MAIA Biotechnology

Feb 27, 2025

Phase 2 THIO-101 Expansion and Registration Treatment Plans Announced

Healthcare

MAIA

NYSE

Rating

Outperform

Unchanged

Current Price

$1.84

Target Price

$14.00

Market Capitalization
48.13M

Shares Outstanding
26.16M

Float
20.96M

Institutional Holdings
5.29%

12-Month Low/High
$1.24/$5.99

Average 90-Day Volume
316790

Fiscal Year End
12/31/2025

Revenues ($ MIL)

Period	2022A	2023E	2024E
Q1	0.0	0.0A	0.0E
Q2	0.0	0.0A	0.0E
Q3	0.0	0.0E	0.0E
Q4	0.0	0.0E	0.0E
	0.0	0.0E	0.0E

EPS ($)

Period	2022A	2023E	2024E
Q1	(0.50)	(0.38)A	(0.45)E
Q2	(0.40)	(0.35)A	(0.50)E
Q3	(0.48)	(0.39)E	(0.47)E
Q4	(0.37)	(0.43)E	(0.50)E
	(1.75)	(1.55)E	(1.92)E

Phase 2 Trial Tests THIO Against THIO With Libtayo. MAIA announced the design of the third stage of the THIO-101 Phase 2 trial, consisting of Expansion and Registration stages. Both stages will enroll patients with non-small cell lung cancer (NSCLC) receiving the regimens as third-line treatment, expected to begin in 1Q25. Following the conclusion of the trial around 4Q25, we expect MAIA to apply for Accelerated Approval from the FDA.

Expansion Stage Is Expected To Begin In 1Q25. The THIO-101 Expansion stage will have two arms to determine the contributions of each drug to patient outcomes. In the first arm, 30 patients will receive the THIO-Libtayo (cemiplimab) combination at the 180mg dose. The second arm will treat 7 patients who were treated with THIO monotherapy to determine its efficacy. If the outcomes of THIO alone are moderate, the treatment arm will be discontinued. If sufficient efficacy is seen, up to 8 more patients will be enrolled for a total maximum enrollment of 48 patients. The primary endpoint is Overall Response Rate (ORR).

Registration Stage Can Support The Application For Accelerated Approval. The Registration stage plans to treat about 100 patients in a single arm with the combination of THIO with Libtayo. If successful, the results will be used in an application for Accelerated Approval from the FDA. This would allow sales as a confirmatory Phase 3 trial is underway.

Phase 3 THIO-104 Confirmatory Trial Is Planned For FY2026. Accelerated Approval requires a Phase 3 confirmatory trial, to be known as THIO-104. This will be a multicenter, open-label trial testing the combination of THIO with a checkpoint inhibitor against a control arm with standard-of-care chemotherapy. Like the Phase 2 trial, it will enroll third-line patients who have progressive disease after at least two courses of chemotherapy, including platinum-based agents, and show resistance to checkpoint inhibitors by SITC criteria. Planned enrollment is for 150 patients in each arm (300 patients total).

Conclusion. The design announcement and start of treatment in the final stages of the Phase 2 THIO-101 trial meets our expected timeframe. In December, MAIA and Regeneron amended their agreement to continue the supply of Libtayo through Phase 2 and Phase 3, maintaining the regimen through the NSLC trials. We reiterate our Outperform rating and $14 price target.

Equity Research

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Refer to the last two pages for Analyst Certification & Disclosures

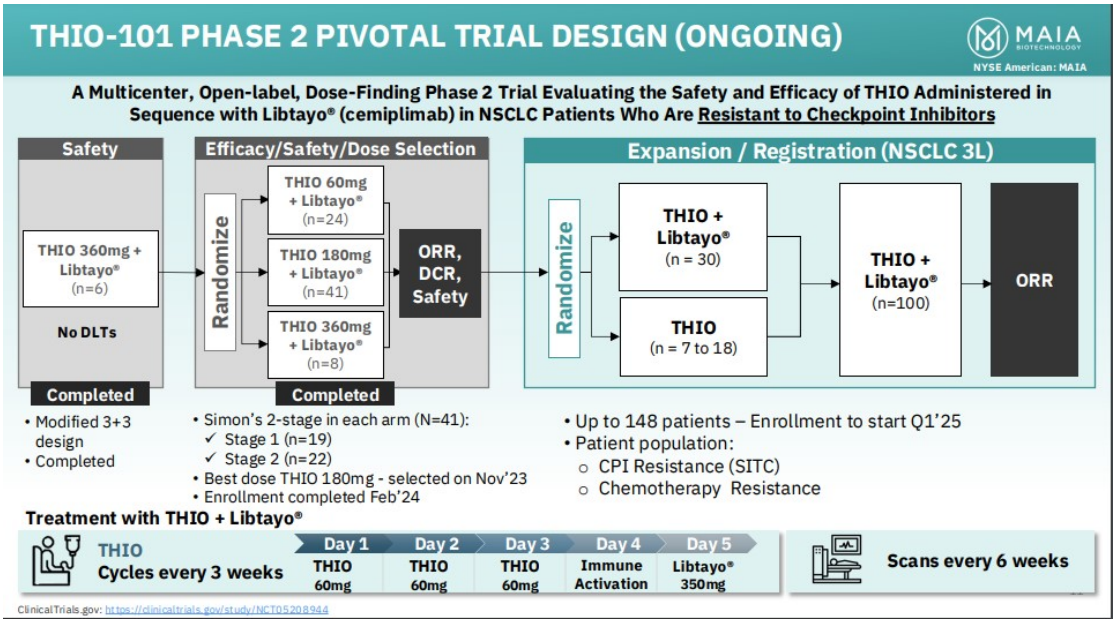
Summary. MAIA announced the design of the third stage of the THIO-101 Phase 2 trial, consisting of Expansion and Registration stages. Both parts will enroll patients with non-small cell lung cancer, receiving the regimen as a third-line therapy. Patient treatment is expected to begin in 1Q25. Following the conclusion of the trial around 4Q25, we expect MAIA to apply for Accelerated Approval from the FDA.

Expansion Stage Is Expected To Begin In 1Q25. The THIO-101 Expansion stage will have two arms to determine the contributions of each drug to patient outcomes. In the first arm, 30 patients will receive the THIO-Libtayo (cemiplimab) combination at the 180mg dose, as administered in earlier the trial. Patients will receive THIO on the first three days, followed by a day of rest to allow for initial killing and for the immune system to respond. Libtayo will be administered on the fifth day.

The second arm will treat a cohort of 7 patients treated with THIO monotherapy to determine efficacy. If the outcomes of the THIO-alone arm are moderate, the treatment arm will be discontinued. If sufficient efficacy is seen, up to 11 more patients will be enrolled for a total maximum enrollment of 48 patients. Patients with inadequate responses will then be switched to the THIO and Libtayo combination. Previous data for THIO monotherapy has shown an 88% disease control rate (DCR), defined as patients with complete responses plus partial responses and stable disease. The primary endpoint in the trial is Overall Response Rate (ORR).

Second Stage Can Support The Application For Accelerated Approval. The Registration stage plans to treat about 100 patients as a single arm with the combination of THIO with Libtayo. If successful, the results will be used in an application for Accelerated Approval from the FDA. This would allow sales in the US as a confirmatory Phase 3 trial is underway.

Exhibit 1: Design of the THIO-101 Trial With The Expansion and Registration Stages.

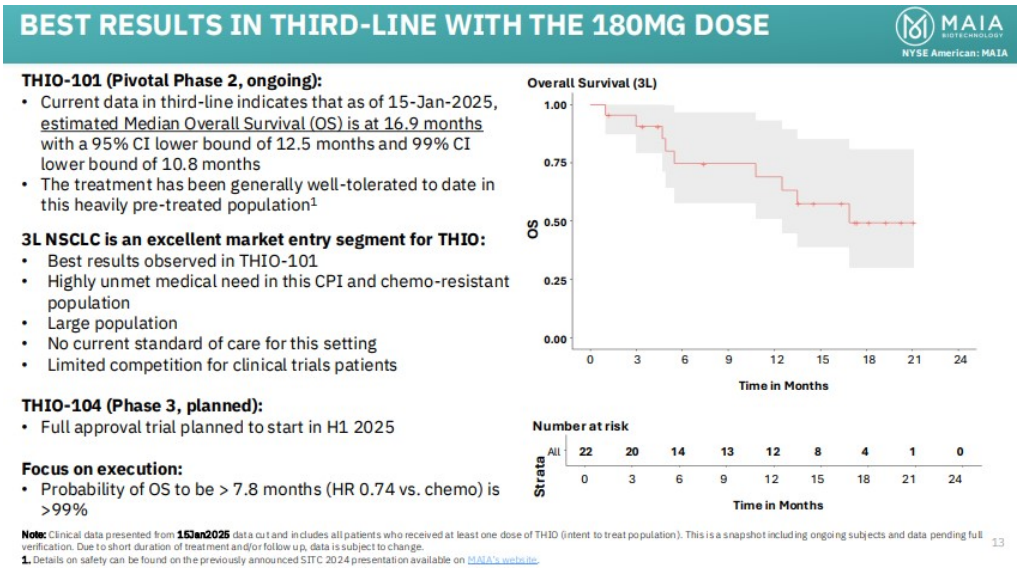


Source: MAIA Biotechnology, Inc.

THIO-101 Interim Data Has Shown Clinically Meaningful Survival. As of January 15, 2025, data indicated that Median Overall Survival (OS) as third line therapy reached 16.9 months. The statistical analysis showed a 95% confidence interval (CI) with its lower bound at 12.5 months and a 99% CI lower bound of 10.8 months. This compares with expected survival of 5.8 months for standard treatments.

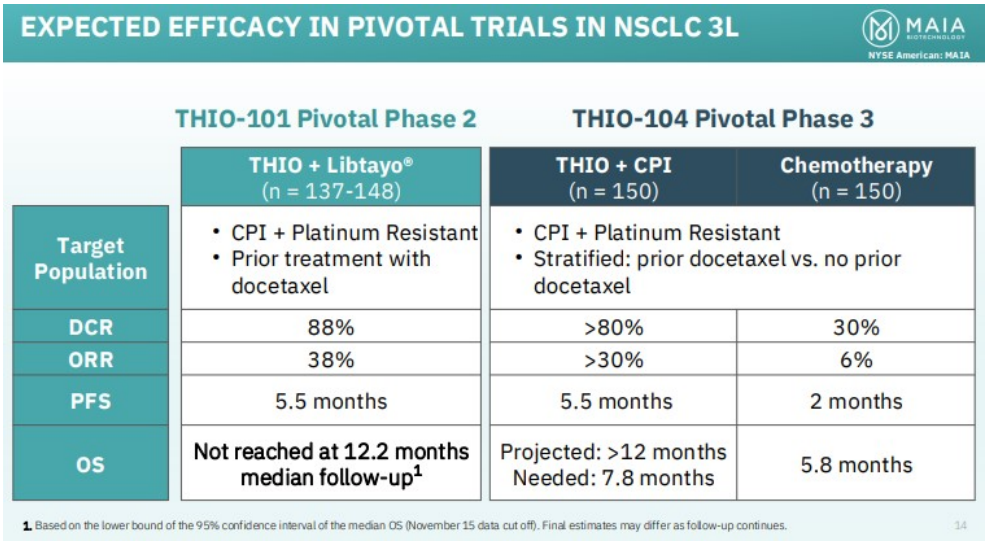
Statistically, the THIO trial needs to show median survival of at least 7.8 months. The previous data has already shown that 99% of the patients will survive at 10.8 months and median survival was 16.9 months. We believe this lowers the risk in the registration stages of the trial.

Exhibit 2. Interim Data From The Phase 2 THIO-101 Trial.



Source: MAIA Biotechnology, Inc.

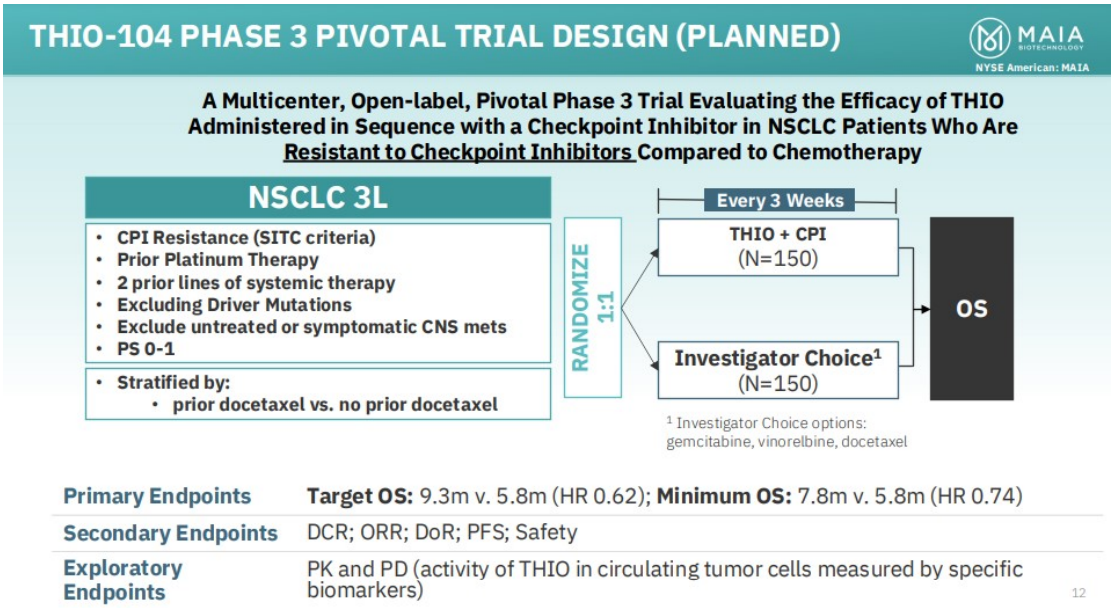
Exhibit 3: Summary Of THIO-101 Data and Projections For Phase 3.



Source: MAIA Biotechnology, Inc.

Phase 3 THIO-104 Confirmatory Trial Is Planned For FY2026. Accelerated approval from the FDA is conditioned on confirmation in a Phase 3 trial, to be known as THIO-104. This will be a multicenter, open-label trial testing the combination of THIO with a checkpoint inhibitor against a control arm with "Investigator's Choice", meaning standard of care chemotherapy. Like the Phase 2 trial, it will enroll third-line patients who have progressive disease after at least two courses of chemotherapy, including platinum-based agents, and have shown resistance to checkpoint inhibitors by SITC criteria. Planned enrollment is for 150 patients in each arm (300 patients total). Clinical sites will be in the US, Europe, and Asia to support worldwide approvals.

Exhibit 4: Design of THIO-104 Confirmatory Trial.



Source: MAIA Biotechnology, Inc.

Supply Agreement Maintains Supply of Libtayo. In December 2024, MAIA and Regeneron modified their collaborative agreement to include Libtayo supplies for the expansion portion of the Phase 2 trial. MAIA will continue to conduct the THIO-101 trial, and Regeneron will provide Libtayo the Expansion and Registration stages.

THIO-102 Is Scheduled To Start In 2H25. A pivotal Phase 2 trial is planned to test THIO in combination with the checkpoint inhibitor tislelizumab (Tevimbra, from BeiGene) in hepatocellular carcinoma (HCC), small cell lung cancer (SCLC) and colorectal cancer (CRC). Additional solid tumors could be added. MAIA has been granted Orphan drug designation (ODD) for HCC and SCLC indications, which may allow smaller patient numbers.

Conclusion. The design announcement and start of treatment in the final stages of the Phase 2 THIO-101 trial meets our expected timeframe. MAIA has secured supplies of checkpoint inhibitors for its trials and has many clinical milestones in 2025. We reiterate our Outperform rating and $14 price target.

Company Profile

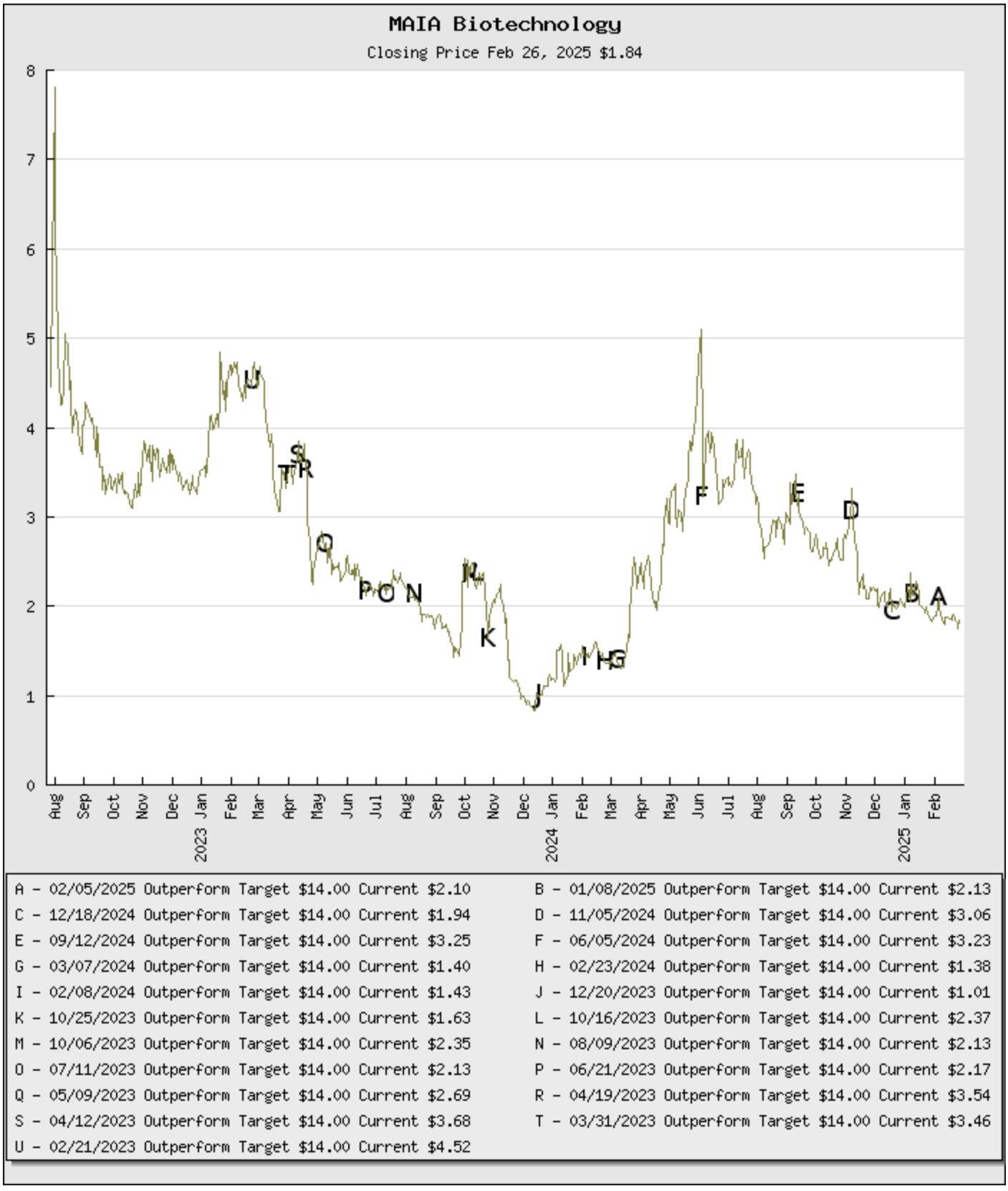
MAIA Biotechnology is a clinical-stage biotechnology company developing telomere-targeting drugs to treat cancer. The lead product, THIO, is a modified nucleoside in a Phase 2 trial for non-small cell lung cancer in combination with Libtayo (cimiplimab, from Regeneron). A second trial in other tumor types is planned for later in 2023.

Fundamental Analysis

In our analysis, we give MAIA Biotechnology a rating of 4.0 checks out of 5 checks. This falls in the upper half of our "above average" range. Our positive fundamental rating is based on the company's position in the oncology and immuno-oncology fields which are expected to continue their growth in sales and market share. Management has extensive experience in research and development, with with a track record of developing successful products in the pharmaceutical industry. For further explanation of our fundamental analysis, please refer to the disclosures at the end of this report.

Valuation Summary

Our Outperform rating and valuation are based on our FY2027 EPS estimate of $2.70, discounted at 30% per year with a multiple of 15X for a price target of $14 per share. This correlates with a market valuation of about $170 million, which we believe is justified for a novel immunotherapy drug serving several large patient populations and several orphan drug indications.



A - 02/05/2025 Outperform Target $14.00 Current $2.10
B - 01/08/2025 Outperform Target $14.00 Current $2.13
C - 12/18/2024 Outperform Target $14.00 Current $1.94
D - 11/05/2024 Outperform Target $14.00 Current $3.06
E - 09/12/2024 Outperform Target $14.00 Current $3.25
F - 06/05/2024 Outperform Target $14.00 Current $3.23
G - 03/07/2024 Outperform Target $14.00 Current $1.40
H - 02/23/2024 Outperform Target $14.00 Current $1.38
I - 02/08/2024 Outperform Target $14.00 Current $1.43
J - 12/20/2023 Outperform Target $14.00 Current $1.01
K - 10/25/2023 Outperform Target $14.00 Current $1.63
L - 10/16/2023 Outperform Target $14.00 Current $2.37
M - 10/06/2023 Outperform Target $14.00 Current $2.35
N - 08/09/2023 Outperform Target $14.00 Current $2.13
O - 07/11/2023 Outperform Target $14.00 Current $2.13
P - 06/21/2023 Outperform Target $14.00 Current $2.17
Q - 05/09/2023 Outperform Target $14.00 Current $2.69
R - 04/19/2023 Outperform Target $14.00 Current $3.54
S - 04/12/2023 Outperform Target $14.00 Current $3.68
T - 03/31/2023 Outperform Target $14.00 Current $3.46
U - 02/21/2023 Outperform Target $14.00 Current $4.52

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Noble intends to seek compensation for investment banking services and non-investment banking services (securities and non-securities related) within the next 3 months.

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The fundamental assessment rating system is designed to provide insights on the company's fundamentals both on a macro level, which incorporates a company's market opportunity and competitive position, and on a micro/company specific level. The micro/company specific attributes include operating & financial leverage, and corporate governance/management. The number of check marks that a company receives is designed to provide a quick reference and easy determination of the company's fundamentals based upon the following five attributes of the company (weighting reflects the importance of each attribute in the overall scoring of company's fundamental analysis):

Attribute	Weighting
Corporate Governance/Management	20%
Market Opportunity Analysis	20%
Competitive Position	20%
Operating Leverage	20%
Financial Leverage	20%

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

Rating	Score	Checks
Superior	9.1 to 10	Five Checks
Superior	8.1 to 9	Four & A Half Checks
Above Average	7.1 to 8	Four Checks
Above Average	6.1 to 7	Three & A Half Checks
Average	5.1 to 6	Three Checks
Average	4 to 5	Two & A Half Checks
Below Average	3 to 3.9	Two Checks
Below Average	2 to 2.9	One & A Half Checks
Low Quality	0 to 1.9	One Check

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or under-served needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

Competitive Position

The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

Operating Leverage

Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

Financial Leverage

A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclicality, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

High rank example: A company with predictable and growing revenue and cash flow with modest debt levels. This may indicate that the company could improve shareholder value through growth investments, including acquisitions, using debt financing.

Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

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Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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Outperform: potential return is >15% above the current price	87%	18%
Market Perform: potential return is -15% to 15% of the current price	13%	6%
Underperform: potential return is >15% below the current price	0%	0%

NOTE: On August 20, 2018, Noble Capital Markets, Inc. changed the terminology of its ratings (as shown above) from "Buy" to "Outperform", from "Hold" to "Market Perform" and from "Sell" to "Underperform." The percentage relationships, as compared to current price (definitions), have remained the same.

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