January 17, 2024

BIOAFFINITY TECHNOLOGIES, INC.

(NasdaqCM: BIAF)

Based in San Antonio, Texas, bioAffinity Technologies, Inc. engages in developing non-invasive diagnostic tests and targeted cancer therapeutics. The company's initial product, CyPath® Lung, is a diagnostic test utilizing flow cytometry and automated analysis developed by machine learning to aid in the early detection of lung cancer. The test is at the nascent stages of a commercial rollout. The company is also in pre-clinical development on researching targeted therapies to treat cancer at the cellular level. The company was founded in 2014.

COMPANY HIGHLIGHTS

* In our view, bioAffinity is well positioned to establish its CyPath® Lung test as a cost-effective, non-invasive, and highly accurate diagnostic tool for the early detection of lung cancer, which is among the most common and deadly forms of cancer. Early diagnosis, before the cancer has spread, is a significant contributor to survival. Research suggests that Stage 1 lung cancer that is detected and treated early can increase the ten-year survival rate to over 90% from a five-year survival rate of approximately 20% for Stages 2-4 and only 5% for Stage 4.
* CyPath® Lung utilizes flow cytometry and a proprietary machine-learning algorithm to profile the approximately 16 million cells in an average sputum sample in about 20-30 minutes, helping to overcome the limitations of traditional analytical throughput. Test validation trial results have achieved superior results of 92% sensitivity and 87% specificity in high-risk patients who had lung nodules 20 mm or smaller.
* bioAffinity is in the early stages of a regional launch for CyPath® Lung, and we view positively recent regulatory progress in securing reimbursement. The Centers for Medicare and Medicaid Services (CMS) has issued a final determination to include CyPath® Lung on its 2024 clinical laboratory fee schedule for payment, which we expect to facilitate reimbursement and enable a broader rollout, utilizing the scalable, CAP/CLIA-certified laboratory acquired in September 2023 from its former partner Precision Pathology Services.

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PRICE CHART

KEY STATISTICS

Key Stock Statistics	
Recent price (1/16/24)	$1.57
Fair Value Estimate	$8.00
52 week high/low	$3.99-$0.95
Shares outstanding (M)	9.5
Market cap (M)	$14.9
Dividend	Nil
Yield	Nil

Sector Overview	
Sector	Healthcare
Sector % of S&P 500	12.6%

Financials ($M, as of 9/30/23)	
Cash & Mkt Securities	4.5
Debt	0.0
Working Capital ($M)	4.0
Current Ratio	3.1
Total Debt/Equity (%)	NM
Payout ratio	NM
Revenue (M) TTM	0.3
Net Income (M) TTM	NM
Net Margin (%) TTM	NM

Risk	
Beta	NA
Inst. ownership	1%

Valuation	
P/E forward EPS	NM
Price/Sales (TTM)	NM
Price/Book	2.7

Top Holders

CapFinancial Partners LLC
Two Sigma Investments LP
Vanguard Group Inc.

Management	
CEO	Ms. Maria Zannes
CFO	Mr. Michael Dougherty
EVP/CSO/CMO	Dr. Vivienne Rebel
Company website	https://bioaffinitytech.com

COMPANY SPONSORED REPORT. SEE LAST PAGE FOR DISCLOSURES.

* We expect bioAffinity to begin a pivotal trial on CyPath® Lung to gain FDA approval as a diagnostic medical device early in 2024. We think FDA approval would enable direct marketing to a larger addressable market, further enhance reimbursement rates, and position the test for enhanced regulatory review in other global jurisdictions. We believe that approval could occur by 2027.
* Over the longer term, we see the potential for bioAffinity to develop and market non-invasive tests for additional diseases, including chronic obstructive pulmonary disease (COPD), and other cancers, and to develop therapeutics for cancer.
* As of September 30, 2023, the company had $4.5 million in cash, compared with $11.4 million at the end of 2022. We expect bioAffinity to raise capital in 2024, which we think has been an overhang on the shares amid a challenging financing environment. However, we think that the current stock valuation assigns almost no value to the company's technology platform and largely de-risked CyPath® Lung test, as well as its long-term commercial prospects.
* Based on our forward enterprise value/revenue analysis, we arrive at a fair value estimate for BIAF of $8.00 per share, well above current levels.

INVESTMENT THESIS

bioAffinity Technologies, Inc. engages in developing non-invasive diagnostic tests for the early detection of lung cancer and other lung mediated diseases, as well as targeted cancer therapeutics. The company is based in San Antonio, Texas, and its R&D activities are conducted in its laboratories at The University of Texas at San Antonio and Precision Pathology Services. Its initial product, CyPath® Lung, a diagnostic test designed for the early detection of lung cancer, is at the nascent stage of a limited launch to beta-test marketing in Texas, before rolling out more broadly.

According to the American Cancer Society (ACS), since peaking in 1991, U.S. cancer death rates have declined by approximately one-third, largely attributable to the introduction of new medicines, particularly for lung cancer. Among therapeutics, newly approved cancer drugs have advanced patient care in several respects, including more orally administered therapies, new drug combination regimens, and new drug categories, such as immuno-oncology drugs. Still, cancer remains the second leading cause of death in the United States. (The ACS estimated 1.9 million cancer diagnoses and 609,000 cancer-related deaths in 2022.) The American Association of Cancer Research (AACR) has estimated that 2030 could see national expenditures for cancer care in the United States near $250 billion.

Despite cancer continuing to drive biopharmaceutical and life science industry sales and R&D investments, lung cancer remains the second most common form of cancer diagnosed in the United States behind breast cancer. Globally, lung cancer is responsible for an estimated 1.8 million deaths annually, representing nearly 20% of all cancer deaths, according to the ACS and the World Health Organization.

In our view, the global market for cancer diagnostic tests is a high-growth market, and this is expected to continue as technology improves and more effectively enables early diagnosis and treatment. According to ResearchAndMarkets, cancer diagnostic tests, including devices, are expected to grow at an 8.9% compound annual growth rate (CAGR) between 2021 and 2025 to nearly $240 billion.

While approved therapeutics have made an impact in extending life, long-term survival prospects for lung cancer have remained quite unfavorable because most cases are diagnosed later in the disease progression after symptoms become noticeable, rendering treatments less effective. Thus, in our view, diagnosing lung cancer before it spreads is key to improving survival rates. Research has suggested that a case of Stage 1 lung cancer that is detected and treated early can increase ten-year survival to more than 90%, versus five-year survival of approximately 20% for Stages 2-4 and only 5% for Stage 4.

In our view, the global market for enhanced screening tools is evident in the U.S. Preventive Services Task Force estimate of 16 million Americans with a high risk for lung cancer and the EU's estimate of up to 34 million Europeans at high risk. Another large high-risk population is in China, with an estimated 300 million smokers.

Current treatments include surgery and radiation for site-specific targets. Chemotherapy is usually systemically administered, but tends to lack selectivity for cancer cells and ineffectively differentiates between normal, healthy cells and cancer cells. For lung cancer, low-dose computed tomography (LDCT) is the only noninvasive method used to screen patients at high risk for lung cancer, and it has been shown to help lower lung cancer mortality rates by 20%. However, this method has a low positive predictive value (the proportion of true positive results for individuals with a positive scan is less than 5%) that can result in many people undergoing unnecessary invasive diagnostic procedures to confirm or rule out the presence of lung cancer, thus undermining its value to patients and the healthcare system.

By contrast, CyPath® Lung is designed to be a cost-effective, non-invasive, early-stage lung cancer diagnostic that strengthens

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PEER COMPARISON

Company	Ticker	Recent Price ($)	52-Week High ($)	52-Week Low ($)	Mkt. Cap ($MIL)	1-yr Price Change (%)	1-yr Rev Growth (%)	1 YR EPS Growth (%)	P/E Ratio	Beta	Yield (%)
BIOAFFINITY TECHNOLOGIES INC	**NASDAQ: BIAF**	**1.57**	**3.99**	**0.95**	**15**	**-2**	**NA**	**NM**	**NM**	**NA**	**NA**
BIODESIX INC	NASDAQ: BDSX	1.90	2.53	1.03	178	-21	NM	NM	NM	1.23	NA
VERACTYE INC	NASDAQ: VCYT	26.62	30.52	19.52	1944	0	35	NM	NM	1.64	NA
LUNGLIFE AI INC	AIM: LLAI	0.56*	1.42*	0.19*	14*	-38	NM	NM	NM	-0.12	NA

* Stock Statistics in British Pound (GBP)

the diagnostic process by improving its predictive value. As a result, fewer patients require invasive diagnostic procedures. More diagnoses can also be made at an earlier stage, reducing the need for more aggressive treatments and hospitalizations, and thus lowering the cost of patient care.

Sample collection is conducted at home and shipped overnight to be processed by technicians skilled in general laboratory techniques. A patient coach is available to assist with collection and sample return. The processed sample is run through a flow cytometer, and data is evaluated in minutes by automated analysis. Patient reports, including a risk assessment, are provided within three days to the ordering physician. The physician can then recommend follow-up testing for patients identified as having higher risk and periodic imaging surveillance for lower-risk patients.

CyPath® Lung uses flow cytometry to analyze cell populations in a person's sputum to find characteristics indicative of lung cancer, including cancer and cancer-related cells that have shed from a lung tumor. Its technology protocol can profile an entire sputum sample, containing an average of about 16 million cells, and provide a report in about 30 minutes, significantly improving throughput, compared with microscopic approaches. The test uses a fluorescent bio-label (the synthetic porphyrin TCPP) that has an unusually high affinity for cancer and cancer-related cells. Thus, the proportion of cells with high TCPP fluorescence intensity in a patient's sputum sample is a significant predictor of lung cancer.

Underpinning its flow cytometry approach, bioAffinity has developed an algorithm using machine learning to distinguish samples from high-risk patients who have lung cancer from those who are cancer-free, and we view CyPath® Lung as the first cancer diagnostic to combine these capabilities. Its most recent test validation trial demonstrated improved results over a microscope-based assay, resulting in 92% sensitivity (the percentage of persons with lung cancer, correctly identified) and 87% specificity (the percentage of persons without lung cancer, correctly identified by the test), in high-risk patients who had lung nodules 20 mm or smaller.

Nodules between 6 mm and 20 mm are considered "indeterminate pulmonary nodules" and are the most difficult for physicians to diagnose. This often leads to unnecessary invasive procedures or risking an opportunity to diagnose at early stage. In the broad patient group, irrespective of nodule size, the CyPath® Lung study showed 82% sensitivity and 88% specificity. In studies to date, 80% of Stage 1 tumors were identified correctly, similar to far more invasive procedures in current use. Moreover, CyPath® Lung has been able to detect various forms of lung cancer.

While CyPath® Lung is intended for use in patients who display a pulmonary nodule requiring follow-up procedures that often are invasive and expensive, we think the test's high specificity and sensitivity, combined with its non-invasive and accessible characteristics, could ultimately enable its use prior to more invasive lung cancer screening.

In our view, CyPath® Lung is well positioned to achieve a meaningful market share of the early-detection lung cancer diagnostic market over time, given a limited competitive landscape, particularly among later development-stage projects. We also see the test's use of lung sputum as the medium for disease detection as a competitive advantage because sputum is in close contact with the lung tumor, is obtained noninvasively, and can be transported easily and non-immediately. Second, the CyPath® platform technology is not a molecular test that requires immediate processing, as compared with tests that collect genetic material. Finally, the test is straightforward in terms of processing, the use of reagents, data acquisition by flow cytometry, and automated analysis powered by a proprietary algorithm.

We are encouraged by survey work (conducted by bioAffinity among pulmonologists and internists) that suggests robust interest and likely adoption for CyPath® Lung based on its compelling commercial profile. We expect the start of a pivotal clinical trial for CyPath® Lung to increase the company's visibility and boost interest in BIAF shares.

We see CyPath® Lung and bioAffinity Technologies' flow cytometry platform being validated by the U.S. military, as evidenced by two small but important clinical trials launched at the Brooke Army Medical Center. According to the study protocols, the U.S. Department of Defense (DOD), which is funding the program, is conducting research on using CyPath® Lung as a front-end diagnostic prior to LDCT, and working with bioAffinity to develop the platform for use with other lung diseases, including chronic obstructive pulmonary disease (COPD).

CyPath® Lung was recently launched as a laboratory developed test (LDT) under the CLIA-certified lab program, through a joint development agreement with Precision Pathology Services. In September 2023, bioAffinity acquired Precision Pathology, which we think should foster a more-efficient launch, due to the consolidation of bioAffinity-led marketing and R&D capabilities with Precision's sales, processing, clinical communications, and billing activities.

bioAffinity initially launched CyPath® Lung in a limited market test focused on pulmonologists in Texas. Before launching the wider rollout, which we expect in early 2024, bioAffinity is using knowledge gained from this soft launch to refine the operating model, including physician ordering, sample collection, and patient report generation and delivery.

We are encouraged by the progress that CyPath® Lung has made in regard to payers and reimbursement. In July 2023, the American Medical Association (AMA) issued a Current Procedural Terminology (CPT) code for use with CyPath® Lung, effective October 1, 2023, for use by private payers and public health insurance programs, including Medicare and Medicaid, when seeking reimbursement. In November 2023, CMS made a final determination for payment for CyPath® Lung for the 2024 calendar year.

We note that CMS approved reimbursement for CyPath® Lung's CPT code, 0406U, at $760 (based on the 2023 fee schedule), which is more than twice the reimbursement amount previously assigned to CPT codes for flow cytometry under which CyPath® Lung was billed prior to the CMS decision. Furthermore, Precision Pathology's contracts with commercial insurance carriers provide for payment of a multiple of the Medicare fee schedule, leading to a listed price of $1,900 for CyPath Lung, or more than double the fee previously listed. We think that CyPath® Lung's inclusion on CMS' 2024 clinical laboratory fee schedule should further facilitate reimbursement for the test among Medicare enrollees and s privately insured patients, and support broader rollout.

As the launch proceeds, we expect bioAffinity to expand its network of prescribing physicians and larger medical systems, boosted by reimbursement rates in place. Through September 30, 2023, the pilot marketing program for CyPath® Lung had 20 physicians enrolled, and bioAffinity expected that figure to expand to more than 80 physicians over the next 12 months, as it expands its sale force from two to five in strategic metropolitan areas of Texas. In November 2023, the company hired Dallas J. Coleman as national director of sales responsible for leading the CyPath® Lung commercial strategy.

Subsequent phases of the launch will include offering CyPath® Lung as a CE-marked in vitro diagnostic (IVD) laboratory-based test in the European Union. The company is assembling regulatory documentation required to submit to a Notified Body for approval, which we think may take 12-18 months due to a backlog of applications. For the longer term, bioAffinity will seek FDA clearance of the CyPath® Lung as a Class II IVD medical device, with the classification tied to the severity of the indication, rather than as a measure of its safety.

The company has completed the design of the pivotal clinical trial, which will require approximately 1,800 participants enrolled at an estimated 20 collection sites. We expect bioAffinity to submit a pre-submission package to the FDA at the beginning of 2024 in order to obtain the FDA's feedback. If authorized, a pivotal clinical trial, expected to last three years, would begin in early 2024. Based on work already done with its contract research organization (CRO) and early efforts to enroll trial sites, we believe the trial could be completed several months ahead of schedule. Upon completion, bioAffinity would plan to submit a de novo classification request to the FDA.

If approved by the FDA, bioAffinity would directly market CyPath® Lung to U.S. physicians and their patients, which we think would significantly expand market penetration. Over the long term, we would expect bioAffinity to seek to extend its market presence to new markets including China, Southeast Asia, Australia, and Central and Eastern Europe. In our view, China represents the largest global market for lung cancer, and we would expect bioAffinity to identify a partner, given the inherent complexity of the Chinese market, while establishing key distributor relationships and building internal management teams to support these relationships in other global markets.

bioAffinity is also developing its flow cytometry platform for other diseases, including COPD and asthma, that can be detected by examining the microenvironment of the lung, and characterizing cell populations in sputum specific to the disease. COPD is currently the fourth leading cause of death globally and, in our view, represents another multi-billion-dollar market opportunity. We see potential for COPD to advance to a proof-of-concept trial in 2024.

Beyond lung cancer, bioAffinity's flow cytometry platform and porphyrin-based technology has the potential for use in diagnosing other common cancers in need of better predictive outcomes, including prostate cancer, the second most commonly diagnosed cancer in men and the sixth in terms of mortality worldwide. Despite the introduction of new tests utilizing urine-based liquid biopsy technologies, prostate cancer detection (which we estimate to represent a $5 billion global market) continues to be dominated by the use of the prostate-specific antigen (PSA) screening test, which has a high specificity (91%) but a low sensitivity (21%, i.e., it misses 80% of men with prostate cancer), and low (30%) positive predictive value. Standard invasive diagnostic options include biopsies, which have a better positive predictive value of 67%. bioAffinity's technology platform also shows promise for use with bladder cancer, which, while less prevalent than many other cancers, has among the highest recurrence rates within five years of the initial diagnosis and higher mortality risk.

In our view, the potential to use the bioAffinity flow cytometry platform with these additional cancers is attractive, as both prostate and bladder cancers are additional examples of disease where early diagnosis holds promise to significantly improve outcomes. Both cancers are marked by survival rates over 90% with early diagnosis, with much poorer results (30% and 5% for prostate and bladder cancer, respectively), if detected after metastasizing.

Beyond diagnostics, bioAffinity is also at the early stages of developing a portfolio of therapeutic candidates through its OncoSelect® Therapeutics Research subsidiary, based on insights gained through its TCPP porphyrin discoveries while working on CyPath® Lung. These potential therapies have killed cancer cells grown in petri dishes without apparent harm to normal cells, using RNA interference to silence genes selectively. OncoSelect® would use a licensing business model for compounds that advance to the clinical stage. Potential targets identified to date include two genes encoding for the cell surface proteins CD320 and LRP2, for which bioAffinity saw evidence of effect in lung, breast, prostate, melanoma, and brain cancer cell lines, but left normal human fibroblast and breast epithelial cells virtually unaffected.

In our view, oncology therapeutics represent the largest market among all therapeutic categories, and this group is projected to grow at above-average rates in the coming years. The market for RNAi-derived therapeutics has grown to six products since the first FDA approval in 2018. However, to date, these therapies have been focused on diseases manifested in the liver. Technology enhancements have led to several candidates targeting solid tumors, and we think this category is very attractive in the long term.

As of September 2023, bioAffinity and its OncoSelect® subsidiary have secured a robust intellectual property portfolio, highlighted by a global patent estate that spans diagnostic applications, therapeutics and its use of TCPP for the diagnosis, monitoring, and treatment of cancer. The company also has multiple patent applications to protect its use of flow cytometry and its AI-powered automated analysis in the detection of lung diseases using sputum as a sample.

We are encouraged by bioAffinity's ability to assemble what we view as a world-class Science and Medical Advisory Board featuring leaders in the field of lung cancer diagnostics and flow cytometry. We expect the company to have access to the expertise and insights of thought leaders, including: Neil Alexis, Ph.D. (University of North Carolina School of Medicine Center for Environmental Medicine, Asthma and Lung Biology), a leader in the use of flow cytometry in the analysis of sputum; Catherine Sears, M.D. (Indiana University School of Medicine), a physician scientist focusing on the impact of DNA damage and repair on the

development of smoking-related lung cancers and on treatment response; Gerard Silvestri, M.D., M.S., FCCP (Medical University of South Carolina), specializing in the evaluation, management, and improvement of outcomes in lung cancer patients; David G. Hill, M.D. (Member of the Lung Association's National Board of Directors and immediate past chair of the Northeast Regional Board of the American Lung Association), an accomplished research author who has been the principal investigator for more than 75 pulmonary research trials; and Sheila Habib, M.D. (Director of Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at the South Texas Veterans Health Care Systems' Audie L. Murphy Memorial Veterans Hospital).

Lastly, we view positively bioAffinity's commitment to communicating its progress with the broader lung disease community through planned messaging and marketing programs and collaborations with key opinion leaders (KOLs) who can present data on CyPath® Lung at industry meetings that can be distributed to stakeholders, including lung cancer advocacy groups. During the second quarter of 2023, bioAffinity presented at prestigious medical and scientific conferences, including Cleveland Clinic, CYTO 2023 (International Society for the Advancement of Cytometry), and University of Massachusetts' RNA Therapeutics Symposium,

RECENT DEVELOPMENTS

In September 2022, bioAffinity completed an initial public offering that included the issuance of 1,282,600 units, each consisting of one share of common stock, one tradeable warrant, and one non-tradeable warrant. Including the subsequent exercise of 1.04 million warrants, bioAffinity raised a total of $15.6 million.

The shares and tradeable warrants trade on Nasdaq under the ticker symbols "BIAF" and "BIAFW," respectively. From the IPO price of $6.13 per share, the stock has declined approximately 75%. In 2023, it declined by 8%, compared with a 24% increase for the S&P 500.

In November 2023, bioAffinity reported results for 3Q 2023, highlighted by revenues of approximately $300,000, compared with nearly $20,000 in the prior quarter, resulting from the contribution of sales acquired from Precision Pathology Services in September 2023. The net loss for the period was $2.3 million or $0.26 per share, compared to a net loss of $4.9 million, or $1.17 for the same period in 2022, with the narrower loss mainly attributable to changes in value of convertible notes in the 2022, which have since been converted into common shares.

In November 2023, bioAffinity announced that CMS finalized payment for CyPath® Lung for 2024. In July 2023, the AMA had issued a CPT code for use with CyPath® Lung, effective October 1, 2023, through which private payers and public health insurance programs, including Medicare and Medicaid, could seek reimbursement.

In November 2023, bioAffinity launched a campaign in partnership with the American Cancer Society (ACS) to increase lung cancer screening in San Antonio.

In November 2023, bioAffinity hired Dallas J. Coleman as national director of sales, responsible for leading the CyPath® Lung commercial strategy effort.

In September 2023, bioAffinity announced the acquisition of Precision Pathology Services, its commercial partner for CyPath® Lung, for $3.5 million, consisting of cash and stock. Precision's founder, Dr. Roby Joyce, will stay on as the Laboratory and Medical Director of the newly created Precision Pathology Laboratory Services subsidiary, and has joined the bioAffinity board of directors.

In the second quarter of 2023, the U.S. DOD purchased CyPath Lung® tests for use in an observational study on active military personnel at high risk for developing lung cancer, and for research on the use of bronchoalveolar lavage fluid to assess cardiopulmonary function and exercise performance in military personnel post COVID-19 infection.

In May 2023, bioAffinity appointed Michael Dougherty as its CFO. Mr. Dougherty was most recently CFO of Amazon's Alexa Business Domains, Amazon's Alexa AI and Voice division, where he was responsible for financial strategy over Alexa's multi-billion-dollar investments in AI-generated customer experiences.

In March 2023, bioAffinity published "Porphyrin-modified beads for use as compensation controls in flow cytometry" in the peer-reviewed Journal of Visualized Experiments (JoVE). The article describes the company's patent-pending protocol to optimize the results of CyPath® Lung testing in the detection of early-stage lung cancer.

In February 2023, bioAffinity appointed healthcare marketing firms Havas Health & You and Trinity Life Sciences to help develop the CyPath® Lung brand, as it prepares for a broader commercial launch later in 2023.

In January 2023, bioAffinity also published "Detection of early-stage lung cancer in sputum using automated flow cytometry and machine learning" in the peer-reviewed journal Respiratory Research.

In January 2023, bioAffinity received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) on its patent application "Porphyrin Compounds and Compositions Useful for Treating Cancer" for the targeted delivery of novel cancer treatments. Upon issuance, the patent awarded to bioAffinity subsidiary OncoSelect will grant protection until 2037.

EARNINGS AND GROWTH ANALYSIS

In 2023 and 2024, we forecast revenues of $2.1 million and $9.0 million, respectively. We expect 2024 results to reflect a full year of revenue contribution from Precision Pathology, whereas 2023 results include such revenues as of the acquisition closing in September 2023.

We think that bioAffinity's acquisition of Precision Pathology should enable the company to better support and market CyPath® Lung over the coming years, and enhance physician onboarding and test logistics coordination. In our view, bioAffinity's refinement of its marketing and branding ahead of a broad rollout should enhance the commercial uptake and physician acceptance.

We expect operating expenses of $9.4 million and $17 million in 2023 and 2024, respectively. We expect cost of goods sold to be in the 10%-15% range, with the balance divided between selling, general and administrative driven by employee compensation and CyPath® Lung marketing expenses, and R&D costs related to the initiation of the CyPath® Lung clinical trial and early-stage research activities.

We anticipate net losses of $0.84 per share in 2023 and $0.95 per share in 2024, assuming a weighted average share count of 8.8 million shares in 2023 and 9.5 million in 2024.

FINANCIAL STRENGTH and DIVIDEND

Our financial strength rating on bioAffinity is Low. As of September 30, 2023, the company had $4.5 million in cash and equivalents, as compared with $8.3 million at June 30, 2023, and $11.4 million at the end of 2022, due in part to $2.5 million used to fund the acquisition of Precision Pathology in September 2023.

The company's operations have been funded by proceeds of its September 2022 IPO, which yielded $15.6 million in gross proceeds ($13.7 million on a net basis) from the offering of 1,282,600 units (each consisting of one share of common stock, one tradeable warrant, and one non-tradeable warrant), and from the subsequent exercise of an additional 1.04 million legacy warrants.

Although we expect bioAffinity to look to raise capital in 2024, we do not see the Precision acquisition meaningfully impacting bioAffinity's cash burn moving forward, as we expect Precision to be near cash-flow breakeven. As Precision's operations are consolidated into bioAffinity, combined with the rollout of CyPath® Lung, we see potential for the acquisition to become accretive to operations as early as 2024.

At September 30, 2023, bioAffinity had $4.0 million in working capital, representing a current ratio of 3.0. Concurrent with its IPO, the company converted more than $20 million in convertible preferred shares and notes payable and related accrued interest into common shares. Although the accumulated deficit was $42.2 million at September 30, 2023, we note that such figures are not atypical of early-stage tech companies and reflect the company's substantial R&D spending.

In 2022, net cash used in operating activities was $4.1 million, compared to $2.0 million used in 2021. bioAffinity used $220,000 in cash for investing activities in 2022, but did not use any cash in investing activities in 2021.

Cash provided by financing activities was approximately $14.3 million in 2022, driven by the IPO. This compared to cash provided by financing activities of $3.3 million in 2021, primarily through the issuance of convertible notes.

As of June 30, 2023, the company had 4.65 million warrants to purchase one share of common stock outstanding, with a weighted-average exercise price of $6.39. These warrants expire at various dates through September 2027.

The company does not pay a dividend, and we do not expect it to pay one for the foreseeable future.

MANAGEMENT

Maria Zannes is bioAffinity Technologies' president and CEO, as well as a company director. Ms. Zannes is a co-founder of bioAffinity and has overseen the establishment of its team of scientists and business network of leaders across the oncology-focused diagnostics and therapeutics landscape. Previously, Ms. Zannes founded The Zannes Firm, focusing on strategic solutions for private industry in the medical, environmental, and energy fields. Ms. Zannes was also president of the Energy Recovery Council, a national trade group for the $10 billion waste-to-energy industry.

Vivienne Rebel, MD, PhD has been chief medical and science officer and executive vice president of bioAffinity Technologies since 2016. Dr. Rebel is a cancer (stem) cell biologist with more than 20 years of experience in scientific research focused on understanding the molecular events that lead to cancer development. She received her M.D. from the Free University in Amsterdam, the Netherlands, and performed her Ph.D. dissertation work at the Terry Fox Laboratory for Hematology/Oncology in Vancouver, B.C., Canada, world-renowned for its work in experimental stem cell biology. She completed her post-doctoral training at the Dana-Farber Cancer Institute, Harvard Medical School, in cancer biology and gene therapy. From 2005 to 2016, she led her own research group at The University of Texas Health Science Center at San Antonio where she first collaborated with bioAffinity and established her own laboratory in cancer (stem) cell biology in the Department of Cellular and Structural Biology. Dr. Rebel received the 2012 Cancer Therapy & Research Center Discovery of the Year Award, is the co-author of more than 50 publications in peer-reviewed journals, and has received funding from federal, state and private funding agencies, including the National Institutes of Health (NIH).

Michael Dougherty, MBA, is bioAffinity's chief financial officer (CFO). Mr. Dougherty was most recently CFO of Amazon's Alexa Business Domains, Amazon's Alexa AI and Voice division, where he was responsible for financial strategy over Alexa's multi-billion-dollar investments in AI-generated customer experiences. Previously, Mr. Dougherty was chief financial and operating officer of TINT, a user-generated content platform, and chief financial officer at Filestack, a secure file handling service provider that was acquired by Idera, Inc

bioAffinity Technologies' board has eight directors, five of whom are independent, which we view favorably as it relates to corporate governance. The board recently was expanded, with the addition of Roby Joyce, M.D., the founder of Precision Pathology Services, who will also continue as the laboratory and medical director of the newly created bioAffinity subsidiary, and Jamie Platt, Ph.D., who was instrumental in two M&A exits for diagnostic companies that were completed in 2022, for a combined value of nearly $1 billion.

Dr. Platt was chief operating officer (COO) of Personal Genome Diagnostics, which was acquired by LabCorp for $575 million. She also served as COO at Inivata Inc. where she led operations in support of a next-generation sequencing (NGS) liquid biopsy laboratory developed test, which was acquired by Neogenomics.

RISKS

Risks to an investment in bioAffinity Technologies include the company's need to obtain substantial additional funding to complete the development and full commercialization of its diagnostic tests and therapeutic product candidates. There is also the risk of delays or difficulties in the enrollment and/or retention of patients in clinical trials; possible difficulties in predicting the results, timing, and cost of its development efforts; and possible complications rolling out CyPath Lung® regionally and nationally under its LDT designation. As well, there is a reliance on securing FDA approval for CyPath® Lung as an IVD under a de novo classification, which we think could occur by 2027.

COMPANY DESCRIPTION

Based in San Antonio, Texas, bioAffinity Technologies, Inc. develops non-invasive diagnostic tests and targeted cancer therapeutics. The company's initial product, CyPath® Lung, is a diagnostic test that uses flow cytometry to aid in the early detection of lung cancer. The test is in the early stages of a commercial rollout. The company is also developing targeted therapies to treat cancer at the cellular level. bioAffinity was founded in 2014.

VALUATION

Over the past 52 weeks, BIAF shares have traded in a range between $4 and $1, and are currently trading around $1.60 per share. We attribute the weakness primarily to the financing overhang and likely dilution in 2024, this amid a challenging financing environment in the life sciences sector, particularly for smaller companies.

In our view, this overhang was exacerbated by an SEC S-1 filing for a potential follow-on offering. However, we think that any effects of share dilution would be offset partially by the enhanced ability for bioAffinity to advance the CyPath® Lung pivotal trial, as well as to maximize the current commercial launch under the CAP/CLIA model and a broadening launch in the U.S.

Despite the uncertainty, we think that the stock weakness is overdone, as it assigns nearly no value to the company's technology platform and largely de-risked CyPath® Lung test, which has demonstrated promising results in a clinical validation study, and its long-term commercial prospects.

To value the shares, we apply a multiple of 5, in line with the average for a group of medical testing and diagnostics peers, to our 2031 revenue estimate of $425 million. Our 2031 revenue estimate is consistent with fifth-year sales for high-growth, FDA-approved cancer diagnostics. We assume FDA approval and launch of the CyPath® Lung test in the second half of 2027.

We think that CyPath® Lung's target market will be among the largest for early cancer diagnostics. We also believe that the test eventually could be used to diagnose other lung conditions, such as COPD, which would represent an additional revenue opportunity. Discounting the projected 2031 enterprise value back at 30% annually, and adjusting for the fully diluted share count of 14.8 million, we arrive at a fair value estimate for BIAF of $8 per share, well above current levels.

Steve Silver,
Argus Research Analyst)

INCOME STATEMENT

Growth Analysis ($MIL)	2021	2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023E	2023E	Q1 2024E	Q2 2024E	Q3 2024E	Q4 2024E	2024E
Revenue	0.0	0.0	0.0	0.0	0.3	1.8	2.1	2.0	2.1	2.4	2.5	9.0
Gross Profit	0.0	0.0					1.8					7.9
G&A	0.9	2.7					7.3					12.6
R&D	1.3	1.3					1.7					3.4
Operating Income	-2.2	-4.0					-7.5					-9.1
Interest Expense	-1.0	-2.5					0.1					0.1
Pretax Income	-6.3	-8.2					-7.4					-9.0
Tax Rate (%)	NA	NA					NA					NA
Net income	-6.3	-8.2					-7.4					-9.0
Diluted Shares	2.7	4.5					8.8					9.3
EPS	-2.36	-1.81	-0.18	-0.20	-0.26	-0.20	-0.84	-0.19	-0.22	-0.26	-0.28	-0.95
Dividend	NA	NA					NA					NA
Growth Rates (%)												
Revenue	NA	NM					NM					NM
Operating Income	NA	NA					NA					NA
Net Income	NA	NA					NA					NA
EPS	NA	NA					NA					NA
Valuation Analysis												
Price ($): High	NA	NA					NA					NA
Price ($):Low	NA	NA					NA					NA
PE: High	NA	NA					NA					NA
PE: Low	NA	NA					NA					NA
PS: High	NA	NA					NA					NA
PS: Low	NA	NA					NA					NA
Yield: High	NA	NA					NA					NA
Yield: Low	NA	NA					NA					NA
Financial & Risk Analysis ($MIL)												
Cash	1.4	11.4					NA					NA
Working Capital	-11.6	10.8					NA					NA
Current Ratio	0.1	10.5					NA					NA
LTDebt/Equity (%)	NM	NA					NA					NA
Total Debt/Equity (%)	NM	2.3					NA					NA
Ratio Analysis												
Gross Profit Margin	NM	NM					86%					88%
Operating Margin	NM	NM					NM					NM
Net Margin	NM	NM					NM					NM
Return on Assets (%)	NA	NA					NA					NA
Return on Equity (%)	NA	NA					NA					NA
Op Inc/Int Exp	NA	NA					NA					NA
Div Payout	NA	NA					NA					NA

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