

June 16, 2025

Company Description

GeoVax Labs, Inc. is a clinical-stage biotechnology company developing next-generation vaccines and immunotherapies for serious infectious diseases and solid tumor cancers. Its lead infectious disease vaccine candidate, GEO-CM04S1, is a multi-antigen COVID-19 vaccine designed to provide broader, longer-lasting protection—especially for immunocompromised individuals. Currently in three Phase 2 trials, GEO-CM04S1 is being studied in healthy adults, Chronic Lymphocytic Leukemia (CLL) patients, and those undergoing stem cell transplant or CAR-T therapy. Although the BARDA-funded Phase 2b trial under Project NextGen ended due to external shifts, GeoVax continues to advance the program, driven by strong interim data and unmet global need. In oncology, GeoVax is advancing Gedeptin®, a gene-directed therapy for solid tumors, into a planned Phase 2 trial for recurrent head and neck cancer, alongside preclinical studies in other tumor types. GEO-MVA, the Company's Mpox and smallpox vaccine candidate, is expected to enter clinical trials soon, addressing global biosecurity risks and vaccine access gaps. Backed by global rights, a robust intellectual property (IP) portfolio, and scalable manufacturing capabilities, GeoVax is supported by an experienced management team with proven success in product development and commercialization.

Key Points

- On June 16, 2025, GeoVax announced that the European Medicines Agency (EMA) has endorsed GeoVax's plan to bypass Phase 1 and 2 trials, allowing the Company's GEO-MVA Mpox/smallpox vaccine to proceed directly to a single Phase 3 immuno-bridging trial using non-inferiority endpoints.
- A successful Phase 3 trial could support a centralized Marketing Authorization Application (MAA) in Europe, while also unlocking access to global health procurement channels including WHO, UNICEF, and GAVI.
- EMA guidance enhances prospects for U.S. and other national Strategic National Stockpile (SNS) inclusions, as well as providing an expansion of overall global MVA-vaccine supply for endemic outbreaks. GEO-MVA is aligned with BARDA's Rapid Response Partnership Vehicle (RRPV) and national goals around domestic vaccine manufacturing and pandemic preparedness.
- GEO-MVA is working to transition from legacy egg-based production to the AGE1 continuous cell line platform—offering faster, lower-cost, and scalable bioreactor-based manufacturing in the U.S. and internationally.
- The WHO has recently issued a fourth declaration of Mpox as a Public Health Emergency of International Concern (PHEIC), and GEO-MVA would provide a critical alternative to the sole current supplier, Bavarian Nordic, which has faced production and supply limitations.
- GEO-MVA targets a \$465M+ preparedness market with global potential of \$10B+ across stockpile and endemic use. GeoVax is the only U.S.-based developer of an MVA-based vaccine for Mpox/smallpox.
- GeoVax holds a portfolio of 135+ granted or pending patents. The Company is further leveraging AI to support trial design, manufacturing, and regulatory planning across its broader pipeline.
- As of March 31, 2025, the Company reported \$7.4 million in cash and expects to initiate clinical trials of GEO-MVA later in 2025.



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GOVX (NASDAQ) One-Year Chart



Ticker (Exchange)	GOVX (NASDAQ)
Recent Price (06/13/2025)	\$1.03
52-week Range	\$0.73-11.18
Shares Outstanding	15.9 mm
Market Capitalization	\$16.4 mm
Avg. Volume	210,900
EPS (Yr ended 03/31/2025)	(\$0.45)
Employees	19

GeoVax Advances GEO-MVA with EMA Support, Targeting Global Vaccine Markets

GeoVax Labs, Inc. has taken a significant step forward in advancing its GEO-MVA vaccine candidate following favorable regulatory feedback from the European Medicines Agency (EMA). On June 16, 2025, the Company announced it received positive Scientific Advice from EMA confirming that a single Phase 3 immuno-bridging trial would be sufficient to support a Marketing Authorization Application (MAA) for GEO-MVA in the EU. Importantly, the guidance allows GeoVax to bypass the typical Phase 1 and Phase 2 trials, accelerating the timeline to potential approval and reducing associated costs and risks.

The proposed Phase 3 trial would compare GEO-MVA to the already approved Imvanex (known as JYNNEOS® in the U.S.) and assess immunogenicity through non-inferiority endpoints. The EMA's Committee for Medicinal Products for Human Use (CHMP) validated the adequacy of GeoVax's preclinical immuno-bridging and toxicity studies, assuming no unexpected findings arise. This alignment with EU regulators not only streamlines GEO-MVA's development in Europe but also lays the groundwork for broader global regulatory engagement, including potential WHO prequalification. This designation would open access to global health purchasing entities such as UNICEF, GAVI, and CEPI—critical distribution channels for epidemic and pandemic preparedness.

This regulatory development comes amid renewed urgency surrounding Mpox outbreaks worldwide. In June 2025, the World Health Organization (WHO) issued its fourth Public Health Emergency of International Concern (PHEIC) declaration for Mpox, highlighting the spread of Clade 1 and 2 variants across 25 African countries, with detections also in Europe, Asia, and the United States. The market currently relies on a single commercial supplier—Bavarian Nordic—which has struggled to meet global demand. GEO-MVA's progress could position GeoVax as the second viable supplier of an MVA-based Mpox and smallpox vaccine, offering strategic diversification to a strained global supply chain.

GeoVax's manufacturing strategy may further differentiate it from competitors. While initial GEO-MVA production uses the traditional Chicken Embryo Fibroblast (CEF) platform, the Company plans to shift to its next-generation AGE1 cell line. This continuous, stirred-tank bioreactor approach is expected to lower production costs, enable faster scale-up, and eliminate the need for embryonated chicken eggs, which is an increasingly outdated method. This modern platform is already supported under the U.S. government's Rapid Response Partnership Vehicle (RRPV) through BARDA and aligns with the White House's EQUIP-A-Pharma and pharma onshoring initiatives.

GeoVax's infrastructure plan envisions not just U.S.-based manufacturing but also partnerships with regional CDMOs to expand capacity globally, including in Europe and low- and middle-income countries. Key collaborators include Oxford Biomedica and EverGlade, providing regulatory and project management support.

The potential market opportunity for GEO-MVA is significant. Bavarian Nordic generated over \$465 million in orthopoxvirus vaccine revenue in 2024, primarily through public health preparedness contracts in the U.S., EU, and Africa. For example, BARDA awarded \$156.8 million for JYNNEOS replenishment, while the EU's rescEU program committed €65 million. GEO-MVA's dual indication for Mpox and smallpox aligns well with stockpile deployment scenarios involving both bioterror threats and emerging infectious disease outbreaks.

GeoVax is currently the only U.S.-based company advancing an MVA-based Mpox/smallpox vaccine. The Company believes its platform is not only differentiated but better suited to scale during crises. With regulatory alignment in Europe, a roadmap toward global procurement access, and domestic production capabilities supported by BARDA, GeoVax is well-positioned to play a meaningful role in orthopoxvirus preparedness. For investors, this represents a potentially de-risked regulatory development in a constrained and highly visible public health market. With a \$10+ billion addressable market across global stockpile and endemic use cases, GEO-MVA offers asymmetric upside should it successfully navigate its Phase 3 trial and secure key contracts.

GeoVax's recent momentum adds to its broader pipeline, which includes programs in COVID-19 (GEO-CM04S1) and immuno-oncology (Gedepin®), as greater detailed in our most recently published update (May 8, 2025), and is backed by a growing IP portfolio with over 135 granted or pending patents. While execution risk remains, particularly around funding and trial timing, the EMA decision significantly advances GEO-MVA's credibility as a near-term product candidate with global relevance.

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