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GeoVax Labs Inc. (GOVX) – Buy Rated

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Completes Enrollment of P2 for COVID-19 Booster

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GeoVax Labs announced that it has met the enrollment target for its Phase 2 clinical trial evaluating GEO-CM04S1 as a booster for healthy patients who have previously received the Pfizer or Moderna mRNA vaccine. The study is designed to evaluate the safety profile and immunogenicity of two GEO-CM04S1 dose levels administered as a COVID-19 vaccine booster among healthy individuals previously vaccinated with one of the FDA approved SARS-CoV-2 mRNA vaccines. The immunological responses measured throughout the study will include both the level of neutralizing antibodies against SARS-CoV-2 variants of concern and specific T cell responses.

New Clinical Trial Initiated for GEO-CM04S1. In July, GeoVax announced the start of a Phase 2 COVID-19 vaccine booster investigator-initiated clinical trial (ClinicalTrials.gov Identifier: NCT05672355) in patients with chronic lymphocytic leukemia (CLL), a recognized high-risk group for whom current mRNA vaccines and monoclonal antibody (MAb) therapies appear inadequate relative to providing protective immunity. As a result of their medical status, CLL patients are largely unable to mount a sufficient antibody response to the mRNA vaccines. The trial is expected to enroll approximately 80 patients, comparing GEO-CM04S1 vs the Pfizer/BioNTech Bivalent vaccine. Completion of patient enrollment is expected within approximately six months. This investigator-initiated trial is being primarily funded by a private family foundation with GeoVax supporting the analysis of samples, so it is expected to have minimal impact on the Company's balance sheet.

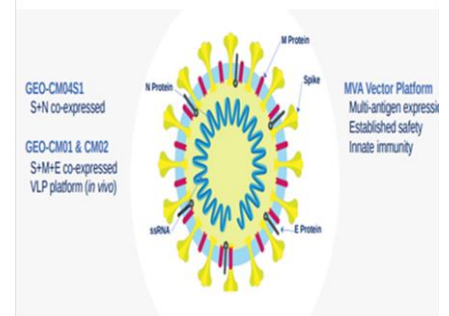
Gedepin Clinical Trial Data. Interim data from the Phase 1/2 clinical trial of Gedepin was presented at the American Association for Cancer Research (AACR) and the American Head and Neck Society (AHNS) joint Head and Neck Cancer Conference in July. The ongoing Phase 1/2 trial (ClinicalTrials.gov Identifier: NCT03754933) is evaluating the safety and efficacy of repeat cycles of Gedepin therapy in patients with recurrent head and neck cancers whose tumor(s) are accessible for injection, and who have no curable treatment options.

What is it? GEO-CM02 – A Covid vaccine for immunocompromised patients. The company is applying its novel Modified Virus Ankara - Virus-Like Particle (GV-MVA-VLPTM) platform to create an effective Covid vaccine for immunocompromised patients where the current vaccines fall short. This vaccine has been shown to induce a balanced antibody and cellular (T-cells) response against the multiple encoded immunogens, potentially limiting immune escape by emerging variants. Expression of the SARS-CoV-2 spike (S), membrane (M), and envelope (E) proteins by MVA supports the in vivo formation of virus-like particles (VLPs), which induce both antibody and T-cell responses.

Valuation: Our valuation is based on Gadeptin and Covid Vaccines (only). We project our model out to 2033. We apply a 30% success probability to our projected revenues in our product model in addition to our 30% risk rate applied in our Free Cash Flow to the Firm (FCFF), discounted EPS (dEPS), and Sum-of-the-Parts (SOP) models. We use a fully diluted out-year share count, assuming multiple raises. The result is equal-weighted, averaged, and rounded to the nearest whole number to derive our 12-month projected price target of \$4.0.

Risks to our thesis include: 1. Regulatory Approvals; 2. Capital Requirements 3. Adoption Rates 4. Intellectual Capital 5. Dilution.

Current Price	\$0.56
Price Target	\$4.00



Source: GeoVax Labs Inc.

Stock Data			
52-Week Range	\$0.51	-	\$1.63
Shares Outstanding (mil.)	26.4		
Market Capitalization (mil.)	\$15		
Enterprise Value (mil.)	-\$3		
Debt to Capital	0%		
Book Value/Share	-		
Price/Book	0.6		
Average Three Months Trading Volume (K)	1,255		
Insider Ownership	1.4%		
Institutional Ownership	6.1%		
Short Interest (mil.)	2.6%		
Dividend / Yield	\$0.00/0.0%		



Our valuation for GeoVax is based on Gadeptin and the Covid vaccine programs only. We do this for conservatism with the understanding that proof of concept in either of the programs has broader implications for the market opportunity for the products and expansion of the platform. We provide our “simplified” product models and assumptions as follows:

Gadeptin

1. We assume a treatable patient population of 22,000.
2. We assume orphan-like drug pricing at \$125,000 per complete therapeutic course.
3. We apply just a 30% probability of success given the early nature of the program.

Covid – Immune Compromised Patients

1. We assume 10% of the total population is treatable for a multitude of reasons for a Covid vaccine that is effective in immune-compromised patients. Our thinking considers patients undergoing cancer treatment, organ transplants, and patients taking therapies such as those for psoriasis, arthritis, and other related therapies that put these groups at risk.
2. We assume a modest cost of therapy of just \$50.00.
3. We apply just a 30% probability of success given the early nature of the program.

Exhibit 1. Gadeptin Model

Head & Neck Cancers	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Disease Prevalance	66,470	67,135	67,806	68,484	69,169	69,861	70,559	71,265	71,977	72,697	73,424
3rd line	21,935	22,154	22,376	22,600	22,826	23,054	23,285	23,517	23,753	23,990	24,230
Market Share				10%	12%	14%	18%	22%	26%	33%	35%
Cost of Therapy				\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000	\$ 125,000
Revenue (\$) - M				282	342	403	524	647	772	990	1,060
Probability of Success				30%	30%	30%	30%	30%	30%	30%	30%
Risk Adjusted U.S. Revenue (\$M)				\$ 85	\$ 103	\$ 121	\$ 157	\$ 194	\$ 232	\$ 297	\$ 318

Exhibit 2. Gadeptin Model

Covid - Immune Compromised Patients	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E
Population	325,000,000	325,000,000	325,000,000	325,000,000	325,000,000	325,000,000	325,000,000	325,000,000	325,000,000	325,000,000	325,000,000
Immune Compromised				10%	11%	12%	13%	14%	15%	15%	15%
Cost of Therapy	\$50	\$50	\$50	\$50	\$50	\$50	\$50	\$50	\$50	\$50	\$50
Market Share	10%	10%	10%	10%	20%	30%	40%	50%	51%	52%	53%
Revenue (\$) - M				\$ 163	\$ 358	\$ 585	\$ 845	\$ 1,138	\$ 1,243	\$ 1,268	\$ 1,292
Probability of Success				30%	30%	30%	30%	30%	30%	30%	30%
Risk Adjusted U.S. Revenue (\$M)				\$ 49	\$ 107	\$ 176	\$ 254	\$ 341	\$ 373	\$ 380	\$ 388

Risks to our thesis include 1. Regulatory Approvals; 2. Capital Requirements 3. Adoption Rates 4. Intellectual Capital 5. Dilution.

- **Regulatory Approvals.** The company’s products require regulatory approvals, and there can be no assurances that the requirements to achieve these approvals can be met.
- **Capital Requirements:** The business requires continued funding; there can be no assurances that the company will be able to raise the needed capital to continue operations.
- **Adoption Rates:** There are no assurances that the projected market share can be met. A combination of factors from pricing and reimbursement to competitive performance are expected to be key factors in driving users to administer these drugs.
- **The Competitive Landscape & IP.** The company does have intellectual property and knows how to preserve its competitive position. However, the company may face competition from well-financed competitors who are already in position in the target markets.
- **Dilution:** The company is likely to incur losses for the foreseeable future until it is able to generate sufficient revenue from product sales. Our model assumes a rising share count. There can be no assurances that the company can successfully raise the capital required to execute its business strategy.

Exhibit 3. Income Statement

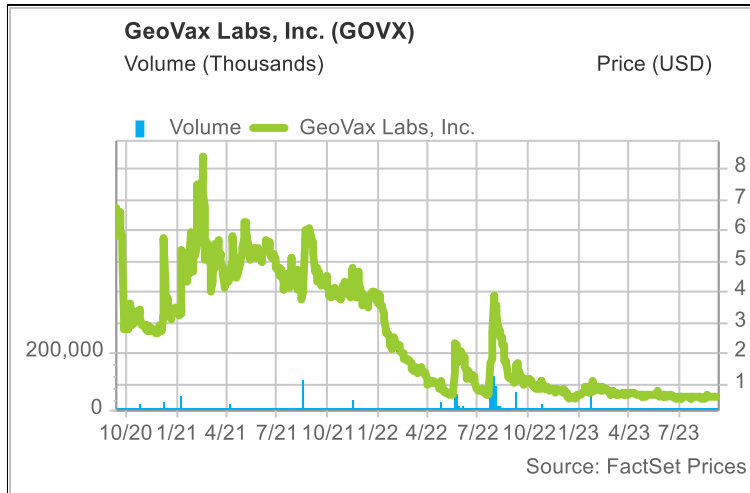
GeoVax: Income Statement '000																					
000 - YE December 31	2022A	1Q23A	2Q23A	3Q23E	4Q23E	2023E	1Q24E	2Q24E	3Q24E	4Q24E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	2033E	
Risk Adjusted Product sales Projections																					
Gadepitin													84,749	102,716	121,034	157,171	194,019	231,588	296,877	318,019	
COVID Immuno-compromised													48,750	107,250	175,500	253,500	341,250	372,938	380,250	387,563	
Grant Revenue	82																				
Total Product Sales	82	-	-	-	-	-	-	-	-	-	-	-	133,499	209,966	296,534	410,671	535,269	604,525	677,127	705,581	
Expenses																					
COGS													26,700	41,993	59,307	82,134	107,054	120,905	135,425	141,116	
COGS %		0%	0%	0%	0%		0%	0%	0%	0%			20%	20%	20%	20%	20%	20%	20%	20%	
Research and Development	9,123	2,819	4,720	2,737	672	10,948	3,153	3,284	3,284	3,416	13,138	15,765	18,918	22,702	22,929	25,222	30,266	36,320	43,584	52,300	
General and Administrative	4,987	1,451	1,459	1,259	867	5,036	1,221	1,272	1,272	1,323	5,087	10,000	22,000	30,000	30,300	30,603	30,909	31,218	31,530	31,846	
Total Operating Expenses	14,110	4,271	6,179	3,996	1,539	15,985	4,374	4,556	4,556	4,738	18,225	25,765	67,618	94,695	112,536	137,959	168,229	188,443	210,540	225,262	
Loss from Operations	(14,029)	(4,271)	(6,179)	(3,996)	(1,539)	(15,985)	(4,374)	(4,556)	(4,556)	(4,738)	(18,225)	(25,765)	65,881	115,271	183,998	272,712	367,039	416,082	466,588	480,319	
Other (income) Expenses																					
Interest Income	7	233	251	-	-	484	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Interest Expense																					
Total other (income) expense	7	233	251	-	-	484	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Net Loss	(14,021)	(4,038)	(5,928)	(3,996)	(1,539)	(15,501)	(4,374)	(4,556)	(4,556)	(4,738)	(18,225)	(25,765)	65,881	115,271	183,998	272,712	367,039	416,082	466,588	480,319	
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	6.588	23.054	55.199	95.449	139.475	158.111	177.303	182.521	
GAAP Net Income (loss)	(14,021)	(4,038)	(5,928)	(3,996)	(1,539)	(15,501)	(4,374)	(4,556)	(4,556)	(4,738)	(18,225)	(25,765)	59,293	92,216	128,798	177,262	227,564	257,971	289,285	297,798	
GAAP-EPS	(0.83)	(0.15)	(0.22)	(0.11)	(0.04)	(0.53)	(0.12)	(0.10)	(0.10)	(0.10)	(0.42)	(0.55)	1.26	1.95	2.72	3.73	4.77	5.38	6.01	6.16	
GAAP EPS (dil)	(0.83)	(0.15)	(0.22)	(0.09)	(0.03)	(0.43)	(0.09)	(0.08)	(0.08)	(0.08)	(0.34)	(0.45)	1.04	1.61	2.24	3.07	3.92	4.43	4.95	5.07	
Wgtd Avg Shrs (Bas) '000	16,973	26,339	26,444	36,470	36,507	31,440	36,543	46,580	46,626	46,673	44,105	46,790	46,977	47,165	47,354	47,544	47,734	47,926	48,118	48,310	
Wgtd Avg Shrs (Dil) '000	16,973	26,339	26,444	46,470	46,517	36,442	46,563	56,610	56,666	56,723	54,140	56,865	57,093	57,321	57,551	57,782	58,013	58,245	58,479	58,713	

Source: Dawson James estimates, company reports

Companies mentioned in this report:

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

- Initiated – Buy – March 3, 2023 – Price Target \$4.0
- Update Report – Buy – March 24, 2023 – Price Target \$4.0
- Update Report – Buy – April 6, 2023 – Price Target \$4.0
- Update Report – Buy – April 11, 2023 – Price Target \$4.0
- Update Report – Buy – April 19, 2023 – Price Target \$4.0
- Update Report – Buy – May 5, 2023 – Price Target \$4.0
- Update Report – Buy – May 25, 2023 – Price Target \$4.0
- Update Report – Buy – July 11, 2023 – Price Target \$4.0
- Update Report – Buy – July 21, 2023 – Price Target \$4.0
- Update Report – Buy – July 24, 2023 – Price Target \$4.0
- Update Report – Buy – August 10, 2023 – Price Target \$4.0
- Update Report – Buy – August 29, 2023 – Price Target \$4.0
- Update Report – Buy – September 12, 2023 – Price Target \$4.0

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- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months.
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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Current as of 22-Aug-23

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	23	65.70%	3	8.60%
Market Perform (Neutral)	12	34.30%	3	8.60%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	6	17.20%

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