MAXIM GROUP

Equity Research
Estimate Change

# bioAffinity Technologies, Inc.

**Buy**

## Slight 3Q24 Revenue Miss, but 2024 Revenue Guidance Reaffirmed; CyPath added to FSS – Reiterate Buy on Expansion Potential

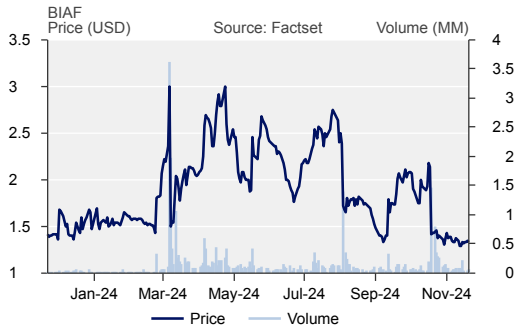
| Diagnostics | |
|---|---|
| **BIAF** – NASDAQ | November 20, 2024 |
| **Closing Price 11/19/24** | **$1.33** |
| Rating: | Buy |
| 12-Month Target Price: | $6.00 |
| 52-Week Range: | $1.21 - $3.62 |
| Market Cap (M): | $20.7 |
| Shares O/S (M): | 15.6 |
| Float: | 60.3% |
| Avg. Daily Volume (000): | 115.0 |
| Debt (M): | $0.3 |
| Dividend: | $0.00 |
| Dividend Yield: | 0.0% |
| Risk Profile: | Speculative |
| Fiscal Year End: | December |

**Revenue ('000)**

| | 2024E | 2025E | 2026E |
|---|---|---|---|
| 1Q | 2,406A | 2,619 | — |
| 2Q | 2,398A | 2,806 | — |
| 3Q | 2,350A | 2,920 | — |
| 4Q | 2,418 | 3,145 | — |
| CY | 9,572 | 11,490 | 13,788 |
| *Prior* | 9,991 | — | |

**GAAP EPS**

| | 2024E | 2025E | 2026E |
|---|---|---|---|
| 1Q | (0.20)A | (0.17) | — |
| 2Q | (0.19)A | (0.17) | — |
| 3Q | (0.16)A | (0.16) | — |
| 4Q | (0.14) | (0.16) | — |
| CY | (0.69) | (0.66) | (0.46) |
| *Prior* | (0.68) | (0.60) | |




For a detailed analysis, see our initiation report, published on July 23, 2024.

***Company description:*** *bioAffinity Technologies, Inc. is a commercial-stage medical diagnostic company focused on cancer detection. Its CyPath Lung utilizes sputum and flow cytometry for the early detection of lung cancer.*


**Anthony Vendetti**
(212) 895-3802
avendetti@maximgrp.com


### Summary


- On 11/14/24, BIAF reported 3Q24 results with revenue slightly below our estimate and a slightly wider GAAP loss per share. Note that we are the only sell-side firm with published estimates, per LSEG.
- CyPath Lung sales of 172 were relatively flat from 168 in 2Q24; and the number of physician offices ordering CyPath Lung was roughly 140, up from ~100 at the end of 2Q24. We expect both metrics to grow in 4Q24.
- BIAF reaffirmed 2024 revenue guidance of $9.6M, implying 4Q24 revenue of $2.4M, below our prior estimate of $2.6M.
- In October 2024, CyPath Lung was added to the US Federal Supply Schedule (FSS), allowing VA and Military Health System physicians to order the test.
- As of 9/30/24, BIAF had cash and equivalents of $757K and debt of $289K. We expect the company to burn ~$2.1M per quarter through 2025 and including net proceeds raised from a recent registered direct and private placement of $2.3M, believe there is sufficient capital to last into 1Q25.
- Based on 3Q24 results, management guidance, and our expectations, we are lowering our 2024 revenue estimate while maintaining our 2025 estimate; and widening our 2024 and 2025 GAAP loss per share estimates. We are also introducing 2026 annual estimates.


### Details

**Bottom line.** Despite the slight 3Q24 revenue miss, we are encouraged by several recent developments that we believe should drive increased testing volume and topline growth. Although the initial commercial focus of CyPath Lung is in Texas, referrals and word-of-mouth from physicians, including KOLs, have driven sales in eleven states, up from eight in 2Q24, and the number of physician offices now offering the test was up roughly 40% sequentially. In October 2024, CyPath Lung was added to the US Federal Supply Schedule, giving veterans at high risk for lung cancer access to this technology, and a recently published economic study highlighted the potential savings generated using CyPath Lung. We believe these advancements lay a solid foundation for driving sales growth and testing volume, and reflect the increasing recognition of the tests value in early lung cancer detection. We expect BIAF to initiate a clinical trial for potential FDA De Novo classification of its CyPath in early 2025 (slightly delayed from our prior expectation of before end of 4Q24), which could broaden adoption. Based on the sales expansion, addition to the FSS, the role CyPath can play in the early detection of lung cancer, and a considerable market opportunity, we reiterate our Buy rating.

**3Q24 results summary.** On 11/14/24, BIAF filed its 10-Q and reported 3Q24 results with total revenue of $2.4M, flat sequentially, and slightly below our estimate of $2.5M. Gross margin of 38.7%, down 260bps q/q, was above our estimate of 36.0%. GAAP loss per share of ($0.16) was slightly wider than our estimate of ($0.15). Note that we are the only sell-side firm with published estimates, per LSEG.

**Compelling valuation.** We derive our 12-month price target of $6.00 by employing a 10-year DCF analysis with an 18% discount rate and a 3% perpetual growth rate. Shares currently trade at an EV/revenue multiple of 1.3x our 2025 estimate, well below the peer average of 5.8x, excluding BIAF. Our price target equates to 5.9x our 2025 revenue estimate, slightly above the peer average, which we believe is justified due to the company's novel diagnostic technology, expansion potential, and significant market opportunity.

**Revising estimates.** Based on 3Q24 results, management guidance, and our expectations, we are lowering our 2024 revenue estimate to $9.6M, from $10.0M, while maintaining our 2025 estimate of $11.5M. We are slightly increasing our 2024 gross margin estimate to 37.9%, from 37.2%, while slightly lowering our 2025 estimate to 38.0%, from 38.7%, respectively. In addition, we are widening our 2024 and 2025 GAAP loss per share estimates to ($0.69) and ($0.66), from ($0.68) and ($0.60) respectively.

**2024 guidance reaffirmed.** Management reaffirmed 2024 revenue guidance of $9.6M, compared to our prior estimate of $10.0M, and up from $7.9M in 2023 on a proforma basis if the acquisition of Precision Pathology Services took place on January 1, 2023. It is important to note that 2024 is the first full year of operating Precision Pathology Services (Precision) as a subsidiary of BIAF, as Precision was acquired in September 2023. Our 2024 estimate includes $0.6M-$0.8M of revenue from CyPath Lung. 2024 revenue guidance implies 4Q24 revenue of $2.4M, up 9.2% y/y, but below our prior estimate of $2.6M.

**CyPath added to Federal Supply Schedule.** In October 2024, CyPath Lung was added to the US Federal Supply Schedule, a procurement system that provides the Veterans Health Administration (VHA) and the Military Health System streamlined access to state-of-the-art healthcare products and services. The VHA, part of the US Department of Veterans Affairs (VA), serves 9.1M veterans each year and is the largest integrated health care system in the country, providing care at 1,380 health care facilities. Approximately 8,000 veterans are diagnosed and treated for lung cancer annually, according to the VA. Veterans are at higher risk for lung cancer due to older age, smoking, and environmental exposure during and after military service. Through programs like the Lung Precision Oncology Program (LPOP), the VA promotes annual lung cancer screening for high-risk individuals.

**CyPath economic study.** On 9/18/24, BIAF announced that a new economic study conducted by Brooke Army Medical Center's Michael Morris, M.D., and VA's Sheila Habib, M.D., found that adding CyPath Lung to the standard of care for Medicare patients with a positive lung cancer screening could have saved an average of $2,773 per patient for total cost savings of $379M in 2022. The peer-reviewed study, 'Economic Evaluation of a Novel Lung Cancer Diagnostic in a Population of Patients with a Positive Low-Dose Computed Tomography Result,' attributes the savings to a reduction in follow-up diagnostic assessments, expensive follow-up procedures, and procedure-related complications. The study found that adding CyPath Lung to the standard of care for private-payer patients with a positive lung cancer screening result could have saved even more, an average of $6,460 per patient. The analysis estimated total healthcare savings of $895M if all individuals screened in 2022 were covered by private insurance. The economic model used in the study evaluated the impact of adding CyPath Lung to the diagnostic pathway for individuals with a positive LDCT, including patients with a primary lung cancer diagnosis. Cost calculations included procedure expenses, the cost of complications and adverse events due to a procedure, and diagnostic assessment costs.

| bioAffinity Technologies<br>3Q24 Comparison | BIAF | Maxim | Difference |
|---|---|---|---|
| **Total revenue** | **$2.4M** | **$2.5M** | **($0.1M)** |
| **Gross Margin** | **38.7%** | **36.0%** | **270bps** |
| **GAAP EPS** | **($0.16)** | **($0.15)** | **($0.01)** |

*Source: Company reports, LSEG, and Maxim Group estimates*

| bioAffinity Technologies<br>3Q24 Income Statement Comparison ('000s) | | | | |
|---|---|---|---|---|
| *Actual vs. Estimates* | **3Q24E** | **3Q24A** | **$ Diff** | **% Diff** |
| **Net revenues** | **2,539** | **2,350** | **(189)** | **(7.4%)** |
| *y/y change* | *751%* | *687%* | | |
| Cost of revenues | 1,625 | 1,440 | (185) | (11.4%) |
| *y/y change* | *2075%* | *1828%* | | |
| % of net revenue | 64.0% | 61.3% | | |
| Gross profit | 914 | 910 | (4) | (0.4%) |
| *y/y change* | *308%* | *307%* | | |
| **Gross margin** | **36.0%** | **38.7%** | | |
| Operating expenses: | | | | |
| Research and development | 390 | 274 | (115) | (29.6%) |
| *y/y change* | *18.0%* | *(16.9%)* | | |
| % of net revenue | 15.4% | 11.7% | | |
| Clinical development | 69 | 94 | 25 | 35.5% |
| *y/y change* | *(35.0%)* | *(11.9%)* | | |
| % of net revenue | 2.7% | 4.0% | | |
| Selling, general and administrative | 2,406 | 2,365 | (41) | (1.7%) |
| *y/y change* | *18.9%* | *16.8%* | | |
| % of net revenue | 94.8% | 101% | | |
| Depreciation and amortization | 150 | 151 | 2 | 1.1% |
| *y/y change* | *160%* | *NA* | | |
| % of net revenue | 5.9% | 6.4% | | |
| Total operating expenses | 3,015 | 2,884 | (131) | (4.3%) |
| *y/y change* | *19.7%* | *14.5%* | | |
| % of net revenue | 119% | 123% | | |
| **Income (loss) from operations** | **(2,101)** | **(1,974)** | **127** | **(6.0%)** |
| *y/y change* | *(8.4%)* | *(14.0%)* | | |
| Total other income/(expense) | - | (24) | | |
| **Total net income/(loss)** | **(2,101)** | **(1,998)** | **102** | **(4.9%)** |
| *y/y change* | *0.0%* | *0.0%* | | |
| **Earnings (loss) per share** | **(0.15)** | **(0.16)** | **(0.01)** | |
| Weighted average common stock - basic | 13,889 | 12,392 | | |
| Weighted average common stock - diluted | 23,066 | 22,719 | | |

*Source: Company reports, LSEG, and Maxim Group estimates*

**bioAffinity Technologies, Inc.**
**Income Statement**
(in $ thousands, except per share data)

**Maxim Group LLC**
Anthony V. Vendetti, Executive Managing Director of Research
(212) 895-3802
avendetti@maximgrp.com

| Fiscal Year ending December 31 | 2022A | 1Q23A | 2Q23A | 3Q23A | 4Q23A | 2023A | 1Q24A | 2Q24A | 3Q24A | 4Q24E | 2024E | 1Q25E | 2Q25E | 3Q25E | 4Q25E | 2025E | 2026E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Net revenues** | **5** | **1** | **20** | **298** | **2,213** | **2,532** | **2,406** | **2,398** | **2,350** | **2,418** | **9,572** | **2,619** | **2,806** | **2,920** | **3,145** | **11,490** | **13,788** |
| *y/y change* | *N/A* | *N/A* | *1411%* | *NA* | *NA* | *NA* | *NA* | *12047%* | *687%* | *9.2%* | *278%* | *8.8%* | *17.0%* | *24.2%* | *30.1%* | *20.0%* | *20.0%* |
| Cost of revenues | 0 | 0 | 1 | 75 | 1665 | 1,741 | 1,573 | 1,408 | 1,440 | 1,523 | 5,945 | 1,637 | 1,740 | 1,810 | 1,934 | 7,121 | 8,273 |
| *y/y change* | *N/A* | N/A | *745%* | *NA* | *NA* | *NA* | *NA* | *NA* | *1828%* | *(8.5%)* | *241%* | *NA* | *NA* | *NA* | *NA* | *19.8%* | *16.2%* |
| % of net revenue | 9.7% | 9.4% | 6.3% | 25.0% | 75.2% | 68.7% | 65.4% | 58.7% | 61.3% | *63.0%* | 62.1% | *62.5%* | *62.0%* | *62.0%* | *61.5%* | 62.0% | *60.0%* |
| Gross profit | 4 | 1 | 19 | 224 | 548 | 792 | 833 | 990 | 910 | 895 | 3,628 | 982 | 1,066 | 1,110 | 1,211 | 4,369 | 5,515 |
| *y/y change* | *N/A* | *N/A* | *NA* | *NA* | *NA* | *N/A* | *N/A* | *5250%* | *307%* | *63.1%* | *358%* | *17.9%* | *7.7%* | *21.9%* | *35.3%* | *20.4%* | *26.2%* |
| **Gross margin** | **90.3%** | **90.6%** | **93.7%** | **75.0%** | **24.8%** | **31.3%** | **34.6%** | **41.3%** | **38.7%** | **37.0%** | **37.9%** | **37.5%** | **38.0%** | **38.0%** | **38.5%** | **38.0%** | **40.0%** |
| Operating expenses | | | | | | | | | | | | | | | | | |
| Research and development | 1,143 | 370 | 335 | 330 | 433 | 1,468 | 394 | 402 | 274 | 394 | 1,464 | 402 | 410 | 409 | 414 | 1,635 | 1,716 |
| *y/y change* | *13.4%* | *32.1%* | *34.9%* | *3.3%* | *46.8%* | *28.5%* | *6.5%* | *20.1%* | *(16.9%)* | *(9.0%)* | *(0.2%)* | *2.0%* | *2.0%* | *49.0%* | *5.0%* | *11.6%* | *5.0%* |
| % of net revenue | N/A | N/A | 1698% | 111% | 19.6% | 58.0% | 16.4% | 16.8% | 11.7% | 16.3% | 15.3% | 15.3% | 14.6% | 14.0% | 13.1% | 14.2% | 12.4% |
| Clinical development | 146 | 20 | 35 | 106 | 95 | 257 | 49 | 51 | 94 | 99 | 293 | 451 | 498 | 550 | 602 | 2,101 | 2,206 |
| *y/y change* | *11.6%* | *(62.6%)* | *24.9%* | *74.6%* | *NA* | *76.3%* | *149%* | *46.0%* | *(11.9%)* | *3.5%* | *14.1%* | *821%* | *868%* | *487%* | *510%* | *617%* | *5.0%* |
| % of net revenue | 3030% | 2131% | 179% | 35.7% | 4.3% | 10.1% | 2.0% | 2.1% | 4.0% | 4.1% | 3.1% | 17.2% | 17.7% | 18.8% | 19.1% | 18.3% | 16.0% |
| Selling, general and administrative | 2,727 | 1,170 | 1,426 | 2,024 | 2171 | 6,791 | 2,186 | 2,473 | 2,365 | 2,501 | 9,524 | 2,601 | 2,720 | 2,885 | 2,951 | 11,157 | 11,715 |
| *y/y change* | *155%* | *196%* | *249%* | *240%* | *63.4%* | *149%* | *86.9%* | *73.3%* | *16.8%* | *15.2%* | *40.3%* | *19.0%* | *10.0%* | *22.0%* | *18.0%* | *17.1%* | *5.0%* |
| % of net revenue | N/A | N/A | 7227% | 678% | 98.1% | 268% | 90.8% | 103% | 101% | 103% | 99.5% | 99.3% | 96.9% | 98.8% | 93.8% | 97.1% | 85.0% |
| Depreciation and amortization | - | - | - | 58 | 192 | 250 | 150 | 151 | 151 | 154 | 606 | 157 | 159 | 159 | 161 | 636 | 668 |
| *y/y change* | *N/A* | *N/A* | *N/A* | *7347%* | *N/A* | *N/A* | *N/A* | *NA* | *NA* | *(20.0%)* | *143%* | *5.0%* | *5.0%* | *5.0%* | *5.0%* | *5.0%* | *5.0%* |
| % of net revenue | - | - | - | 19.3% | 8.7% | 9.9% | 6.2% | 6.3% | 6.4% | 6.4% | 6.3% | 6.0% | 5.7% | 5.4% | 5.1% | 5.5% | 4.8% |
| **Total operating expenses** | **4,015** | **1,559** | **1,797** | **2,518** | **2,891** | **8,765** | **2,778** | **3,078** | **2,884** | **3,147** | **11,887** | **3,611** | **3,787** | **4,003** | **4,128** | **15,529** | **15,638** |
| *y/y change* | *82.0%* | *114%* | *162%* | *158%* | *77.7%* | *118%* | *78.2%* | *71.3%* | *14.5%* | *8.9%* | *35.6%* | *30.0%* | *23.0%* | *38.8%* | *31.2%* | *30.6%* | *0.7%* |
| % of net revenue | N/A | N/A | 9104% | 844% | 131% | 346% | 115% | 128% | 123% | 130% | 124% | 138% | 135% | 137% | 131% | 135% | 113% |
| **Income (loss) from operations** | **(4,011)** | **(1,558)** | **(1,778)** | **(2,295)** | **(2,342)** | **(7,973)** | **(1,945)** | **(2,088)** | **(1,974)** | **(2,253)** | **(8,259)** | **(2,629)** | **(2,721)** | **(2,893)** | **(2,917)** | **(11,160)** | **(10,122)** |
| *y/y change* | *81.8%* | *114%* | *160%* | *135%* | *44.2%* | *98.8%* | *24.9%* | *17.4%* | *(14.0%)* | *(3.8%)* | *3.6%* | *35.1%* | *30.3%* | *46.6%* | *29.5%* | *35.1%* | *(9.3%)* |
| % of net revenue | N/A | N/A | N/A | (769%) | (106%) | (315%) | (80.8%) | (87.1%) | (84.0%) | (93.2%) | (86.3%) | (100.4%) | (97.0%) | (99.1%) | (92.8%) | (97.1%) | (73.4%) |
| Other (income)/expense | | | | | | | | | | | | | | | | | |
| Interest income | 47 | 37 | 44 | 27 | 14 | 122 | 6 | 5 | 2 | - | 14 | - | - | - | - | - | - |
| Interest expense | (2,533) | - | (1) | (9) | (27) | (37) | (24) | (22) | (22) | - | (67) | - | - | - | - | - | - |
| Other income (expense) | - | - | - | (12) | (15) | (28) | 5 | 0 | (5) | - | (1) | - | - | - | - | - | - |
| Total other income/(expense) | (4,141) | 37 | 43 | 6 | (28) | 57 | (13) | (17) | (24) | - | (54) | - | - | - | - | - | - |
| Net income/(loss) before income taxes | (8,152) | (1,521) | (1,736) | (2,289) | (2,371) | (7,916) | (1,958) | (2,105) | (1,998) | (2,253) | (8,314) | (2,629) | (2,721) | (2,893) | (2,917) | (11,160) | (10,122) |
| Provision for income taxes | (2) | 12 | 5 | 2 | 2 | 21 | 4 | - | 3 | - | 6 | - | - | - | - | - | - |
| **Net income/(loss) from operations** | **(8,154)** | **(1,533)** | **(1,740)** | **(2,291)** | **(2,373)** | **(7,937)** | **(1,962)** | **(2,105)** | **(2,001)** | **(2,253)** | **(8,320)** | **(2,629)** | **(2,721)** | **(2,893)** | **(2,917)** | **(11,160)** | (10,122) |
| **Earnings (loss) per share** | **(1.81)** | **(0.18)** | **(0.20)** | **(0.26)** | **(0.25)** | **(0.91)** | **(0.20)** | **(0.19)** | **(0.16)** | **(0.14)** | **(0.69)** | **(0.17)** | **(0.17)** | **(0.16)** | **(0.16)** | **(0.66)** | **(0.46)** |
| Weighted average common stock - basic | 4,499 | 8,434 | 8,521 | 8,697 | 9,329 | 8,748 | 9,915 | 11,389 | 12,392 | 15,585 | 12,320 | 15,785 | 15,985 | 17,985 | 18,185 | 16,985 | 21,985 |
| Weighted average common stock - diluted | 9,955 | 13,990 | 14,077 | 14,164 | 14,796 | 14,081 | 19,373 | 20,566 | 22,719 | 25,912 | 22,142 | 26,112 | 26,312 | 28,312 | 28,512 | 27,312 | 32,312 |

*Sources: Company reports and Maxim Group estimates*

## DISCLOSURES


| Maxim Group LLC Ratings Distribution | | | As of: 11/19/24 |
|---|---|---|---|
| | | % of Coverage Universe with Rating | % of Rating for which Firm Provided Banking Services in the Last 12 months |
| **Buy** | Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months. | **83%** | **51%** |
| **Hold** | Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months. | **17%** | **60%** |
| **Sell** | Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months. | **0%** | **0%** |
| | **See valuation section for company specific relevant indices* | | |

I, **Anthony Vendetti**, attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

**Maxim Group makes a market in bioAffinity Technologies, Inc.**

**Maxim Group expects to receive or intends to seek compensation for investment banking services from bioAffinity Technologies, Inc. in the next 3 months.**

**BIAF:** For bioAffinity Technologies, Inc. we use the NASDAQ index as the relevant index.

**Valuation Methods**
**BIAF:** Our 12-month price target for bioAffinity Technologies, Inc. is derived using a 10-year DCF analysis.

**Price Target and Investment Risks**
**BIAF:** Aside from general market conditions and other economic risks, risks particular to our bioAffinity Technologies, Inc. price target and rating include: the need and ability to raise capital, which could lead to shareholder dilution, or if unsuccessful could result in ceasing operations; history of operating losses; key personnel risk; unfavorable healthcare regulatory reform; dependence on only one product; products may never gain acceptance; reliance on third-party manufacturers; highly competitive industry; failure to obtain third-party payer coverage; loss of payer coverage; launch of competitive products; technology could become obsolete;

ability to protect intellectual property; uncertainty regarding future product approval and acceptance; clinical trials necessary to support regulatory submission are expensive and data may not support approval; high share ownership concentration; and ability to comply with NASDAQ listing requirements.

## RISK RATINGS

Risk ratings take into account both fundamental criteria and price volatility.

**Speculative** – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

**High** – Fundamental Criteria: This is a risk rating assigned to companies having below-average revenue and earnings visibility, negative cash flow, and low market cap or public float. Accordingly, fundamental risk is expected to be above the industry. Price Volatility: The price volatility of companies falling within this category is expected to be above the industry. High-risk stocks may not be suitable for a significant class of individual investors.

**Medium** – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

**Low** – Fundamental Criteria: This is a risk rating assigned to companies that may have above-average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to be below the industry.

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## ADDITIONAL INFORMATION IS AVAILABLE UPON REQUEST

# Corporate Headquarters

**New York City**
300 Park Ave., 16TH Floor
New York, NY 10022
Tel: 212-895-3500

Capital Markets/Syndicate
212-895-3695

Corporate Services
212-895-3818

Equity/Options Trading
212-895-3796

Equity Research
212-895-3736

Fixed Income Trading
212-895-3875

**South Florida Hub**
555 Washington Ave., Suite 320
Miami Beach, FL 33139
Tel: 786-864-0880

Global Equity Trading
212-895-3623

Institutional Sales/Sales Trading
212-895-3873

Prime Brokerage
212-895-3668

Wealth Management
212-895-3540

**Stamford, Connecticut**
700 Canal Street
Stamford, CT 06902

**Red Bank, New Jersey**
68 White Street, 2nd Floor
Red Bank, NJ 07701
Tel: 732-784-1900

**Fort Lauderdale, Florida**
1 East Broward Blvd, Suite 1430
Fort Lauderdale, FL 33301

**Woodbury, New York**
100 Crossways Park Dr West, Suite 207
Woodbury, NY 11797
Tel: 516-393-8300