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Nov 30, -0001

MAIA Biotechnology

Phase 3 THIO-104 Begins, Capping Off A Significant Year

Healthcare

MAIA NYSE

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Rating

Outperform

Unchanged

Current Price

\$1.35
Target Price

\$14.00

Market Capitalization 49.99m

Shares Outstanding 37.03m

Float 25.06m

Institutional Holdings 6.41%

12-Month Low/High \$0.87/\$2.74

Average 90-Day Volume **769800**

Fiscal Year End **12/31/2025**

Phase 3 Trial Has Treated Its First Patient. MAIA has begun its pivotal Phase 3 trial for THIO in NSCLC (non-small cell Lung Cancer), meeting our expected timeframe. In October, the Phase 2 THIO-101 trial began its Part C and will continue as the Phase 3 is running. These trials are the latest in a series of positive announcements for THIO (ateganosine) clinical development, keeping it on schedule for additional milestones in 2026.

Trial Design Can Lead To First Approval. The Phase 3 THIO-104 is an open-label trial is testing ateganosine in combination with an CPI (immune checkpoint inhibitor) as a third-line treatment in patients who are resistant to CPIs and chemotherapy. Patients who have failed two courses of chemotherapy including CPIs will be randomized into two groups to receive either the ateganosine/CPI combination or standard of care chemotherapy. The primary endpoint is Overall Survival (OS).

Trial Parallels The Phase 2 Trial Showing Improved Efficacy. The previous Phase 2 trial, reported earlier in 2025, showed median survival of 17.8 months compared with about 5.8 months for chemotherapy in published studies. Progression-free survival was 5.6 months compared with expected PFS of 2.5 months. MAIA has received Fast Track designation for ateganosine for the treatment of NSCLC, and we believe similar trial results could lead to the first FDA approval.

The Ateganosine Regimen Has A Two Mechanisms Of Action. We attribute ateganosine's higher level of efficacy to its mechanisms of action, starting with its targeting of the chromosomal teleomeres. This action causes cell death, starting an immune response in the cancer cell. When patients receive the PD-1 checkpoint inhibitor cemiplimab, it allows the immune cells to recognize and kill additional cancer cells.

Conclusion. The start of Phase 3 is an important milestone toward FDA approval. If the study replicates the recent data from the Phase 2 trial, ateganosine could become significant new therapy for third-line NSCLC. We believe this would also provide significant proof-of-concept to support earlier use. We are reiterating our Outperform rating and \$14 price target.

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Refer to the last two pages for Analyst Certification & Disclosures

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	

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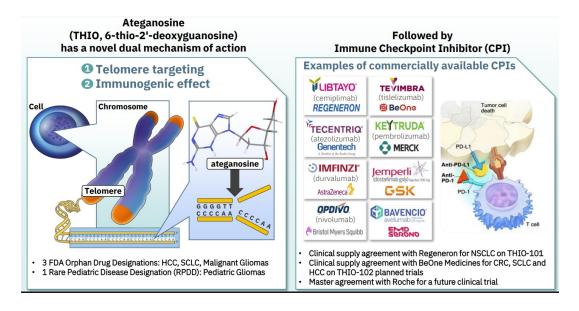
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Summary. As the year draws to a close, MAIA has announced the start of patient treatment in the Phase 3 trial testing at leganosine (THIO) in NSCLC (non-small cell lung cancer). Patients are eligible for enrollment after failing at least two courses of therapy with standard of care (SoC) chemotherapy including an immune checkpoint inhibitor (CPI, either anti-PD-1 or anti PD-L1). The patients enrolled have advanced NSCLC and have either stopped responding or developed resistance after treatment with a PD-1 inhibitor.

The design is similar to the Phase 2 trial, which began its Part C in October. This part of the trial tests the ateganosine/CPI combination against ateganosine monotherapy. Recent Phase 2 trial data presented at scientific meetings has continued to show large improvements in Overall Survival (OS) and Progression Free Survival (PFS) compared with published studies. This data was updated previous presentations with an analysis date of September 17, 2025. Additional updates are expected in 2026.

Ateganosine Has A Dual Mechanism of Action. Ateganosine is a nucleotide analogue that targets the chromosome's telomere, structures at the tips of the DNA chain needed for reproduction. As the cell replicates its DNA, ateganosine is taken up by the teleomeres, causing DNA errors and leading to death of the cancer cell. As the contents of the dead cell are released, both innate (cGAS/STING) and adaptive (T-cell) immune responses are activated, attracting immune cells into the tumor. Next, treatment with the PD-1 checkpoint inhibitor cemiplimab allows the immune cells to recognize the cancer cell and kill it.

Exhibit 1. Ateganosine Has Two Mechanisms of Action. Upon administration, ateganosine is taken up by cancer cells with active telomerase. It targets the telomers of a chromosome, causing breaks and killing the cell. This results in an immune response within the tumor. Next, an immune checkpoint inhibitor allows the immune cells to recognize the cancer cells and kill them.



Source: MAIA Biotechnology, Inc.

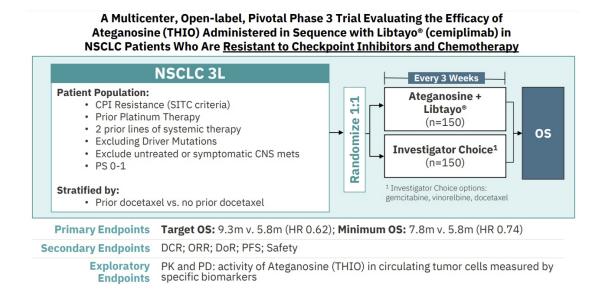
The Phase 3 Trial Has Begun Treating Patients. In December 2025, MAIA announced that it began treating patients in the Phase 3 THIO-104 confirmatory trial. The planed enrollment is for about 300 patients who have received at least two previous courses of treatment and have become refractory or resistant to SoC chemotherapy and checkpoint inhibitors.

The patients will be randomized 1:1 into two groups. The first will receive the ateganosine followed by a standard course of cemiplimab (Libtayo, an anti-PD-1 from Regeneron). The second group will receive the standard of care chemotherapy (Investigator's Choice of regimens). The study design follows the Phase 2 trial, where significant improvements in Overall Survival and Progression Free Survival were seen with the combination of ateganosine and cemiplimab.

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Exhibit 2. Design Of The Phase 3 Trial. The Phase 3 trial will be an open-label trial testing ateganosine with cemiplimab against a standard of care chemotherapy regimen (Investigator's Choice). Target enrollment is for 150 patients in each arm, or about 300 patients total.



Source: MAIA Biotechnology, Inc.

The Phase 2 THIO-101 Trial Has Begun Part C. THIO-101 is an open-label, dose-finding study in patients with advanced NSCLC that have not responded or have relapsed after first-line treatment with a PD-1 or PDL-1 checkpoint inhibitor. Patients in Parts A and B have received ateganosine followed by a standard regimen of cemiplimab. This combines the initial killing effect from ateganosine and the immune response that results with PD-1 inhibition by cemiplimab.

MAIA announced that Part C of the Phase 2 THIO-101 trial started treatment in October 2025. Like the Phase 3, it is enrolling patients for third-line treatment for advanced or metastatic non-small cell lung cancer (NSCLC) that are resistant to chemotherapy and checkpoint inhibitors. Part C of the trial has two treatment arms, with a Simon two-stage design testing ateganosine with cemiplimab against ateganosine alone. This contrasts with the Phase 3 that tests the combination against standard of care chemotherapy.

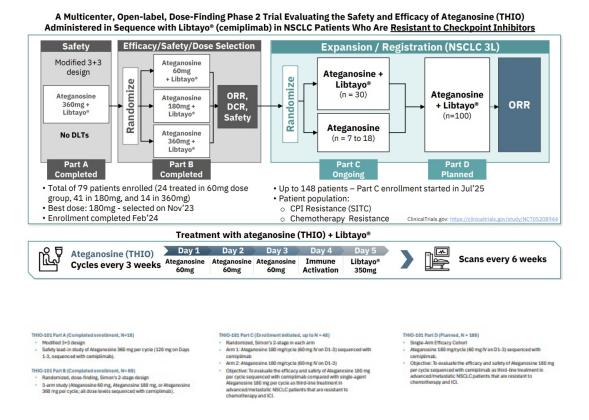
The objective is to obtain data on safety and efficacy of the combination compared with ateganosine alone. Part C has a target enrollment of up to 48 patients who will receive receive either 60mg of on days one through three (180mg total), or both ateganosine and regular regimens of cemiplimab.

Patient enrollment for Parts A and B were completed with 79 patients in February 2024, with the optimal 180mg dose selected in November 2023. Part D is planned as a single-arm study with about 100 patients to determine efficacy and safety of the 180mg dose in combination with cemiplimab as third-line treatment. The primary endpoint is ORR.

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Exhibit 3. Schematic Diagram Of The Phase 2 THIO-101 Study. The trial compares the combination of ateganosine and cemiplimab against ateganosine alone.



Source: MAIA Biotechnology, Inc.

Interim Data Showed Improved Survival and PFS. Data updates were presented at the ESMO (European Society for Medical Oncology) conference in October and the SITC (Society for the Immunotherapy of Cancer) conference in November. These presentations continued to show strong data from the Phase 2 trial and the trial design for Phase 3.

- Overall Survival. As of the September 17, 2025 cutoff date for analysis, median overall survival (OS) was 17.8 months, compared with expected survival of 5.8 months. The 95% confidence interval (CI) has lower bound of 12.5 months and a 99% CI lower bound of 10.8 months, consistent with the prior data readout in May 2025. This can be interpreted to mean that 99% of the patients will survive longer than expected after treatment with THIO.
- **Progression Free Survival.** The progression free survival (PFS) in THIO-101 was 5.6 months, more than double the standard of care PFS of 2.5 months. One patient that began therapy in March 2023 has shown survival of 30 months, or 912 days.

We Believe Ateganosine Could Become An Important New Drug. We see these results show a substantial improvement over current therapies with standard-of -care drugs with checkpoint inhibitors. MAIA has received Fast Track designation for ateganosine for the treatment of NSCLC, which could allow for accelerated approval.

Conclusion. The start of Phase 3 is a milestone that is important progress toward FDA approval. If the study replicates the recent data from the Phase 2 trial, ateganosine could become significant new therapy for 3rd-line NSCLC. We believe this would also provide significant proof-of-concept to support earlier use as a first-line or second-line regimen. We are reiterating our Outperform rating and \$14 price target.

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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 Phase 3 trial began treating patients in December 2025.

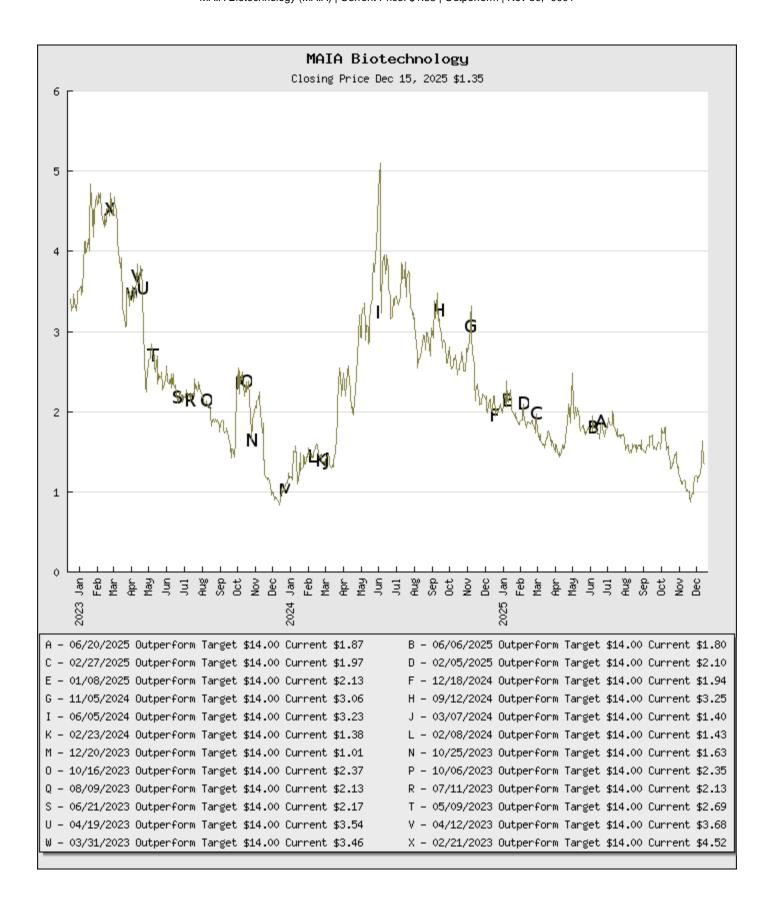
Fundamental Analysis

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.

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FUNDAMENTAL ASSESSMENT

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 underserved 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.

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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.

ANALYST CREDENTIALS, PROFESSIONAL DESIGNATIONS, AND EXPERIENCE

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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NOBLE RATINGS DEFINITIONS	% OF SECURITIES COVERED	% IB CLIENTS
Outperform: potential return is >15% above the current price	85%	15%
Market Perform: potential return is -15% to 15% of the current price	15%	5%
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.

Additional information is available upon request. The recipient of this report who wishes further information regarding the subject company or the disclosure information mentioned herein, should contact by mail or phone.

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