Zacks Small-Cap Research

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GeoVax Labs Inc. (GOVX-OTC)

GOVX: Zacks Company Report

Entering into Zika, Cancer immunotherapy

Current Price (31/05/2016)	$0.07
Valuation	**$0.25**

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. The entry into Zika and oncology immunotherapy further expands pipeline.

We continue to believe the upside potential to the company shares.

SUMMARY DATA

52-Week High	**$0.27**
52-Week Low	**$0.12**
One-Year Return (%)	**-53.07**
Beta	**0.68**
Average Daily Volume (sh)	**12,332**
Shares Outstanding (mil)	**37**
Market Capitalization ($mil)	**$2.6**
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	0.16 A	0.43 A
2016	0.05 A	0.05 E	0.05 E	0.05 E	0.20 A
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 A	-$0.08 A
2016	-$0.04 A	-$0.02 E	-$0.02 E	-$0.02 E	-$0.10 E
2017					-$0.06 E

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WHAT'S NEW

Update on First Quarter Financials

The Company reported revenues of $47,600 for the three months ended March 31, 2016, related to grants from the NIH. This compares to $103,424 of grant revenues reported for the same period in 2015.

R&D expenses were $438,004 for the three months ended March 31, 2016, compared with $403,629 for the comparable period in 2015.

G&A expenses were $906,505 and $401,441 for the three months ended March 31, 2016 and 2015, respectively. G&A expense for the 2016 period includes a non-cash charge of $469,799 related to certain stock purchase warrant modifications.

Net loss for the three months ended March 31, 2016 of $1,296,279, or $0.04 per share. For the three months ended March 31, 2015, the Company reported a loss of $700,454, or $0.02 per share.

Cash balances were $669,482 at March 31, 2016, as compared to $1,060,348 at December 31, 2015.

Update on HIV Program

In April 2016, GeoVax received a Notice of Award from the U.S. National Institutes of Health for a Phase II Small Business Innovative Research (**SBIR**) grant in support of its **clade B HIV vaccine development program** for the Americas. The grant award of $740,456 will fund the first year of a two-year project period with a total budget of $1,398,615. The grant will support **preclinical studies** testing the ability of a bivalent (two component) protein boost to enhance the efficacy of the GeoVax Clade B HIV vaccine **(GOVX-B11).**

GOVX-B11 is a DNA/MVA vaccine that expresses non-infectious virus-like particles (VLPs). Clinical trials for GOVX-B11 have been conducted by the NIH-supported HIV Vaccine Trials Network (HVTN) with funding from the National Institute of Allergy and Infectious Disease (NIAID). The HVTN has tested various doses and combinations of the DNA and MVA vaccines in 500 humans with very encouraging results and plans to test **a protein boost in combination with GOVX-B11 in humans.** The preclinical study funded by this grant will evaluate the potential of a protein boost to increase vaccine efficacy in non-human primates.

We view this grant valuable to GeoVax as it not only boosts the company's balance sheet, but more importantly, it validates the company's HIV technology and the achievements the company has made in the past few years.

Update on Zika Vaccine Program (GOVX-ZM01

In early February, 2016, GeoVax started a program to develop a vaccine for the prevention of **Zika virus** infections using its novel MVA-VLP vaccine platform. The company believes that it can rapidly advance a vaccine candidate to human clinical testing.

GeoVax is forming **a number of collaborations** to speed the development process of a safe and effective Zika vaccine.

GeoVax has been engaged with scientists at three renowned institutions:

- the CDC for animal testing and access to Zika convalescent sera to help in vaccine development;
- the University of Georgia (UGA) for alternative animal testing models and vaccine development;

- the University of Texas Medical Branch (UTMB) for additional reagents necessary for testing GeoVax's vaccine candidates.

The GeoVax Zika vaccine (designated **GOVX-ZM01**) utilizes the company's proven Modified Vaccinia Virus Ankara –Virus-Like Particle (MVA-VLP) platform that supports in vivo production of non-infectious VLP from the cells of the very person receiving the vaccine.

The Zika Epidemic

Recent outbreak of Zika virus in America makes the WHO to designate the Zika virus and its suspected complications in newborns an international public health emergency. The Zika epidemic, currently in 24 countries in the Americas, is transmitted by mosquitos and is expected by the WHO to reach most of the Western Hemisphere, infecting up to 4 million people by year's end. The Centers for Disease Control and Prevention (CDC) has issued a travel advisory for people traveling to regions within the Zika virus outbreak, which include popular vacation destinations including Brazil, the site of the 2016 Summer Olympic Games. More than 30 cases have been reported in the United States, imported by travelers visiting affected regions.

Zika virus is a member of the Flaviviridae family, which includes dengue fever, yellow fever, Japanese encephalitis, tick-borne encephalitis, and West Nile viruses. There is an alarming association between Zika infections and **severe birth defects**, including over 4000 cases of microcephaly in Brazil since fall 2015, 270 of which showed confirmed evidence of infection. Microcephaly is a congenital condition marked by an abnormally small head and incomplete brain development. A potential link to Zika infection is also suspected in adults diagnosed with Guillain-Barré syndrome, a rare autoimmune disorder that can cause paralysis.

Other than mosquito control, no approved preventive or therapeutic products are currently available to fight Zika infections. Public health officials recommend avoiding exposure to Zika, delaying pregnancy, and following basic supportive care after infection. A vaccine is urgently needed to prevent a Zika pandemic.

GeoVax's Vaccine Technology has the Potential to Target Zika Vaccine

GeoVax's MVA-VLP vaccine platform is uniquely suited to apply to the Zika virus. This platform has been proven to produce in vivo non-infectious virus-like particles (VLPs) for both HIV and Ebola vaccines. We believe the MVA-VLP platform can demonstrate the same with Zika. Producing VLPs in the very person being vaccinated mimics a natural infection, stimulating the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection. As an additional advantage, the company's vaccine platform has already been proven safe in humans through multiple clinical trials involving over 500 individuals in the company's HIV program.

The Zika vaccine team in GeoVax will be led by its Senior Vice President of Research and Development, Farshad Guirakhoo, PhD. Dr. Guirakhoo played pivotal roles in the development and licensure of human vaccines against Flaviviruses including dengue and Japanese encephalitis. His extensive experience and expertise with Flavivirus vaccine development gives the company an advantage over competitors and will shorten the time until a Zika vaccine can be brought to market by GeoVax and its partners.

GeoVax Expands into Oncology Immunotherapy Program

On Dec 8, 2015, GeoVax announced that it has begun a new program to evaluate its MVA-VLP vaccine platform for use in **cancer immunotherapy**, and has entered into a Collaborative Research Agreement with the University of Pittsburgh for selection and testing of vaccine candidates.

Cancer vaccine or immunotherapy has become the key player in the fight against cancer. The FDA has recently approved a few cancer vaccines/immunotherapies. These include Provenge from Dendreon for

the treatment of prostate cancer, Ketruda from Merck for the treatment of lung cancer and melanoma, Opdivo from Bristol-Myers Squibb for the treatment of melanoma, lung cancer and kidney cancer, and Yervoy from Bristol-Myers Squibb for the treatment of melanoma. The cancer immunotherapy will become a multibillion-dollar market in a few years.

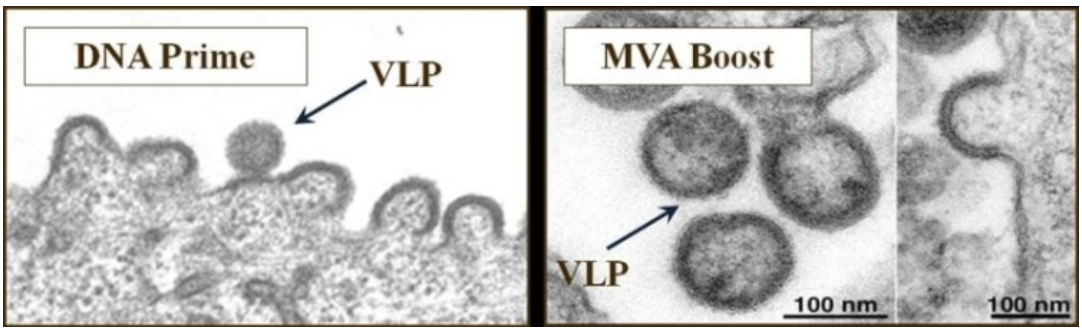
Some tumor-associated antigens are over-expressed or aberrantly expressed in many types of cancer. These antigens in the actual tumors are often recognized as abnormal by patients' immune systems but are not sufficiently immunogenic to trigger an effective immune response. The tumor antigens must be presented to the body in a different form, or in a different way, to enlist the immune system in fighting the cancer. GeoVax's MVA-VLP platform may be able to do exactly this.

The Company's vaccine technology incorporates two vaccine delivery components:

- a recombinant DNA (deoxyribonucleic acid, the primer) and
- a recombinant poxvirus, known as MVA (modified vaccinia Ankara, the booster)

When used together, the recombinant DNA component is used to **prime** the immune response, which is then **boosted** by administration of the recombinant MVA component. However, in certain settings the recombinant **MVA alone** may be sufficient for priming and boosting the immune responses.

Both the DNA and MVA vaccines produce **virus-like particles (VLP)**. Expression of multiple proteins by the vaccine is important because each protein provides targets for cytotoxic T-cells. Elicitation of a multi-target T-cell response limits immune escape, just as multi-drug therapies limit drug escape.



For the DNA Prime, VLPs are seen budding from a DNA-expressing cell. For the MVA boost, fully formed particles as well as a budding particle are shown. The VLPs display trimeric membrane-bound forms of the viral envelope glycoprotein (Env). The VLPs are immature and are rendered non-infectious by deletion of essential genes and introduction of inactivating mutations in essential viral enzymes.

VLPs are designed to elicit:

- protective antibodies – block infection
- cytotoxic T cells – type of white blood cell that kills infected cells

Similarly, GeoVax believes that certain cancer antigens can be genetically modified and delivered using its MVA-VLP platform to train a patient's own immune system to selectively seek and destroy those cells bearing such antigens.

GeoVax's MVA-VLP vaccine platform will allow co-expression of specific cancer antigens and immunomodulatory elements (if needed) tailored to induce a patient's humoral and cellular responses to effectively target and destroy cancer cells.

We welcome the company's decision to expand its platform into the application of cancer immunotherapy. This will further demonstrate the broad utility of the company's MVA vaccine vector beyond infectious diseases for a wide range of possible vaccines.

The cancer immunotherapy program is a new area for GeoVax. The company's primary focus will continue to be infectious disease targets, as with its HIV and Ebola vaccine programs, but the application of its vaccine technology to oncology offers the prospect of addressing some very important unmet medical needs, as well as a significant opportunity to increase shareholder value.

The company has entered a research collaboration with the University of Pittsburgh, which will screen GeoVax's antigen-expressing vaccine candidates using monoclonal antibodies and select vaccines for testing in animal models. The company intends to pursue additional collaborations with leading research institutions and others with novel cancer antigens or technologies suitable for use with its MVA-VLP platform.

GeoVax to Collaborate with USAMRIID on Testing of Hemorrhagic Fever Vaccine

On Feb 29, 2016, GeoVax announced that it has entered into a Cooperative Research and Development Agreement for Material Transfer with the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) to collaborate on GeoVax's effort to develop a vaccine against **hemorrhagic fever viruses.**

Pursuant to the agreement, GeoVax and USAMRIID will share materials and related information for in vitro and in vivo assessment of GeoVax's MVA-VLP **tetravalent vaccine** against Ebola Zaire, Ebola Sudan, Marburg, and Lassa fever viruses.

Researchers at USAMRIID have generated and characterized, in great detail, a wide panel of anti-filovirus and Lassa virus antibodies with different specificities and functionalities. One of these antibodies is now part of ZMapp, an experimental drug comprising three chimeric monoclonal antibodies first tested in humans during the 2014 Ebola epidemic.

Hemorrhagic fever viruses fatal to humans are endemic to Africa where reservoirs remain in animal hosts such as bats, and as the 2014/15 Ebola epidemic showed, these viruses may quickly spread beyond the borders where the outbreak first begins.

GeoVax has demonstrated 100% protection in small animal models. The next step will be testing in non-human primates.

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 2015, 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.

Attractive Valuation

We have a fair valuation of $0.25 per share for GeoVax.

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 IIb 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 and recent expansion to Zika vaccine and oncology immunotherapy 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 $2.6 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 $0.25 represents a market cap of $9 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 March 31, 2016 stood at $0.7 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
HIV - Clade B (U.S., Western Europe)					
Preventive Vaccine					Phase 2a completed Preparing for Phase 2b efficacy
Preventive Vaccine + protein boost					NIH-supported Phase 1 Commencing H1 2016
Immunotherapy ("Shock & Kill")					Pending support
HIV - Clade C (Africa)					
Preventive Vaccine					NIH grant support
Hemorrhagic Fever Viruses					
Monovalent Vaccine (single-strain)					Rodent challenge completed Preparing for primate studies
Tetravalent Vaccine					Constructs under development
Cancer Immunotherapy					
Platform Development					Collaboration with Univ. of Pittsburgh Constructs being designed

PROJECTED INCOME STATEMENT

	2015A (Dec)				2016E (Dec)					2017E (Dec)	2018E (Dec)	2019E (Dec)	2020E (Dec)
$ in million except per share data	Q2	Q3	Q4	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE	FYE
Grant revenue	$0.07	$0.09	$0.16	$0.43	$0.05	$0.05	$0.05	$0.05	$0.20	$1.00	$1.50	$2.00	$3.00
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	$10.00
Total Revenues	**$0.07**	**$0.09**	**$0.16**	**$0.43**	**$0.05**	**$0.05**	**$0.05**	**$0.05**	**$0.20**	**$1.00**	**$1.50**	**$2.00**	**$13.00**
YOY Growth	-60.3%	-71.1%	-28.4%	-51.5%	-54.0%	-30.0%	-46.2%	-68.8%	-53.8%	406.1%	50.0%	33.3%	550.0%
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	1.50
Gross Income	**$0.07**	**$0.09**	**$0.16**	**$0.43**	**$0.05**	**$0.05**	**$0.05**	**$0.05**	**$0.20**	**$1.00**	**$1.50**	**$2.00**	**$11.50**
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%	88.5%
R&D	$0.38	$0.38	$0.53	$1.69	$0.44	$0.45	$0.50	$0.55	$1.94	$2.50	$3.00	$4.00	$6.00
% R&D	538.2%	406.5%	328.9%	395.5%	920.2%	900.0%	1000.0%	1100.0%	980.8%	250.0%	200.0%	200.0%	46.2%
SG&A	$0.36	$0.34	$0.33	$1.43	$0.91	$0.45	$0.45	$0.50	$2.31	$2.50	$3.50	$4.80	$6.00
%SG&A	511%	361%	204%	334%	1904%	900%	900%	1000%	1167%	250%	233%	240%	46%
Operating Income	**($0.7)**	**($0.6)**	**($0.7)**	**($2.7)**	**($1.3)**	**($0.9)**	**($0.9)**	**($1.0)**	**($4.0)**	**($4.0)**	**($5.0)**	**($6.8)**	**($0.5)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-		
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	**($0.7)**	**($0.6)**	**($0.7)**	**($2.7)**	**($1.3)**	**($0.9)**	**($0.9)**	**($1.0)**	**($4.0)**	**($4.0)**	**($5.0)**	**($6.8)**	**($0.5)**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.5	$0.5	$0.5
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($0.7)**	**($0.6)**	**($0.7)**	**($2.7)**	**($1.3)**	**($0.9)**	**($0.9)**	**($1.0)**	**($4.0)**	**($4.0)**	**($5.5)**	**($7.3)**	**($1.0)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-
Diluted Shares Out	32.0	32.0	31.9	32.0	34.6	37.0	42.0	46.0	39.9	65.0	75.0	85.0	95.0
Reported EPS	**($0.02)**	**($0.02)**	**($0.02)**	**($0.08)**	**($0.04)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.10)**	**($0.06)**	**($0.07)**	**($0.09)**	**($0.01)**
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	**($0.7)**	**($0.6)**	**($0.7)**	**($2.7)**	**($1.3)**	**($0.9)**	**($0.9)**	**($1.0)**	**($4.0)**	**($4.0)**	**($5.5)**	**($7.3)**	**($1.0)**
Non GAAP EPS	**($0.02)**	**($0.02)**	**($0.02)**	**($0.08)**	**($0.04)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.10)**	**($0.06)**	**($0.07)**	**($0.09)**	**($0.01)**

Source:company filings and Zacks estimate

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HISTORICAL STOCK PRICE



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