

December 13, 2022

## 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 to aid in the early detection of lung cancer. The test is at the nascent stages of a commercial roll-out. 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

- \* BIAF: A Potential Advance in the Early Detection of Cancer
- \* In our view, bioAffinity is well positioned to establish its CyPath® Lung test as a cost-effective, non-invasive tool to aid in 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.
- \* CyPath® Lung utilizes flow cytometry and proprietary machine learning algorithms to profile the approximately 20 million cells in an average sputum sample in less than 20 minutes. This approach has helped overcome the limitations of traditional analytical throughput, and test validation trial results achieved superior results of 92% sensitivity and 87% specificity in high-risk patients who had lung nodules 20 mm or smaller.
- \* bioAffinity, in partnership with Precision Pathology Services under the latter's CLIA-certified laboratory, is in the nascent stages of a regional launch plan and is expected to roll out more broadly through 2023. bioAffinity plans to conduct a pivotal trial on CyPath® Lung in order to gain FDA approval, which would enable direct marketing to a larger addressable market, which we believe could occur by early 2027.

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### KEY STATISTICS

#### Key Stock Statistics

Recent price (12/12/22)	\$2.00
Fair Value Estimate	\$9.00
52 week high/low	\$15.55-\$1.92
Shares outstanding (M)	8.4
Market cap (M)	\$16.8
Dividend	Nil
Yield	Nil

#### Sector Overview

Sector	Healthcare
Sector % of S&P 500	15.2%

#### Financials (\$M, as of 9/30/22)

Cash & Mkt Securities	13.5
Debt	0.8
Working Capital (\$M)	12.6
Current Ratio	9.6
Total Debt/Equity (%)	6.5%
Payout ratio	NM
Revenue (M) TTM	NM
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	1.7

#### Top Holders

Citadel Advisors LLC  
 Jane Street Group LLC Asset Management  
 UBS Asset Management

#### Management

CEO	Ms. Maria Zannes
EVP/CSO/CMO	Dr. Vivienne Rebel
CFO	Mr. Michael Edwards
Company website	<a href="https://bioaffinitytech.com">https://bioaffinitytech.com</a>

### PRICE CHART



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- \* Over the longer term, we see potential for bioAffinity to develop and market non-invasive tests for additional lung diseases as well as other cancers, and to develop therapeutics for cancer, which would represent additional potential value drivers.
- \* bioAffinity raised gross proceeds of \$15.6 million from a September 2022 initial public offering (IPO) that included the issuance of share/warrant units, as well as from the exercise of some legacy warrants. As such, we view the company as sufficiently capitalized into 2024, which we view favorably amid the currently challenging and volatile financing conditions for small-cap companies.
- \* Based on our E/V-to-revenue valuation analysis, we arrive at a fair value estimate for BIAF of \$9.00 per share, well above its current level.

## INVESTMENT THESIS

bioAffinity Technologies, Inc. engages in developing non-invasive diagnostic tests for the early detection of lung cancer and other lung mediated diseases, and targeted cancer therapeutics. The company is based in San Antonio, Texas, and its R&D activities are born out of laboratories at The University of Texas at San Antonio. Its initial product, CyPath® Lung, a diagnostic test designed for the early detection of lung cancer, is at the nascent stage of a regional launch in the southwestern United States. We anticipate a national launch, in partnership with Precision Pathology Services, to be initiated in the second half of 2023.

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 advances in treatments, including 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, and 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, and the American Cancer Society (ACS) expects 1.9 million cancer diagnoses and 609,000 cancer-related deaths this year.

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.

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 can more effectively enable 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, as most cases are diagnosed later in the disease progression after symptoms become noticeable, rendering treatments less effective. Thus, in our view, diagnosing lung cancer earlier before it spreads is key to profoundly 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 over 90%, versus five-year survival of approximately 20% for Stages 2-4.

In our view, the global market for enhanced screening tools is evident in the United States' Preventive Services Task Force classification of 18 million Americans who are high-risk for lung cancer and the European Union's estimate of up to 34 million at high risk. In addition, China, with an estimated 300 million smokers, represents the world's largest market for lung cancer prevalence.

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 differentiate 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 can modestly help lower lung cancer mortality rates. However, this method has a low positive predictive value (the proportion of true positive results 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 can improve positive predictive value, resulting in fewer patients unnecessarily subjected to invasive diagnostic procedures. Sample collection is conducted at home and shipped overnight to be processed by technicians skilled in general laboratory techniques. The processed sample is run through a flow cytometer, with data evaluated in minutes by automated analysis leading to a patient report. Patient reports are provided within three days of sample receipt to the ordering physician, who can then advise those patients identified for more aggressive follow-up testing to confirm a suspected lung cancer diagnosis.

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

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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	2.00	15.55	1.92	17	NM	NA	NM	NM	NA	NA
BIODESIX INC	NASDAQ: BDSX	1.52	6.00	0.96	116	-69	20	NM	NM	1.73	NA
VERACTYE INC	NASDAQ: VCYT	29.09	45.58	14.85	2089	-35	87	NM	NM	1.39	NA
LUNGLIFE AI INC	AIM: LLAI	1.03*	2.10*	1.00*	26*	-46	-5	NM	NM	NA	NA

\* Stock Statistics in British Pound (GBP)

sputum sample, containing an average of about 20 million cells in less than 20 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 had 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. In the broad patient group, irrespective of nodule size, the study showed 82% sensitivity and 88% specificity. In studies to date, 80% of Stage 1 tumors were correctly identified, 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, 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, can be obtained noninvasively and transported easily and non-immediately, as would a molecular test collecting genetic material. Second, the CyPath® platform technology is not a molecular test that requires immediate processing, as compared with those tests collecting genetic material. Finally, the test is straightforward in terms of processing, use of reagents and automated data acquisition and analysis.

We are encouraged by survey work conducted by bioAffinity, which has shown robust interest and likely adoption among pulmonologists and internists, the primary audience for such a test. In our view, a non-invasive test using sputum as a sample with 80% sensitivity and 80% or greater specificity for detecting lung cancer in patients at high risk is likely to support a compelling commercial profile for CyPath® Lung as an adjunct with LDCT screening and diagnosis, since physicians currently have few, if any, non-invasive and cost-effective options to diagnose lung cancer in high-risk individuals displaying pulmonary nodules. Thus, we think the commencement of a pivotal clinical trial for CyPath® Lung to enhance corporate visibility for bioAffinity is likely over the coming years.

CyPath® Lung is at the nascent stage of its commercial launch, as a laboratory developed test (LDT) under the CLIA certified lab program, through bioAffinity's joint development agreement with

Precision Pathology Services. Under the agreement, bioAffinity receives a 50% royalty on CyPath® Lung test gross revenues and is responsible for conducting R&D, sales and marketing, while Precision handles matters related to the sale, processing, clinical communications and billing for the test.

CyPath® Lung's initial market is in Texas, and a limited test-market launch to pulmonologists in the San Antonio market has already begun. The two companies plan to test and refine, if needed, the operating model, including physician ordering, sample collection, and patient report generation and delivery, before scaling to a wider rollout. Test availability is expected to expand throughout the southwestern region of the U.S. in 2023, with nationwide sales likely to commence by early 2024. Subsequent phases of the launch will include offering CyPath® Lung as a CE-marked IVD laboratory-based test, where regulatory procedures are still ongoing, to be sold in the European Union via strategic laboratory channels, commencing in mid-2024, starting in the Netherlands.

For the longer term, bioAffinity will seek FDA clearance of the CyPath® Lung as a Class II in-vitro diagnostic (IVD) medical device. The company is working to finalize the design of the pivotal clinical trial that it has determined 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 in early 2023 in order to obtain the FDA's feedback. If authorized, a pivotal clinical trial expected to last two to three years would commence in the first half of 2023. Based on work already done with its contract research organization (CRO) and early efforts to enroll trial sites, we see the potential for the trial to come in at the lower end of this two-to-three-year range. Upon completion, bioAffinity would plan to submit a de novo classification request to the U.S. 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 current CLIA lab model, and would likely enable higher reimbursement rates. 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 that can be determined by examining the micro-environment of the lung, including Chronic Obstructive Pulmonary Disease (COPD) and asthma, which the company believes can also use antibodies that characterize 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.

Outside the lung, bioAffinity also plans on developing diagnostic tests for prevalent cancers in need of better predictive outcomes, including prostate cancer, which is 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 as 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. Benchmark invasive options include biopsies, which have a better positive predictive value of 67%. bioAffinity is also examining bladder cancer, which, while less prevalent than many other leading cancers, has among the highest cancer recurrence rates within five years of the initial diagnosis, and carries a higher risk for life.

In our view, bioAffinity's focus on 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 in CyPath® Lung. These potential therapies have killed cancer cells grown in petri dishes without apparent harm to normal cells, using RNA interference to selectively silence genes. 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 represents 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 August 2022, 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 automated analysis in the detection of lung diseases using sputum as a sample.

We are encouraged by bioAffinity's assembling of 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, 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, while also promoting messaging around routine screening at earlier stages of disease.

## 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. Since pricing its IPO at \$6.13 per share, the share price has declined by approximately 65%, compared to a 1% increase for the S&P 500.

In November 2022, bioAffinity reported financial results for the nine months ended September 30, 2022. Revenues of approximately \$2,500 reflect the nascent commercial launch of the CyPath® Lung test in San Antonio, Texas. The net loss for the nine-month period totaled \$6.5 million, more than 60% of which is attributable to interest expenses and adjustments related to the extinguishment and conversion of debt.

In October 2022, Sheila Habib, MD, Director of the Pulmonary Lung Nodule Clinic and the Lung Cancer Screening Program at the South Texas Veterans Health Care Systems' Audie L. Murphy Memorial Veterans' Hospital, joined the Company's Scientific and Medical Advisory Board.

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, its partner Precision Pathology Services received continued accreditation for its laboratory and for CyPath® Lung test as a laboratory developed test (LDT), by the College of American Pathologists (CAP) in accordance with CAP/CLIA regulatory standards and regulations.

In the quarter ended June 30, 2022, bioAffinity recognized initial royalty revenue on sales of its CyPath® Lung test.

## EARNINGS AND GROWTH ANALYSIS

Over the next few years, we expect bioAffinity to generate revenues from royalties on sales by Precision Pathology Services of CyPath® Lung, which we expect will begin in earnest in the final quarter of 2022. Although Precision placed CyPath Lung on its list of offered tests in the second quarter this year, product marketing was limited until the completion of bioAffinity's IPO in September, which provided funding to assemble an expert marketing team to support the launch. We project revenues to grow modestly until mid-2023, at which time CyPath® Lung should expand across the southwestern U.S. and then nationally. In 2022, we forecast CyPath® Lung sales of \$50,000 and \$1.4 million in 2023, resulting in revenues to bioAffinity of \$25,000 and \$0.7 million, respectively.

bioAffinity's cost of sales are related to inventory production and usage, and shipments of collection kits to patients and health-care providers. The company has partnered with GO2 Partners for the components and storage of the collection kits. R&D expenses are related to lab operations, CyPath® Lung clinical activities, as well as earlier-stage development work. General and administrative costs are related to employee compensation, professional services, and general operating expenses as a public company.

In 2023, we expect operating expenses to increase, given higher testing volumes and inventory material buildup, the initiation of the pivotal FDA clinical study of CyPath® Lung and early-stage research in other areas. We forecast operating expenses of \$3.8 million in 2022 and \$9.5 million in 2023, with R&D accounting for more than 60% of this total.

We anticipate net losses of \$1.95 per share in 2022, with approximately half of the net loss for the year attributable to fair value adjustments and interest costs related to convertible notes, which were converted to common shares in conjunction with its September 2022 IPO. In 2023, we forecast a \$1.00 per share net loss, on increased operating costs and a higher share count.

## FINANCIAL STRENGTH and DIVIDEND

Our financial strength rating on bioAffinity is Medium-Low. As of September 30, 2022, the company had \$13.5 million in cash and equivalents on its balance sheet, boosted by its September 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.

At September 30, 2022, bioAffinity had \$12.6 million in working capital, representing a current ratio of 9.6. 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, leaving only \$325,000 in convertible notes outstanding. Although the accumulated deficit was \$35.0 million at September 30, we note that such figures are not atypical of early-stage tech companies and reflect the company's substantial spending on new product research and development.

During the first nine months of 2022, net cash used in operating activities was approximately \$2.8 million, compared with \$1.4 million used during the same period in 2021. For 2021, net cash used in operating activities was \$2.0 million, compared with \$2.2 million used in 2020.

bioAffinity has not used any cash in investing activities in the latest nine months, or in the year earlier period. In 2021, the company did not use any cash in investing activities, compared to \$3,000 used for the year ended December 31, 2020.

Cash provided by financing activities was approximately \$14.9 million for the first nine months of 2022, driven by its IPO, compared to cash provided of \$1.6 million for the same period of 2021. In 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 its 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 received forgiveness on its second PPP loan draw. In 2020, net cash provided by financing activities was \$1.5 million from the issuance of convertible notes, and an initial draw on its PPP Loan of \$239,000 in April 2020. In June 2021, the company received a notice of forgiveness on its first PPP draw.

We think cash use is likely to increase over the next year as the company initiates its pivotal clinical trial on CyPath® Lung.

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

## MANAGEMENT

Ms. Maria Zannes is bioAffinity Technologies' President and CEO, as well as a company director. She brings more than 30 years of executive-level management experience. Ms. Zannes is a co-founder who has overseen the establishment of bioAffinity's team of scientists and business network of leaders in 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, during which she oversaw the successful reorganization and development of Biomoda, Inc., as its CEO. Ms. Zannes was also president of the Energy Recovery Council, a national trade group for the \$10 billion waste-to-energy industry. She received her B.A. in Journalism from the University of New Mexico and her J.D. from the University of Puget Sound in Washington State.

bioAffinity Technologies' board has seven directors, five of whom are independent, which we view favorably as it relates to corporate governance.

## RISKS

Risks to an investment in bioAffinity Technologies include its need to obtain substantial additional funding to complete the development and commercialization of its diagnostic tests and therapeutic product candidates; the risk of experiencing delays or difficulties in the enrollment and/or retention of patients in clinical trials; the difficulty in predicting the results, timing, and cost of its development efforts; and reliance on securing FDA approval for CyPath® Lung as an IVD under de novo classification, which the company anticipates by early 2027, after an expected filing in the second quarter of 2026.

## COMPANY DESCRIPTION

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 to aid in the early detection of lung cancer that is at the nascent stages of a commercial roll-out. 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.

## VALUATION

We do not believe the recent BIAF share price near \$2.00 adequately reflects the company's technology platform and long-term commercial profile. In our view, the company has demonstrated promising results in a clinical validation study that provides confidence that a pivotal trial, expected to begin in 2023, is likely to confirm these results.

To value the shares, we apply a 5X multiple to our forecasted 2031 revenue estimate of \$475 million. This multiple is consistent with the average for a global basket of Medical Testing, Analyzing and Diagnostic peers, and our revenue estimate is consistent with fifth-year sales for FDA approved, high growth cancer diagnostics. We assume FDA approval and launch in 2027.

We think that CyPath® Lung's target market will be among the largest for early cancer detecting diagnostics. Further, we see potential for CyPath® Lung's use for additional lung indications such as COPD in this timeframe, which would represent an additional upside revenue opportunity. We discount the projected enterprise value back at 30% annually and, adjusting for the fully diluted share count of 13.8 million, we arrive at a fair value estimate for BIAF of \$9.00 per share, well above current levels.

Steve Silver,  
Argus Research Analyst

**INCOME STATEMENT**

<b>Growth Analysis (\$MIL)</b>	2020	2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022E	2022E	Q1 2023E	Q2 2023E	Q3 2023E	Q4 2023E	2023E
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.2	0.2	0.3	0.7
Gross Profit	0.0	0.0					0.0					0.7
G&A	1.0	0.9					2.1					3.5
R&D	1.6	1.3					1.8					5.9
Operating Income	-2.6	-2.2					-3.8					-8.7
Interest Expense	-0.4	-1.0					-2.5					0.0
Pretax Income	-7.3	-6.3					-8.0					-8.7
Tax Rate (%)	NA	NA					NA					NA
Net income	-7.3	-6.3					-8.0					-8.7
Diluted Shares	2.7	2.7					4.4					8.7
EPS	-2.72	-2.36	-0.55	-0.03	-1.17	-0.19	-1.94	-0.21	-0.26	-0.26	-0.27	-1.00
Dividend	NA	NA					NA					NA
<b>Growth Rates (%)</b>												
Revenue	NA	NA					NM					2700%
Operating Income	NA	NA					NA					NA
Net Income	NA	NA					NA					NA
EPS	NA	NA					NA					NA
<b>Valuation Analysis</b>												
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
<b>Financial &amp; Risk Analysis (\$MIL)</b>												
Cash	0.1	1.4					NA					NA
Working Capital	-11.0	-11.6					NA					NA
Current Ratio	0.0	0.1					NA					NA
LTDebt/Equity (%)	NM	NM					NA					NA
Total Debt/Equity (%)	NM	NM					NA					NA
<b>Ratio Analysis</b>												
Gross Profit Margin	NM	NM					NM					NM
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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