Zacks Small-Cap Research

May 7, 2014
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GeoVax Labs Inc. (GOVX-OTC)

GOVX: Positive data reported for GOVX-B11 Phase I trial, 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 (05/06/14)	$0.28
Twelve- Month Target Price	**$1.00**

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. 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	**$0.27**
One-Year Return (%)	**-48.15**
Beta	**1.71**
Average Daily Volume (sh)	**33,547**
Shares Outstanding (mil)	**25**
Market Capitalization ($mil)	**$7**
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	0.22 E	0.22 E	0.22 E	0.82 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 E	-$0.03 E	-$0.03 E	-$0.11 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 Reports First Quarter Financials with Cash on Budget

GeoVax reported grant revenues of $157,340 for the 1Q14. The revenue is related to its grants from the National Institutes of Health (NIH) in support of its HIV/AIDS vaccine development efforts. This compares to $797,040 of grant revenue reported for 1Q13. As of March 31, 2014, there is approximately $665,000 of unused grant funds available for use during 2014.

R&D expenses were $402,860 for 1Q14, compared with $881,988 for 1Q13. R&D expenses include direct costs funded by the NIH grants, as well as vaccine manufacturing costs and expenses related to the Phase I clinical trial of the Company's therapeutic HIV vaccine. Costs associated with the clinical trials of GeoVax's preventive HIV vaccine, being conducted by the HIV Vaccine Trials Network (HVTN), are being funded directly by the NIH and are therefore not reflected in GeoVax's financial statements.

General and administrative (G&A) expenses for 1Q14 were $371,802, compared with $612,943 for 1Q13.

Net loss for 1Q14 was $614,918, or $0.02 per share, based on 24.8 million weighted average shares outstanding. For the three months ended March 31, 2013, net loss was $696,797, or $0.03 per share, based on 20.2 million weighted average shares outstanding.

At March 31, 2014, GeoVax had cash balances of $2,010,326. There was no debt on its balance sheet as of March 31, 2014. Current cash balance, together with our projected cash inflow, can last through the 1Q2015.

Therapeutic HIV Vaccine Update

On Jan 13, 2014, GeoVax announced preliminary top-line results from **GV-TH-01**, a **Phase I** clinical trial investigating the ability of the Company's **unadjuvanted DNA/MVA vaccine GOVX-B11** vaccine to control HIV infections in patients who initiated antiretroviral drug treatment within 18 months of seroconversion.

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.

Preliminary data have demonstrated that during the vaccination phase of the trial, enhanced CD8+ T cells were elicited in 8 of 9 patients and enhanced CD4+ T cell and antibody responses 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 have lower levels of re-

emergent virus. These results and other positive observations from this study have given the Company rationale to proceed with its **therapeutic vaccine** clinical development program.

GeoVax expects to formally publish study results for GV-TH-01 in a scientific journal in late-2014.

Based on the results from GV-TH-01, GeoVax is formulating plans for a **follow-on Phase I** clinical trial investigating the treatment of HIV-positive individuals with its GM-CSF adjuvanted DNA/MVA vaccine **(GOVX-B21) in combination with standard-of-care** antiretroviral drug therapy. This proposed trial would involve more patients than the GV-TH-01 trial and, unlike GV-TH-01, would include a placebo control arm. The study design is also expected to more closely resemble the likely commercial therapeutic use of an HIV vaccine. The primary and secondary objectives of the study will be to evaluate the safety and immunogenicity of GOVX-B21. An exploratory objective will be to investigate the vaccine's effect on reducing HIV viral reservoirs as an indicator of the potential for an eventual cure.

Initiation of this trial is subject to financing availability, and GeoVax intends to seek NIH as well as private support.

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/GOVX-B21 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 completed a **Phase I** trial (HVTN 094) of the adjuvanted DNA/MVA vaccine **(GOVX-B21)** being conducted by the HIV Trials Network (HVTN) with funding from the National Institutes of Health (NIH), and a **Phase IIa** trial (HVTN 205) of **GOVX-B11.**

Comparison of data between HVTN 094 and HVTN 205 **has not** shown a significant benefit for adding the adjuvant to the vaccine for preventive use. Following an extensive review of preclinical and clinical data, GeoVax has decided to advance **GOVX-B11** to the next stage of clinical testing.

GeoVax is now in planning discussions with the HVTN and NIH for a **Phase II** efficacy trial of GOVX-B11, and several scenarios are being considered. In GeoVax's recent public statements, the possible addition of **a protein boost** to GOVX-B11 was discussed; but recent conversations with the HVTN leads the Company to believe that this may not be required for a Phase II trial to proceed. Specific details of the Phase II efficacy trial will be clearer after further data analysis and input from the HVTN and NIH in mid-2014. GeoVax believes that GOVX-B11 is ready for a **Phase IIb** placebo-controlled efficacy trial.

GeoVax expects the trial to begin during **2015** subject to the NIH funding.

Valuation and Recommendation

We maintain our Outperform rating on GeoVax. Our 12-month price target is $1.00.

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** 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 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 attractive. With a decent pipeline and mid-stage candidates, GeoVax is only valued at about $7.5 million in market cap. This is a discount in our view. We understand that HIV/AIDS vaccines have been 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 and 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 $1.00 represents a market cap of $25 million.

But Keep in Mind the 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	$0.22	$0.22	$0.22	$0.82	$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**	**$0.22**	**$0.22**	**$0.22**	**$0.82**	**$1.50**	**$1.50**	**$2.50**	**$22.50**
YOY Growth	-6.9%	-37.7%	57.0%	-62.0%	-9.0%	-80.3%	-50.2%	-78.1%	25.6%	-66.2%	83.6%	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**	**$0.22**	**$0.22**	**$0.22**	**$0.82**	**$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	$0.50	$0.65	$0.70	$2.25	$2.75	$3.50	$5.50	$8.00
% R&D	110.7%	125.3%	87.5%	342.8%	120.6%	256.7%	227.3%	295.5%	318.2%	275.8%	183.3%	233.3%	220.0%	35.6%
SG&A	$0.61	$0.42	$0.32	$0.45	$1.79	$0.37	$0.40	$0.45	$0.50	$1.72	$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)**	**($0.11)**	**($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)**	**($0.11)**	**($0.09)**	**($0.11)**	**($0.19)**	**$0.11**

Source: Company filings and Zacks Research estimates

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