial Officer

Exhibit 32.1

Certification Pursuant to
18 U.S.C. Section 1350
As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-K of bioAffinity Technologies, Inc., a Delaware Corporation ("Company"), for the year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof ("Report"), each of the undersigned officers of the Company hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of such officer's knowledge:

1) the Report complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the year ended December 31, 2022 (the last date of the period covered by the Report).

/s/ Maria Zannes
Maria Zannes
President and Chief Executive Officer
Date: March 31, 2023

/s/ Michael Edwards
Michael Edwards
Chief Financial Officer
Date: March 31, 2023