

GeoVax Labs

Jan 21, 2025

Gedepin To Begin Phase 2 Clinical Trial

Healthcare

GOVX

NCM

Rating

Outperform

Unchanged

Current Price

\$2.22

Target Price

\$12.00

Market Capitalization

20.95m

Shares Outstanding

9.44m

Float

4500000

Institutional Holdings

4.76%

12-Month Low/High

\$1.09/\$11.18

Average 90-Day Volume

1860000

Fiscal Year End

2025-12-31

Revenues (\$ MIL)

Period	2023A	2024E	2025E
Q1	0.0	0.0A	3.2E
Q2	0.0	0.3A	3.4E
Q3	0.0	2.8A	3.4E
Q4	0.0	3.1E	3.7E
	0.0	6.2E	13.7E

EPS (\$)

Period	2023A	2024E	2025E
Q1	(2.30)	(2.47)A	(0.43)E
Q2	(3.37)	(1.99)A	(0.50)E
Q3	(4.75)	(0.91)A	(0.61)E
Q4	(4.29)	(1.00)A	(0.68)E
	(14.29)	(5.23)A	(2.22)E

GeoVax Starts The Year By Announcing Phase 2 Trial For Gedepin. GeoVax has announced that a Phase 2 trial for Gedepin, its gene therapy for delivering cytotoxic cancer drugs, is planned to start in 1H25. As we expected, the trial will test Gedepin with a checkpoint inhibitor in patients with recurrent squamous cell carcinoma of the head and neck (SCCHN).

Gedepin Delivers A Gene To Activate The Cancer Drug In The Tumor. Gedepin is based on the Gene-Directed Enzyme Prodrug Therapy (GDEPT) technology platform. It uses an adenovirus vector to deliver the E. coli PNP gene to cancer cells. Once inside the cells, the gene produces an enzyme that converts an inactive prodrug (fludarabine) into an active cytotoxic drug. This increases the drug's potency inside the cancer cells while avoiding healthy tissue. Gedepin has completed Phase 1/2 trials in advanced head and neck cancer and has been granted Orphan Drug Designation for oral and pharyngeal cancers.

Trial Will Test Gedepin In Combination With A Checkpoint Inhibitor. The Phase 2 trial will test Gedepin in combination with an immune checkpoint inhibitor (ICI), the current standard of care in SCCHN. Gedepin leads to an initial round of tumor cell killing, stimulating an immune response in the tumor microenvironment that increases the population of killer T-cells. The ICI allows the immune cells to recognize the tumor cells as cancerous and carry out further killing steps. This combination provides two mechanisms to kill the tumor cells.

GeoVax Has Many Milestones Ahead For 2025. Over the past 12 months, CM-04S1 has made strong progress in all three Phase 2 indications. The vaccine stimulates both humoral and cellular immunity, providing robust and durable protection against the COVID-19 virus. A significant development was its selection for a BARDA-sponsored Phase 2b trial testing efficacy in comparison to an approved COVID-19 vaccine. GeoVax has started recognizing revenues for work done in preparation for the trial, expected to begin in 2H25.

Conclusion. Advancing Gedepin to the Phase 2 trial is good news that is consistent with our expected timeframe. We believe CM-04S1 can produce better protection than the mRNA vaccines, and look forward to additional clinical data, including Phase 2 booster study in healthy adults, expected in 1H25. We are reiterating our Outperform rating and \$12 price target.

Equity Research

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**Refer to the last two pages for
Analyst Certification & Disclosures**

Company Profile

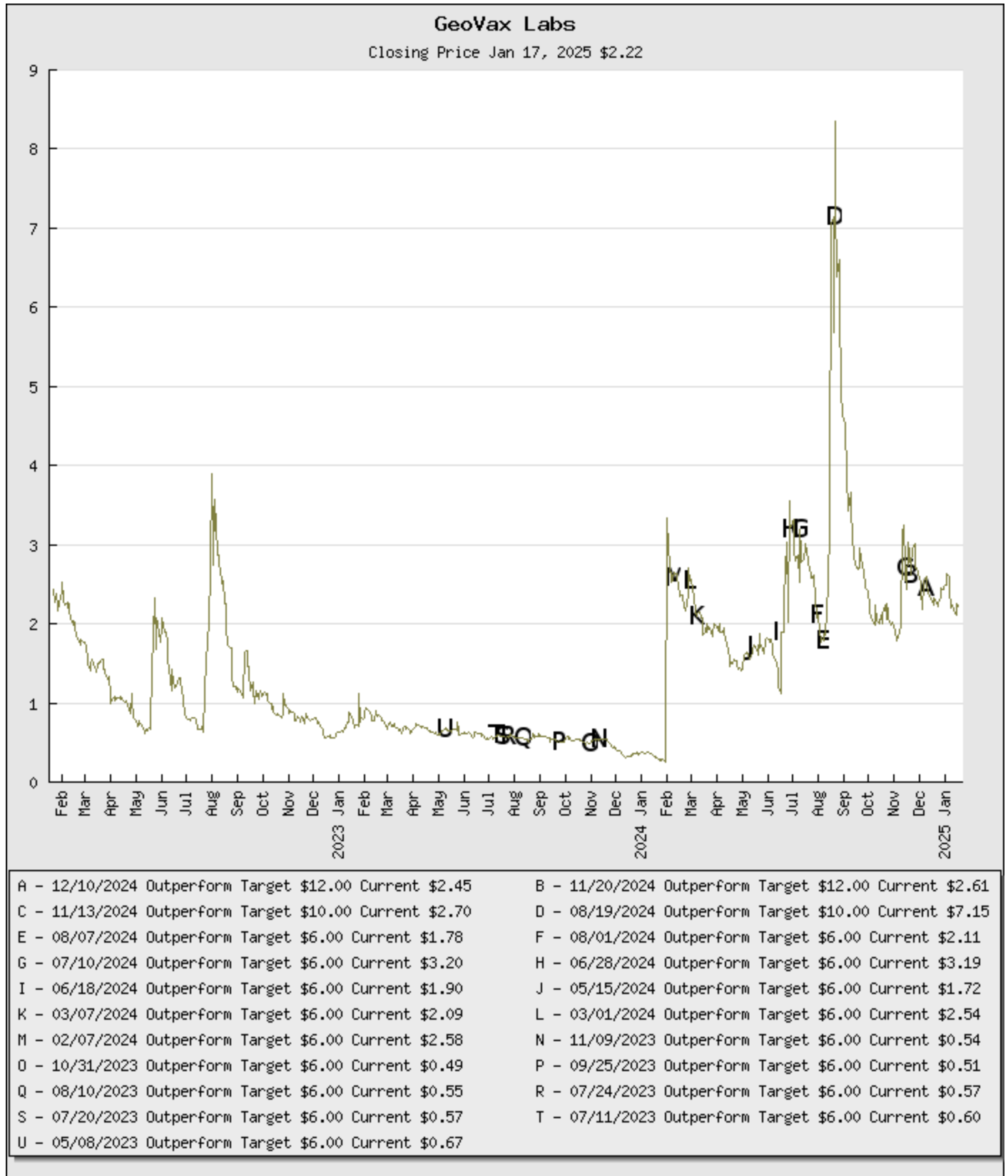
GeoVax Labs is developing gene therapies, immunotherapies, and vaccines for cancer and infectious diseases. Gedeptin, its lead cancer product, is a gene-directed therapy for cancer. The treatment delivers a gene to the cancer cells that converts an inactive prodrug into an active cytotoxic drug within the tumor cells. GeoVax's second technology platform is in vaccines against infectious diseases. CM04S1 is a next-generation COVID-19 vaccine.

Fundamental Analysis

In our assessment, we give GOVX a score of 4.0 out of 5.0, which falls within the upper half of the "Above Average" range of 3.0 to 4.0 and warrants 4.0 checks. Our positive fundamental rating is based on the company's introduction of its gene therapy technology in development and the COVID-19 vaccine. We view the quality of management and the Board of Directors as above average due to extensive industry experience. For further explanation of our fundamental analysis, refer to the disclosures at the end of this report.

Valuation Summary

We value GEOX based on our estimated revenues from Gedeptin in the head and neck cancer indication. Our price target is based on our estimated EPS of \$1.45 per share in FY2026, the first year of sales after product launch. We discount this estimate at 30% per year to allow for company risk, industry risk, and market risk. Our price target is \$10 per share. Risk factors include regulatory obstacles, technology risk, clinical trial risk, and financial risks.



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Noble is not a market maker in the Company.

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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 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.

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 cyclicalities, 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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NOBLE RATINGS DEFINITIONS	% OF SECURITIES COVERED	% IB CLIENTS
Outperform: potential return is >15% above the current price	86%	18%
Market Perform: potential return is -15% to 15% of the current price	14%	5%
Underperform: potential return is >15% below the current price	0%	0%

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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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