Zacks Small-Cap Research

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Grant Zeng, CFA
312-265-9466
gzeng@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

GeoVax Labs Inc. (GOVX-OTC)

GOVX: On track to advance Ebola & HIV Programs---Buy

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/15/2013
Current Price (11/11/15)	$0.12
Twelve- Month Target Price	**$0.50**

UPDATE

GeoVax continues to move forward with its Ebola and HIV programs.

We expect for the HVTN114 trial to start enrolling patients by the end of the year. Additionally, GeoVax recently signed an agreement with the NIAID for development of Ebola and Marburg vaccines. The company also has been awarded a grant in support of its Clade C HIV vaccine program.

We continue to be bullish on the company's shares based on the stage of development and upside potential to the emerging story.

SUMMARY DATA

52-Week High	**$0.27**
52-Week Low	**$0.12**
One-Year Return (%)	**-53.07**
Beta	**0.68**
Average Daily Volume (sh)	**12,332**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$4**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**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)
2014	0.16 A	0.18 A	0.32 A	0.22 A	0.88 A
2015	0.10 A	0.07 A	0.09 A	0.10 E	0.37 E
2016					0.50 E
2017					1.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014	-$0.02 A	-$0.03 A	-$0.02 A	-$0.03 A	-$0.10 A
2015	-$0.02 A	-$0.02 A	-$0.02 A	-$0.02 E	-$0.08 E
2016					-$0.06 E
2017					-$0.06 E

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WHAT'S NEW

Update on Third Quarter Financials Ended September 30, 2015

Total revenue for 3Q15 was $93,130, primarily derived from grants from the NIH in support of the company's HIV/AIDS vaccine development programs. This compares to $322,086 grant revenue reported for the comparable periods of 2014. According to the company, as of September 30, 2015, there is $260,522 in approved grant funds remaining and available for use.

R&D expenses for 3Q15 were $378,521, as compared to $425,498 for the comparable periods of 2014.

G&A expenses for 3Q15 were $335,932, as compared to $411,814 for the comparable periods of 2014.

Net loss for 3Q15 was $619,899 ($0.02 per share), compared to $514,515 ($0.02 per share) for the same period in 2014.

As of September 30, 2015, cash balance was $1,821,037, as compared to $1,101,651 at December 31, 2014.

In February, 2015, GeoVax announced an equity financing providing up to $6 million in new capital to the company. Under terms of the transaction, the company sold $3.0 million in Series C convertible preferred stock. The Series C preferred stock is convertible at any time into 16.667 million shares of common stock at $0.18 per share. Investors also received 16.667 million warrants to purchase GeoVax common stock at any time over the next five years for $0.22 per share. GeoVax also granted the investors a one-year overallotment option to purchase up to an additional $3.0 million in common stock plus warrants under the aforementioned terms.

Also in early July, GeoVax received a Notice of Award from the U.S. National Institutes of Health for a Small Business Innovative Research (SBIR) grant in support of its **clade C** HIV vaccine development program for Africa. The grant award of $299,585 is for the first year of a two-year project period beginning July 1, 2015.

Current cash balance, combined with estimated cash inflow, will last into the middle of 2016 according to our financial model.

Update on Ebola/Marburg Vaccine Programs

In April, 2015, GeoVax entered into a Research Collaboration Agreement with the NIAID for development of GeoVax's vaccines against Ebola and Marburg viruses. The terms of the agreement call for NIAID to contribute materials, reagents, and scientific advice for vaccine development. GeoVax is responsible for preparing MVA Ebola and Marburg for animal studies, with NIAID then conducting those studies in guinea pigs, hamsters, and non-human primates.

GeoVax already initiated the Ebola and Marburg vaccine programs, and we are encouraged that the company will be working closely with the NIAID to advance those programs quickly through development and preclinical testing.

GeoVax Ebola Vaccine Proven Effective in Rodent Models

In early September, GeoVax announced positive **animal data** from its Ebola vaccine candidate, **GOVX-E301**, in rodent models. GOVX-E301 provided 100 percent protection in guinea pigs and Syrian golden hamsters, two rodent models for Ebolavirus infections. The GOVX-E301 vaccine uses a recombinant modified vaccinia Ankara (MVA) vector to express non-infectious virus-like particles (VLPs) using genetic sequences from the 2014 Ebolavirus outbreak in West Africa.

Per management, the next steps will be vaccination and challenge studies in **nonhuman primates** while also preparing for cGMP manufacturing of the vaccine for human clinical trials. The company is ready for **human clinical trials** during **1H17**.

However, we are unsure of the details in regards to the size or cost of that trial at this time, which will largely depend on the results obtained with first-generation vaccines currently being tested along with whether GeoVax is able to find a development partner and whether any type of government funding would be available.

Update on HIV Preventive Vaccine Programs

HVTN 114 Trial for GOVX-B11

In early April, 2015, the HVTN has approved a concept protocol and assigned a trial number, HVTN 114, to the next clinical trial of **GOVX-B11**.

The purpose of the HVTN 114 trial is to test whether the addition of **"protein boosts**" will increase the antibody responses elicited by GOVX-B11 in participants from the HVTN 205 **Phase 2a** clinical trial. Protein boosts may augment antibody responses that can block virus infections (neutralizing antibody) and cause ADCC. Proteins added to HIV vaccines have shown some success in other trials, particularly in the RV144 vaccine trial conducted in Thailand. The HVTN is testing whether this "dual-action" approach will be a prudent and cost-effective path forward for supporting large clinical trials.

As a reminder, the HVTN 205 Phase 2a clinical trial was designed to evaluate the safety and immunogenicity of GOVX-B11 in healthy, HIV-uninfected adults. The study included 299 participants that were randomly assigned to three study arms: 149 participants received two injections of the DNA vaccine followed by two injections of the MVA vaccine (DDMM arm), 75 participants received three MVA injections and one placebo injection (MMPM arm), and 75 participants received four injections of placebo. Results from the trial showed robust antibody responses to HIV Env that endured for at least six months after vaccination.

The HVTN 114 study will include up to 100 individuals who participated in the HVTN 205 Phase 2a trial of GOVX-B11, which concluded in 2012. The vaccine boosts will consist of MVA62B with or without a gp120 protein vaccine. The gp120 protein, AIDSVAX® B/E, will be supplied by Global Solutions for Infectious Diseases (GSID) and is the same protein used to boost immune responses in the partially successful RV144 vaccine trial in Thailand. Participants in the trial will receive either A) MVA62B alone; B) MVA62B with AIDSVAX® B/E; or C) the AIDSVAX® B/E alone. Since HVTN 205 included two different vaccine regimens, HVTN 114 will allow for five separate study groups (up to 20 in each group), and participants will be assigned to each group depending upon their initial vaccine regimen from HVTN 205.

The study's primary objectives are to A) determine the safety of administration of MVA62B and AIDSVAX® B/E given together or separately in patients who had previously been vaccinated in HVTN 205 and B) determine the HIV-specific antibody response to MVA62B and AIDSVAX® B/E given together or separately. Secondary objectives of the study include detailed analysis of the antibody/cellular immune responses and to compare the durability of this response at six months after the boosts.
We estimate that the trial will begin enrolling patients in late 2015.

The Accelerated Preventive HIV Vaccine Program

GeoVax also plans to pursue a **dual pathway** for advancing GOVX-B11 into **pivotal human efficacy trials**. The rationale for moving GOVX-B11 into a **Phase 2b** trial without the use of "protein boosts" is supported by the clinical data derived from the Phase 1 and Phase 2a clinical trials involving approximately 500 individuals. The vaccine has generated favorable immune responses, durability, and

safety characteristics. In addition, preclinical protection studies in non-human primates show that GOVX-B11 demonstrates the best protection of any HIV vaccine advancing in clinical trials.

It appears that GOVX-B11 is sufficient on its own to generate an immune response that could potentially result in decreased incidence of infection without the necessity for a gp120 “protein boost”, as gp120 is a highly variable protein that results in an antibody response that typically wanes over time. We believe this is the reason that GeoVax is planning to go forward with a Phase 2b trial of GOVX-B11 that will run in parallel to the “protein boost” clinical trial to be performed by the NIAID.

Currently, the company is working with its consultants, advisors, and clinical research organizations to develop the protocol, timeline and budget for a Phase 2b clinical trial of GOVX-B11. We believe the trial could be performed with approximately 2500 individuals (split 1:1 between GOVX-B11 and placebo) at a cost of approximately $30 million. We do not foresee GeoVax initiating the trial until at least a portion of the funding to cover the trial costs has been secured. The company has initiated an outreach program to philanthropic organizations to seek the funds required to initiate the trial. We anticipate the company will release more details on the trial protocol and funding opportunities over the next few months.

Clade C HIV Program

In early July, GeoVax received a notice of award from the NIH for a Small Business Innovative Research (SBIR) grant in support of its **clade C** HIV vaccine development program for Africa. The grant award of $299,585 is for the first year of a two-year project period beginning July 1, 2015.

While GOVX-B11 is designed for the epidemic in developed world, this SBIR grant will support the preclinical testing in non-human primates of a vaccine designed for the clade C subtype of HIV prevalent in developing world. This project is the first to use GeoVax’s vaccine technology for the developing world, and builds on the company’s clade B HIV vaccine, GOVX-B11.

Based on the safety and reproducible immunogenicity of GOVX-B11, we believe that the clade C vaccine will show similar promise.

With the NIH grant support and based on the previous favorable safety and efficacy data of GOVX-B11, we believe the timeline for the Clade C HIV vaccine program will be definitely shortened.

Another Path for HIV Immunotherapy Program

GeoVax still believes that its DNA/MVA vaccines, or a component subset, may be effective as shock agents, and plans to evaluate the concept in future clinical trial. Recently, GeoVax decided to focus its cash resources on the Ebola/Marburg program, but is actively seeking support from a third party to help out with further development of the immunotherapy program.

A major challenge in the development of HIV therapeutics is the ability of HIV to persist in host cells in a latent pro-viral form, invisible to the immune system and inaccessible to antiretroviral drugs. In response to this problem, the NIH and other leaders in the HIV field have developed a new concept: the “shock and kill” strategy, in which patients remain on standard-of-care anti-retroviral drug therapy while a second drug (“shock agent”) is used to activate latent HIV and a third drug (“kill agent”) is used to recognize and eliminate cells that harbor the latent HIV reservoir. GeoVax believes that GOVX-B11 may be that much need shock agent, and plans to test the drug in in its ability to complement drug therapies with this “shock and kill” strategy.

Management may also look to combine the vaccine with other therapeutic agents to work towards the ability to prevent re-emergence of latent virus in the absence of drugs. GeoVax is planning an additional study to further evaluate the vaccine's ability to act as a "shock agent.” The timetable and specific clinical plans will be dependent upon the company’s ability to secure external funding for the program, and on the nature of any potential collaboration GeoVax may establish.

Attractive Valuation

We maintain our Buy rating for GeoVax and our price target is $0.50 per share.

GeoVax has developed the technology for the development of both preventive and therapeutic HIV/AIDS vaccines. The Company's vaccine candidates are the only HIV vaccines for America/Europe entering efficacy trial.

There is a compelling amount of data to indicate the GOVX-B11 could be successful without the "protein boost", thus we believe the plan to move forward with GOVX-B11 in a separate Phase 2b study is a good one, provided the company can secure the necessary funding under favorable terms. Continued development of the new Ebola/Marburg vaccine program further expands the company's pipeline.

GeoVax has a strong position in intellectual property. The excellent relationship with Emory University put the Company in a better position to get the most advanced vaccine technology in the first hand, therefore providing a sustainable growth engine for the Company.

The Company has a modest cash burn rate ($2 to $3 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 boost trial and/or Phase IIb trial 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. We believe this could be a major valuation inflection for the company in 2016 or 2017.

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 $4.5 million in market cap. This is a huge 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/Ebola 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 $0.50 represents a market cap of $16 million.

But risks 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 as of September 30, 2015 stood at $1.8 million, which can only last through the middle of 2016. We remind investors that equity financing will dilute existing shareholder base.

Program	Preclinical	Phase 1	Phase 2	Phase 3	Status
Ebola / Marburg					
Epidemic Vaccines (single-strain)					Animal challenge studies commencing in 2015
3-Strain (+Marburg) Vaccine					Constructs under development
HIV – Clade B (developed world)					
Preventive Vaccine					Phase 2a completed (unboosted)
Preventive Vaccine					Protein boost trial commencing 2015
Immunotherapy					Pending support
HIV – Clade C (developing world)					
Preventive Vaccine					NIH grant support

PROJECTED INCOME STATEMENT

	2014A (Dec)						2015E (Dec)				2016E (Dec)	2017E (Dec)	2018E (Dec)
$ in million except per share data	Q1	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE
Grant revenue	$0.16	$0.18	$0.32	$0.22	$0.88	$0.10	$0.07	$0.09	$0.10	$0.37	$0.50	$1.00	$1.50
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
Total Revenues	**$0.16**	**$0.18**	**$0.32**	**$0.22**	**$0.88**	**$0.10**	**$0.07**	**$0.09**	**$0.10**	**$0.37**	**$0.50**	**$1.00**	**$1.50**
YOY Growth	-80.3%	-59.2%	-67.9%	27.8%	-63.5%	-34.1%	-60.3%	-71.1%	-55.3%	-58.3%	35.9%	100.0%	50.0%
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
Gross Income	**$0.16**	**$0.18**	**$0.32**	**$0.22**	**$0.88**	**$0.10**	**$0.07**	**$0.09**	**$0.10**	**$0.37**	**$0.50**	**$1.00**	**$1.50**
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%
R&D	$0.40	$0.52	$0.43	$0.47	$1.81	$0.40	$0.38	$0.38	$0.40	$1.57	$2.00	$3.00	$4.00
% R&D	256.7%	286.7%	132.1%	209.3%	205.3%	390.3%	538.2%	406.5%	400.0%	425.7%	400.0%	300.0%	266.7%
SG&A	$0.37	$0.35	$0.41	$0.68	$1.81	$0.40	$0.36	$0.34	$0.34	$1.44	$1.50	$2.00	$3.50
%SG&A	236%	192%	128%	304%	205%	388%	511%	361%	340%	392%	300%	200%	233%
Operating Income	**($0.6)**	**($0.7)**	**($0.5)**	**($0.9)**	**($2.7)**	**($0.7)**	**($0.7)**	**($0.6)**	**($0.6)**	**($2.6)**	**($3.0)**	**($4.0)**	**($6.0)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-400.00%	-400.00%
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
Pre-Tax Income	**($0.6)**	**($0.7)**	**($0.5)**	**($0.9)**	**($2.7)**	**($0.7)**	**($0.7)**	**($0.6)**	**($0.6)**	**($2.6)**	**($3.0)**	**($4.0)**	**($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	$0.5
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($0.6)**	**($0.7)**	**($0.5)**	**($0.9)**	**($2.7)**	**($0.7)**	**($0.7)**	**($0.6)**	**($0.6)**	**($2.6)**	**($3.0)**	**($4.0)**	**($6.5)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	62.5%
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-400.0%	-433.3%
Diluted Shares Out	24.8	25.0	25.3	31.5	26.6	32.0	32.0	32.0	40.0	34.0	50.0	65.0	75.0
Reported EPS	**($0.02)**	**($0.03)**	**($0.02)**	**($0.03)**	**($0.10)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.08)**	**($0.06)**	**($0.06)**	**($0.09)**
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*
Non GAAP Net Income	**($0.6)**	**($0.7)**	**($0.5)**	**($0.9)**	**($2.7)**	**($0.7)**	**($0.7)**	**($0.6)**	**($0.6)**	**($2.6)**	**($3.0)**	**($4.0)**	**($6.5)**
Non GAAP EPS	**($0.02)**	**($0.03)**	**($0.02)**	**($0.03)**	**($0.10)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.08)**	**($0.06)**	**($0.06)**	**($0.09)**

Source:company filings and Zacks estimate

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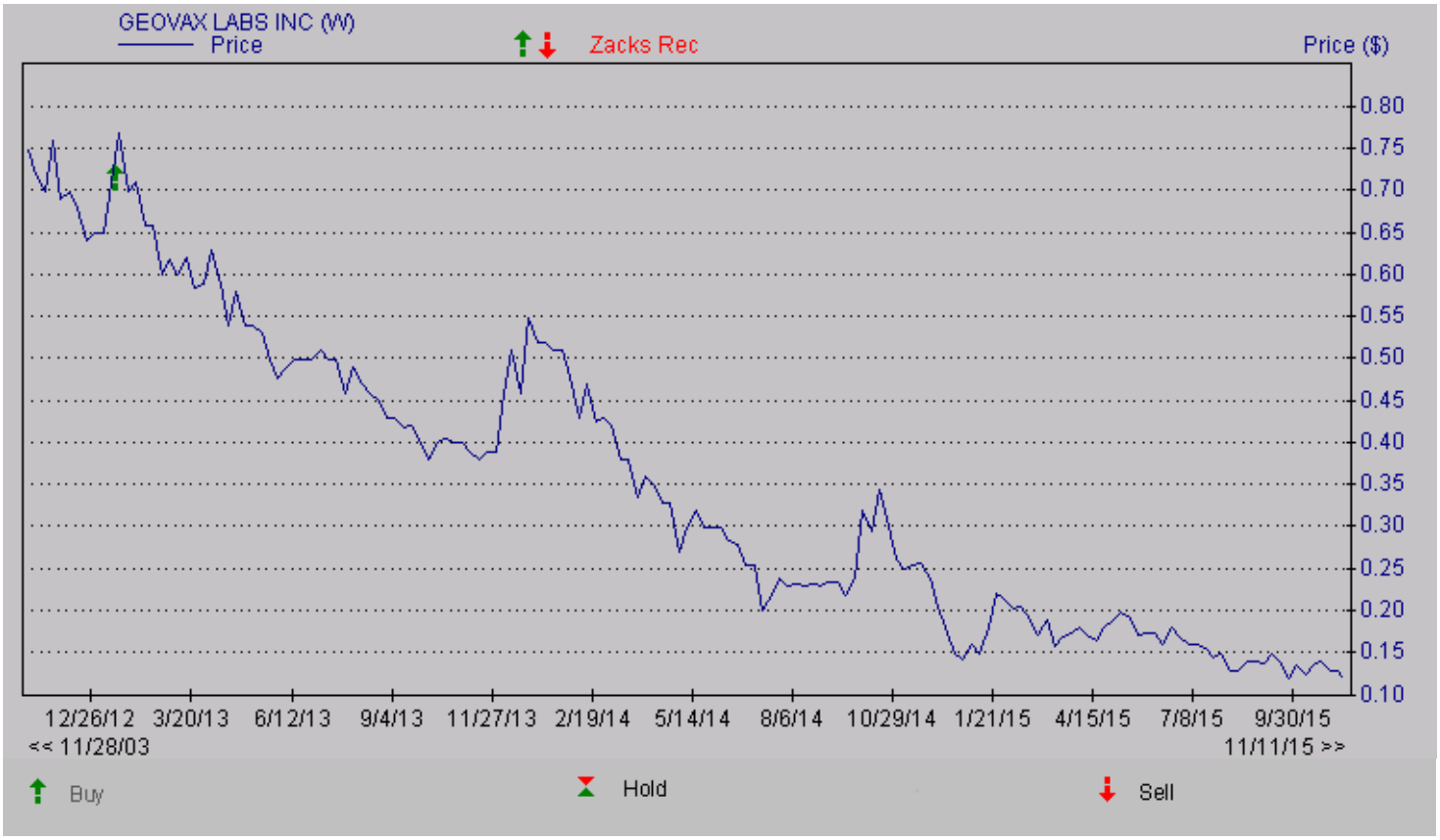

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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