Zacks Small-Cap Research

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GeoVax Labs Inc. (GOVX-OTC)

GOVX: New Ebola vaccine program added, on track to advance its HIV vaccine programs--Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/15/2013
Current Price (10/03/14)	$0.32
Twelve- Month Target Price	**$1.50**

OUTLOOK

GOVX is a unique developer for both preventive and therapeutic HIV vaccines. The Company's preventive HIV vaccine is one of the most advanced in development. Both HIV/AIDS vaccine and treatment markets are huge and GOVX has the potential to be a key player in the two markets. The addition of Ebola vaccine program further expands its pipeline.

Management will continue to create shareholder value by generating new clinical data, bringing in government support and partnership.

We believe valuation is attractive with the potential for substantial returns.

SUMMARY DATA

52-Week High	**$0.89**
52-Week Low	**$0.20**
One-Year Return (%)	**-16.05**
Beta	**1.60**
Average Daily Volume (sh)	**117,445**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**36.8**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**10.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0.80 A	0.44 A	1.00 A	0.18 A	2.42 A
2014	0.16 A	0.18 A	0.18 E	0.18 E	0.70 E
2015					1.50 E
2016					1.50 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.03 A	-$0.02 A	-$0.01 A	-$0.04 A	-$0.11 A
2014	-$0.02 A	-$0.03 A	-$0.03 E	-$0.03 E	-$0.12 E
2015					-$0.09 E
2016					-$0.11 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

GeoVax Expands Pipeline by Initiating Ebola Vaccine Development Program

On October 2, 2014, GeoVax (GOVX) announced that it had initiated a new program for the development of **Ebola vaccine** to prevent Ebola infection.

This initiative follows recent **Ebola epidemic** in Africa and an Ebola case in the US. Currently there is no proven therapy available for Ebola virus. A safe and effective vaccine against Ebola is desperately needed.

According to the Company's news release, GeoVax is developing two Ebola vaccines, **GOVX-E301** and **GOVX-E302**. Both are recombinant MVA (modified vaccinia Ankara) vaccines designed to produce non-infectious virus-like particles (VLPs) displaying the Ebola virus glycoprotein. GOVX-E301 is being developed as a single-dose vaccine for epidemic response against the ZEBOV strain of Ebola, the virus responsible for the current outbreak. GOVX-E302 is being developed for routine immunization and is designed to protect against all three versions of Ebola known to be lethal in humans. GOVX-E302 is anticipated to be used in a two-dose regimen.

The development of the new Ebola vaccine program is based on the Company's unique recombinant **MVA platform**. GeoVax is using the platform to develop both preventive and therapeutic HIV vaccines. So far, GeoVax's recombinant MVA vaccines have been successfully evaluated in clinical trials against HIV, in which they have shown excellent **safety** and **immunogenicity**. GeoVax's rMVA technology also raises highly **durable** vaccine responses, by far the most durable in the field of HIV vaccines. One more advantage of rMVA technology is that GeoVax's rMVA vector is based on an attenuated smallpox virus. Following smallpox eradication in 1980, smallpox vaccinations were stopped, leaving all but the elderly unvaccinated and without **pre-existing immunity**.

Based on these findings from HIV clinical trials, we think the MVA platform is also suited to develop the Ebola vaccine. MVA-vectored Ebola vaccines have the unique attributes required for success and may offer superior results over other Ebola vaccines in development.

According to management, GeoVax is fast tracking this program with the objective of having an 'epidemic-ready' GOVX-E301 vaccine available **by 2016**.

GeoVax's Ebola vaccine development efforts will be facilitated by the Company's close proximity to, and collaboration with, the U.S. Centers for Disease Control (CDC) in Atlanta and its experts and Biosafety Level 4 (BSL-4) facilities for testing vaccine responses against lethal hemorrhagic viruses.

We think GeoVax's Ebola vaccine program is a natural extension of its MVA vaccine delivery platform. It is a complementary asset to its HIV vaccine programs and further **expands** the Company's pipeline.

We Raise Our Price Target to $1.50

We maintain our Outperform rating on GeoVax and raise our 12-month price target to $1.50 per share due to the addition of the new Ebola vaccine program to its pipeline.

GeoVax has developed the technology for the development of both **preventive** and **therapeutic** HIV/AIDS vaccines. The Company's preventive vaccine is one of the most advanced under development, which has completed Phase IIa and will enter into Phase IIb clinical trials soon.

The Company's preventive HIV vaccine is the only HIV vaccines for America/Europe entering efficacy trial.

GeoVax plans to initiate a second **Phase I/II** trial with its 2nd generation therapeutic vaccine in 2014. GeoVax should be entering into a **Phase IIb** trial with its preventive vaccine (GOVX B11) in 2015. As other HIV vaccines have fallen by the wayside over the past several years, GeoVax continues to move forward with its unique approach to HIV prevention and treatment through effective vaccination.

The addition of the new **Ebola vaccine** program further expands the Company's pipeline.

The Company has a modest cash burn rate ($4 to $5 million annually) due to generous government support. Down the road, we believe GeoVax will continue to seek non-dilutive government and non-government support for its HIV vaccine development. If the planned Phase IIb trial for preventive HIV vaccine proves to be positive, we believe it would be likely for the Company to find a partner from big pharma or biotech companies who seek to boost or enter into the anti-HIV/AIDS market.

Based on the current fundamentals of the Company, we believe current valuation is very attractive. With a decent pipeline and mid-stage candidates, GeoVax is only valued at about $8.0 million in market cap. This is a deep discount in our view. We understand that HIV/AIDS vaccines are tough to develop and that this is a high risk area for any biotech company especially for smaller ones with limited resources. However, we think GeoVax has done great job so far in the HIV/AIDS vaccine area. With the addition of Ebola vaccine program, the Company is well positioned to continue to create shareholder value down the road.

We see GeoVax as a risk reward opportunity with significant long term positive returns. Our price target of $1.50 represents a market cap of $38 million.

Second Quarter Financials Reported with a Conservative Cash Burn

On August 7, 2014, GeoVax Labs announced its financial results for the second quarter ended June 30, 2014 and provided a clinical development update.

Grant revenues were $180,441 for 2Q14, which was related to grants from the **NIH** in support of its HIV/AIDS vaccine development programs. For 2Q13, GeoVax reported grant revenue of $441,561.

As of June 30, 2014, there is approximately $484,500 in unused grant funds remaining and available for use.

R&D expenses were $516,202 for 2Q14, as compared to $553,199 for the comparable periods of 2013. R&D expenses included direct costs funded by NIH grants, as well as vaccine manufacturing and testing costs and expenses related to the Company's HIV immunotherapy program.

G&A expenses were $344,862 for 2Q14, compared to $415,784 for 2Q13.

Net loss was $679,537 ($0.03 per share) for 2Q14, compared to $526,284 ($0.02 per share) for the same period in 2013.

As of June 30, 2014, GeoVax held a cash balance of $1,371,802, as compared to $2,010,326 at March 31, 2014.

On July 16, 2014, GeoVax received a Notice of Award from the NIH for a Small Business Innovative Research (SBIR) grant. This grant award is approximately $290,000, which is for the second year of a two-year project period.

This grant will support the continued preclinical studies evaluating the ability of protein boosts to augment antibody responses that can block virus infections and cause antibody dependent cellular cytotoxicity (ADCC antibody).

Current cash balance, together with our projected cash inflow, can last through the 1Q2015.

Therapeutic HIV Vaccine Update

GeoVax recently completed the first **Phase I** trial (**GV-TH-01**) investigating the ability of the Company's **unadjuvanted DNA/MVA vaccine GOVX-B11** vaccine to control HIV infections in HIV-infected patients.

GV-TH-01 is an open label Phase I treatment interruption trial investigating the safety and immunogenicity of the Company's DNA/MVA vaccine in **9 HIV-infected patients** who had initiated drug treatment within 18 months of seroconversion and had stably controlled virus for at least 6 months. Patients were vaccinated with two DNA inoculations followed by two MVA inoculations at intervals of two months. Eight weeks following the last inoculation, patients suspended drug therapy for a 12 week period. Vaccinated patients' ability to control the time and temporal height of re-emergent virus in the absence of drugs was then observed. Drug treatment was re-instituted after 12 weeks, and trial participants were observed for an additional 6 months.

The **primary endpoint** of this study is to evaluate the safety of GOVX-B11 in HIV-positive patients with well-controlled infections who are being treated with oral HIV medications. A **secondary objective** is to evaluate the immunogenicity of the GOVX-B11 vaccine during the vaccination phase of the trial. An **exploratory objective** of the study is to evaluate the ability of the vaccinated patient to control re-emergent virus during a 12-week drug treatment interruption period.
Excellent safety was observed throughout the trial, with none of the 9 participants needing to reinstate antiretroviral drugs during the treatment interruption phase of the trial.

GeoVax's analysis of the trial data indicates that, during the vaccination phase of the trial, evidence of the beneficial effect of vaccine was measured by enhanced CD8+ T cells elicited in **8 of 9 participants** and enhanced CD4+ T cells in **5 of 9 participants**. Antibody responses were boosted in **4 of 9** participants. Analyses during the treatment interruption phase suggested that individuals with the best immune responses to the vaccine had lower levels of re-emergent virus.

The Company plans to publish the full study results for GV-TH-01 in a scientific journal in late 2014.

Although the GV-TH-01 results were not suggestive of a significant clinical benefit of GOVX-B11 alone, the immune response data from the trial have given GeoVax a foundation for proceeding with the development of **an immunotherapy program** as part of the NIH's "cure agenda."

GeoVax is currently developing a protocol for a **Phase I/II** clinical trial using a **proprietary agent** to induce latently infected cells to produce virus ("shock") while the infected patient remains on ART. Successful re-activation of viral reservoirs is the first step towards a "shock and kill" approach to reducing viral reservoirs.

The positive data from the Phase I trial of GOVX-B11 is another achievement for GeoVax. We are very pleased with the safety of the vaccine and its ability to enhance immune responses in infected and drug-treated patients. The opportunity for GOVX-B11/proprietary agent lies in its ability to **complement drug therapies**, which can control virus spread but not recognize and kill infected cells, with a vaccine response capable of recognizing and eradicating infected cells.

Preventive HIV Vaccine Update

GeoVax has recently completed a **Phase I** trial (HVTN 094) of the adjuvanted DNA/MVA vaccine **(GOVX-B21)** and a **Phase IIa** trial (HVTN 205) of **GOVX-B11.** All of the human clinical trials of GeoVax's preventive HIV vaccines have been conducted by the HIV Vaccine Trials Network (HVTN) with funding from the NIH.

Based on analysis of all available data generated to date, GeoVax is advancing **GOVX-B11** to the next stage of human clinical testing, and is in planning discussions with the HVTN and NIH for a **Phase IIb** efficacy trial.

The Phase IIb trial is expected to involve as many as 4,000 subjects (vaccine + placebo) with an estimated cost in excess of $50 million. While GeoVax expects the NIH to fund this trial, any formal commitment may not occur until **2015**. In advance of this commitment, GeoVax has requested approximately $3 million for the production of the DNA component of its vaccine regimen in sufficient quantities for the proposed Phase IIb trial. The Company expects a response from the NIH to this request during the third quarter of 2014. Should this funding be unavailable, GeoVax will seek other sources for funding vaccine production.

Two Major Risks

Risk must be taken into account when investors add positions.

One major risk is **development/regulatory risk**. We remind investors that GeoVax's HIV/AIDS vaccines are still in mid-stage development and the Company still needs to navigate through the regulatory process in the US and around the world, which proves to be long and tough. When it comes to HIV/AIDS vaccine, investors should be aware that this has been a tough area to tackle considering the failed developments already.

Cash burn is still a concern. Although most of GeoVax's clinical trials have been supported by the government grants, there is no guarantee that the Company will continue to get enough support to continue late stage clinical studies. In such a case, the Company needs alternative financing measures, which include equity or debt financing. Current cash can only last through the 1Q15. We remind investors that equity financing will dilute existing shareholder base.

PROJECTED INCOME STATEMENT

	2013A (Dec)					2014E (Dec)					2015E (Dec)	2016E (Dec)	2017E (Dec)	2018E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Grant revenue	$0.80	$0.44	$1.00	$0.18	$2.42	$0.16	$0.18	$0.18	$0.18	$0.70	$1.50	$1.50	$2.50	$2.50
Product Revenue	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$20.00
Total Revenues	**$0.80**	**$0.44**	**$1.00**	**$0.18**	**$2.42**	**$0.16**	**$0.18**	**$0.18**	**$0.18**	**$0.70**	**$1.50**	**$1.50**	**$2.50**	**$22.50**
YOY Growth	-6.9%	-37.7%	57.0%	-62.0%	-9.0%	-80.3%	-59.2%	-82.1%	2.7%	-71.2%	115.2%	0.0%	66.7%	800.0%
CoGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Income	**$0.80**	**$0.44**	**$1.00**	**$0.18**	**$2.42**	**$0.16**	**$0.18**	**$0.18**	**$0.18**	**$0.70**	**$1.50**	**$1.50**	**$2.50**	**$22.50**
Gross Margin	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
R&D	$0.88	$0.55	$0.88	$0.60	$2.92	$0.40	$0.52	$0.65	$0.70	$2.27	$2.75	$3.50	$5.50	$8.00
% R&D	110.7%	125.3%	87.5%	342.8%	120.6%	256.7%	286.7%	361.1%	388.9%	325.5%	183.3%	233.3%	220.0%	35.6%
SG&A	$0.61	$0.42	$0.32	$0.45	$1.79	$0.37	$0.35	$0.45	$0.50	$1.67	$2.00	$2.50	$5.50	$8.50
%SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Operating Income	**($0.7)**	**($0.5)**	**($0.2)**	**($0.9)**	**($2.3)**	**($0.6)**	**($0.7)**	**($0.9)**	**($1.0)**	**($3.2)**	**($3.3)**	**($4.5)**	**($8.5)**	**$6.0**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-340.00%	26.67%
Other Net	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($0.7)**	**($0.5)**	**($0.2)**	**($0.9)**	**($2.3)**	**($0.6)**	**($0.7)**	**($0.9)**	**($1.0)**	**($3.2)**	**($3.3)**	**($4.5)**	**($8.5)**	**$6.0**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.5
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($0.7)**	**($0.5)**	**($0.2)**	**($0.9)**	**($2.3)**	**($0.6)**	**($0.7)**	**($0.9)**	**($1.0)**	**($3.2)**	**($3.3)**	**($4.5)**	**($8.5)**	**$5.5**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-164.7%
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-340.0%	24.4%
Diluted Shares Out	20.2	21.1	21.7	21.9	21.2	24.8	25.0	30.0	31.0	27.7	35.0	40.0	45.0	50.0
Reported EPS	**($0.03)**	**($0.02)**	**($0.01)**	**($0.04)**	**($0.11)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.12)**	**($0.09)**	**($0.11)**	**($0.19)**	**$0.11**
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($0.7)**	**($0.5)**	**($0.2)**	**($0.9)**	**($2.3)**	**($0.6)**	**($0.7)**	**($0.9)**	**($1.0)**	**($3.2)**	**($3.3)**	**($4.5)**	**($8.5)**	**$5.5**
Non GAAP EPS	**($0.03)**	**($0.02)**	**($0.01)**	**($0.04)**	**($0.11)**	**($0.02)**	**($0.03)**	**($0.03)**	**($0.03)**	**($0.12)**	**($0.09)**	**($0.11)**	**($0.19)**	**$0.11**

Source: Company filings and Zacks Research estimates

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