

GeoVax Labs, Inc. GOVX- OTCQB

August 14, 2018

Company Description

GeoVax Labs, Inc. ("GeoVax" or "the Company") is a clinical-stage biotechnology company developing preventative and therapeutic human vaccines against infectious diseases and cancer. The Company's patented Modified Vaccinia Ankara Virus-Like Particle (MVA-VLP) technology is the foundation for producing non-infectious virus-like particles (VLPs) from the cells of the individual receiving the vaccine. Producing VLPs in a vaccinated individual mimics a natural infection, stimulating both the humoral and cellular arms of the immune system to recognize, prevent, and control the target infection should it appear, while maintaining the safety characteristics of a replication-defective vector. GeoVax is focused on developing vaccines against hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), Zika virus (ZIKV), malaria, and human immunodeficiency virus (HIV). The Company also has programs to develop a vaccine to treat chronic Hepatitis B virus (HBV) infection and to apply its MVA-VLP technology to cancer immunotherapy (immuno-oncology). Furthermore, GeoVax recently announced that it is collaborating with Emory University to develop a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). GeoVax believes its expertise is complementary to a range of other human diseases for which there is an unmet medical need, and thus, has plans to expand its pipeline.

Key Points

- On August 14, GeoVax announced the appointment of David Dodd as Chairman, President, and CEO, in conjunction with the retirement of Robert McNally, Ph.D., President and CEO. Mr. Dodd will assume this new, expanded role upon Dr. McNally's retirement, effective September 1. Mr. Dodd brings significant experience leading and developing multiple companies in the life science industry. Dr. McNally will continue to serve on the GeoVax Board of Directors.
- GeoVax recently issued a corporate overview of its research and development (R&D) programs and reported its financial results for the quarter ended June 30, 2018.
- The Company's programs are enabled through grants from government agencies, including the National Institute of Allergy and Infectious Diseases (NIAID) and the Centers for Disease Control and Prevention, as well as collaborations with academic and research institutions, such as the HIV Vaccine Trials Network (HVTN), Emory University, University of Pittsburgh, Georgia State University, the Burnet Institute (Australia), the Institute for Human Virology at the University of Maryland, The Scripps Research Institute, and the University of Texas Medical Branch. The Company additionally has corporate collaborations with American Gene Technologies International, Inc. (AGT), CaroGen Corporation, Vaxeal Holding SA, and ViaMune, Inc. By means of working with multiple collaborators on a variety of vaccine candidates, GeoVax is able to manage development risk by creating many paths on the road to selecting the best vaccine candidate.
- To advance its Lassa Fever vaccine, during the quarter, GeoVax was awarded a Fast-Track Phase I/II SBIR grant by the NIAID of \$300,000 for Phase I of the project, with an expected total project budget of up to \$1.9 million.
- The NIAID also announced during the quarter that it has awarded GeoVax a \$300,000 SBIR grant for the second year of the project to advance development of the Company's Zika vaccine (GEO-ZM02). This grant is to support late stage preclinical testing in non-human primates to prepare for human clinical trials.
- GeoVax's preventive HIV vaccine program (GOVX-B11) continued with clinical trial support from NIAID, with the next trial expected to commence later this year or in early 2019. The Company's collaboration with AGT for the use of GeoVax's vaccine in combination with AGT's gene therapy to develop a functional cure for HIV is on track to enter a Phase 1 trial sponsored by AGT; the trial could begin during the first quarter of 2019.



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GOVX (OTC.BB) One-Year Chart



Ticker (Exchange)	GOVX (OTC.BB)
Recent Price (08/14/18)	\$0.035
52-week Range	\$0.020 to \$0.100
Shares Outstanding	~155.2 million
Market Capitalization	~\$5.94 million
Avg. 10-day Volume	425,167
EPS (Qtr. ended 06/30/18)	(\$0.00)
Employees	9



RECENT DEVELOPMENTS

Key milestones achieved by GeoVax year-to-date include:

- Lassa Fever Vaccine. GeoVax was awarded a Fast-Track Phase I/II SBIR grant by the NIAID to advance its Lassa Fever vaccine (GEO-LM01). The \$300,000 initial grant is for Phase I of the project, with an expected total project budget of up to \$1.9 million. This grant is to enable preclinical testing of the Company's vaccine candidates in preparation for human clinical trials. The work is being performed in collaboration with the Institute of Human Virology at the University of Maryland, The Scripps Research Institute, and the University of Texas Medical Branch.
- Zika Vaccine. NIAID also awarded GeoVax a \$300,000 SBIR grant for the second year of the project to advance development of the Company's Zika vaccine (GEO-ZM02). This grant is to support late stage preclinical testing in non-human primates to prepare for human clinical trials.
- HIV Program. GeoVax's preventive HIV vaccine program (GOVX-B11) continued with clinical trial support from NIAID and the next trial is expected to commence later this year or in early 2019. The Company's collaboration with American Gene Technologies International, Inc. (AGT) for use of GeoVax's vaccine in combination with AGT's gene therapy to develop a functional cure for HIV is on track to enter a Phase 1 trial sponsored by AGT. AGT's estimates the trial could begin during the first quarter of 2019.
- Oncology Program. The Company commenced a collaboration with Vaxeal Holding SA, expanding its cancer vaccine program to include the design, construction, characterization, and animal testing of vaccine candidates to use GeoVax's MVA-VLP vaccine platform with Vaxeal's proprietary designed genetic sequences. This project is complementary to GeoVax's ongoing collaboration with ViaMune, Inc. for co-developing cancer immunotherapies. GeoVax is also collaborating with the University of Pittsburgh and their Professor, Dr. Olja Finn, to use combined technologies for abnormal MUC1 secreting tumors.
- Hepatitis B Program. GeoVax began a collaboration with CaroGen Corporation to develop a combination immunotherapy treatment for chronic hepatitis B virus (HBV) infection. This project includes testing GeoVax's MVA-VLP-HBV vaccine candidate in combination with CaroGen's HBV Virus-like Vesicles (VLVs) vaccine candidate in prophylactic and therapeutic animal models of HBV infection. Data is now being compiled for GeoVax's HBV vaccine design, which is being tested in animal models at Georgia State University.
- HPV/HNC Program. The Company began a collaboration with Dr. Rafi Ahmed at the Emory University Vaccine Center for development of a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC).
- Ebola Vaccine. GeoVax published exceptional results from a rigorous preclinical study of its Ebola vaccine in the peer-reviewed open access journal Scientific Reports by Nature Research. In this study, the Company demonstrated 100% single-dose protection provided by its vaccine to rhesus macaques challenged with a lethal dose of Ebola virus. The article can be viewed at www.nature.com/articles/s41598-017-19041-y.
- *Malaria Vaccine*. The Company continued work on its malaria vaccine program in collaboration with the Burnet Institute in Australia. There has been encouraging preclinical proof of concept immunogenicity data.



- Scientific Conferences. GeoVax continues to attend and present at various scientific conferences, including the ChinaBio Partnering Forum at the 36th Annual J.P. Morgan Healthcare Conference, WHO consultation for Ebola/Marburg viruses as part of the WHO's research and development (R&D) roadmaps process for priority diseases, American Society for Microbiology (ASM) Biothreats conference, the World Vaccine Congress, the National Foundation for Infectious Diseases (NFID) Annual Conference on Vaccinology Research, the ASM Microbe conference, and the American Society for Virology Annual Meeting. These venues provide valuable networking opportunities to bring its technologies to the attention of the broader scientific community and to potential collaborators and partners.
- During the 2018 World Vaccine Congress, GeoVax had its work recognized by peers through winning the "Best Biotech" Vaccine Industry Excellence (VIE) Award (Figure 1). GeoVax was also a finalist for the "Best Prophylactic Vaccine" VIE Award for its Zika vaccine. Moreover, during the BIO International Convention, GeoVax was a finalist for the Pipelines of Promise award.

Figure 1 BEST BIOTECH" AWARD FROM THE 2018 WORLD VACCINE CONGRESS



Source: GeoVax Labs, Inc.

RECENT FINANCIAL RESULTS

GeoVax report its financial results on August 7, 2018. For the three months ended June 30, 2018, GeoVax reported a net loss of \$637,043 (less than \$0.01 per share) versus \$516,881 (\$0.01 per share) for the same period in 2017. For the six months ended June 30, 2018, the Company's net loss was \$1,258,856 (\$0.01 per share) versus \$1,065,222 (\$0.02 per share) in 2017.

The Company reported grant and collaboration revenues of \$93,265 and \$314,564 for the three-month and sixmonth periods of 2018, respectively, versus \$352,137 and \$647,872, for the comparable periods of 2017. As of June 30, 2018, there is \$771,951 in approved grant funds remaining and available for use. Research and development (R&D) expenses were \$372,202 and \$859,196 for the three-month and six-month periods of 2018, respectively, versus \$518,098 and \$1,069,893 for the comparable periods of 2017. R&D expenses include reimbursable costs funded by NIAID grants—noting that much of the variance between the periods relates to the timing of external expenditures associated with the grants.

General and administrative (G&A) expenses were \$359,197 and \$716,425 for the three-month and six-month periods of 2018, respectively, versus \$352,191 and \$644,858 for the comparable periods of 2017. The increase in G&A expense for the six-month period ended June 30, 2018 versus 2017 is largely due to stock-based compensation expense associated with common stock issued for investment banking fees.

GeoVax reported cash balances of \$190,969 at June 30, 2018 versus \$312,727 at December 31, 2017. GeoVax continues to be funded by grant funding, collaborations, and equity raises. The Company continues to have a very low burn rate, operating at under \$3 million per year, which is low relative to the pipeline activity underway.



TIMELINE OF EVENTS

August 14, 2018—Announced the appointment of David Dodd as Chairman, President and CEO, upon the retirement of Bob McNally, Ph.D., as President and CEO, effective September 1. Dr. McNally will continue to serve as a member of the GeoVax Board of Directors.

July 30, 2018—Announced that it is collaborating with Emory University to develop a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). The GeoVax/Emory collaboration will include testing GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV in the laboratory of Dr. Rafi Ahmed, Director of the Emory Vaccine Center. Dr. Ahmed, a member of the National Academy of Sciences, is a world-renowned immunologist whose work during the past decade has been highly influential in shaping understanding of memory T cell differentiation and T and B cell-mediated antiviral immunity.

July 9, 2018—Announced that its Chief Scientific Officer, Dr. Farshad Guirakhoo, was to deliver a talk during the American Society for Virology (ASV) 2018 Annual Meeting, being held July 14-18, 2018 at the University of Maryland in College Park, MD. Dr. Guirakhoo's presentation is entitled "Development of a Safe and Effective Zika Vaccine Based on the NS1 Protein" and was delivered during a workshop session at the conference.

May 30, 2018—Announced that it would be presenting its latest data in a late-breaking poster presentation during the 2018 American Society for Microbiology (ASM) Microbe Conference, being held June 7-11, 2018 in Atlanta, GA. Two presentations to be given during the ASM conference were entitled: (1) Development of Vaccines from A to Z, for AIDS and Zika and Many More in Between, Using a Novel MVA Vector Platform Technology, and (2) Development of Single-Dose Vaccines for Emerging Infectious Diseases, Preclinical Data for Novel Ebola, Lassa fever and Zika Vaccines.

May 24, 2018—Announced that the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has awarded the Company a Small Business Innovative Research (SBIR) grant in support of its novel Zika vaccine development program. The grant award of \$300,000 will fund the second year of a two-year project period with a total budget of \$600,000. The grant, entitled "Advanced Preclinical Testing of a Novel Recombinant Vaccine Against Zika Virus", supports advanced preclinical testing of GeoVax's vaccine candidate (designated GEO-ZM02) in non-human primates in preparation for human clinical trials. GEO-ZM02 is a novel vaccine approach to protect against Zika virus (ZIKV), using GeoVax's Modified Vaccinia Ankara (MVA) vector to express the ZIKV non-structural protein 1 (NS1).

May 22, 2018—Announced that it was scheduling corporate partnering meetings during the 2018 BIO International Convention, held in Boston on June 4-7, 2018. Additionally, GeoVax was declared a finalist in the Pipelines of Promise category for the Buzz of BIO contest. This recognizes GeoVax as one of the most innovative and promising biotechnology companies at the 2018 BIO International Convention.

April 19, 2018—Announced that its Chief Scientific Officer, Dr. Farshad Guirakhoo, was an invited speaker at the 2018 Annual Conference on Vaccinology Research, sponsored by the National Foundation for Infectious Diseases, held in Bethesda, MD on April 23-25. Dr. Guirakhoo delivered his talk entitled "Development of Single-Dose Vaccines for Ebola, Lassa Fever, and Zika Using a Novel MVA Vector Platform Technology" on April 24. Dr. Guirakhoo presented data showing single dose efficacy of GeoVax's Ebola, Lassa, and Zika vaccines against lethal challenges in appropriate animal models.

April 10, 2018—Announced that the NIAID has awarded the Company a Fast Track Phase I/II Small Business Innovative Research (SBIR) grant in support of its novel Lassa virus vaccine development program. The \$300,000 grant is for Phase I of the project; the Company anticipates a total project budget of up to \$1.9 million following the anticipated Phase II award.

April 5, 2018—Announced that it won "Best Biotech" at the World Vaccine Congress Vaccine Industry Excellence (ViE) Awards. These awards recognize the efforts, accomplishments, and positive contributions of companies and individuals in the vaccine industry. GeoVax was also an award finalist for "Best Prophylactic Vaccine" (for its novel Zika vaccine).



POTENTIAL MILESTONES

Zika

- Determine immunogenicity and efficacy in non-human primates (funded by NIAID SBIR grant)
- Determine correlation of protection by passive protection studies in mice
- Produce GMP vaccine
- File IND with the FDA
- Initiate Phase 1 clinical trial

ΗIV

- Initiate Phase 1 HIV clinical trial by AGT (gene therapy cure trial), (Q1 2019)
- Complete evaluation of patient inoculations for HVTN 114 Phase 1 trial testing the ability of "late boosts" to increase the antibody responses elicited by GOVX-B11 (Q4 2018)
- Initiate Phase 1 HIV protein boost clinical trial by HVTN (pathway to efficacy trial), (Q1 2019)

Cancer Immunotherapy

 Continue its collaboration with ViaMune, Inc. to co-develop the companies' respective cancer immunotherapy programs. Encouraging preliminary data were presented in August 2017; follow-on studies are being planned. Goal is to eventually get this into Phase I human clinical trials

Malaria

Preclinical data on efficacy of malaria vaccine via relationship with Burnet Institute (Q4 2018)

HPV

Begin testing therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC) via new collaboration with Emory University to test GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV

Hepatitis B

Continue to compile data on its Hepatitis B vaccine, with some data expected to be report in the near term

Corporate

- Move one or two of its programs into Phase 1 human trials, and subsequently pursue a licensure
- Establish strategic collaboration resulting in capital investment and acceleration of specific development program(s)



VALIDATION OF MVA-VLP VACCINE PLATFORM

GeoVax's product pipeline is based on its Modified Vaccine Ankara (MVA) Virus-Like Particle (VLP) vaccine platform, which supports in vivo production of non-infectious VLPs from the cells of the actual person receiving the vaccine. This technology mimics a natural infection and stimulates both the humoral and cellular arms of the immune system to recognize, prevent, and control target infections.

The Company's original application of its technology was to develop preventive HIV vaccines. Recently, it has expanded to preventive vaccines for Zika Virus, hemorrhagic fever viruses (Ebola, Sudan, Marburg, and Lassa), and malaria, as well as therapeutic vaccines for HIV, chronic Hepatitis B infections, and cancers. GeoVax continues to add to an encouraging data set for its MVA-VLP platform, with preclinical proof-of-concept in four disease indications (HIV, Zika, Lassa, and Ebola). As well, the data has demonstrated excellent safety and immunogenicity in clinical trials of its HIV vaccine in 500 individuals, providing the basis for expecting clinical efficacy for the current vaccine development programs.

In addition, this data shows promise as it relates to future pipeline expansion for further disease indications. The platform has the following manufacturing advantages: (1) no purification issues such as associated with synthetic VLPs produced in vitro; (2) no adjuvant needed; and (3) no vector immunity (no smallpox vaccine in routine use).

HIV Preventive Vaccines

The Company's most advanced program is a prophylactic vaccine (GOVX-B11) for the clade B subtype of HIV, the most common form of HIV in North America, Western Europe, Australia, and Japan. This program has completed Phase 1 and Phase 2a human clinical trials, which were conducted by the HIV Vaccine Trials Network (HVTN) with funding from the NIAID. In January 2017, the HVTN initiated a Phase 1 human clinical trial of GOVX-B11 to evaluate the durability of immune responses elicited by the vaccine and the effects of late boosts (additional vaccinations) on the antibody responses elicited by the GOVX-B11.

The next planned clinical trial of GOVX-B11 is expected to be an additional Phase 1 trial, evaluating the safety and immunogenicity of a prime-boost regimen of GOVX-B11 with and without two additional protein boosts. This trial is expected to conducted by HVTN with funding from NIAID, with an anticipated start date of Q1 2019. Both this trial as well as HVTN 114 are intended to contribute critical data to determine the regimen for use in a future Phase 2b efficacy trial.

The Company is also continuing preclinical work funded by grants from the NIAID for its vaccine for the clade C HIV subtype, which is prevalent in Africa. In October 2017, GeoVax reported the elicitation of a key precursor for a broadly neutralizing antibody for the HIV CD4 binding site—a material advantage in advancing HIV vaccine development. The findings were published in the peer-reviewed open access journal PLOS ONE (http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0177863).

HIV Therapeutic Vaccine ("Functional Cure" Program)

GeoVax began a collaboration with American Gene Technologies International, Inc. (AGT) in March 2017 with the goal of developing a functional cure for HIV infection through AGT's gene therapy technology combined with GeoVax's HIV vaccine. The Company expects AGT to initiate human clinical trials of the companies' combined technologies in Q1 2019.

Zika Vaccine

GeoVax presented data at multiple conferences showing that a single dose of its Zika vaccine (GEO-ZM02) gave 100% protection in mice challenged with a lethal dose of Zika virus (ZIKV) delivered directly into the brain. These conferences included the American Society for Microbiology (ASM) conference (ASM MICROBE 2017) in New Orleans, LA in June 2017 and later in August at the 5th Annual Meeting of Cambridge Healthtech Institute, Immuno-Oncology Summit, in Boston, MA, as well as in October 2017, at the 18th World Vaccine Congress Europe in Barcelona, Spain. This is the first report of (1) a Zika vaccine based on the ZIKV non-structural (NS1) protein, and (2)



single-dose protection against ZIKV using an immunocompetent lethal mouse challenge model. The vaccine was tested at the Centers for Disease Control and Prevention (CDC) in Ft. Collins, CO with funding from the CDC. GeoVax's approach to a Zika vaccine uniquely uses the non-structural protein NS1 instead of the commonly used structural proteins for immunogens, avoiding potential Antibody Dependent Enhancement (ADE) of infection—a safety concern for Zika vaccines based on structural proteins.

Preclinical efficacy of GEO-ZM02 was published in the peer-reviewed open access journal Scientific Reports by Nature Research under the title of *"A Zika Vaccine Targeting NS1 Protein Protects Immunocompetent Adult Mice in a Lethal Challenge Model"* (http://rdcu.be/yasq). As well, in June 2017, the National Institutes of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), awarded GeoVax a Small Business Innovative Research (SBIR) grant of \$600,000 to support advanced preclinical testing, including non-human primate studies, for its Zika vaccine development program to prepare for a Phase 1 human clinical study.

In May 2018, it was announced that the NIAID had awarded the Company a grant award of \$300,000 to fund the second year of a two-year project period with a total budget of \$600,000. The grant, entitled "Advanced Preclinical Testing of a Novel Recombinant Vaccine Against Zika Virus", supports advanced preclinical testing of GeoVax's vaccine candidate.

Lassa Fever Vaccine

GeoVax made significant strides, as announced in July 2017, in developing a vaccine candidate to protect against Lassa hemorrhagic fever virus (LASV). Efficacy testing in a murine challenge model (using a chimeric LASV reassortant) showed a single intramuscular dose of GEO-LM01 provided 100% protection to mice infected with a lethal dose of the challenge virus directly delivered into the brain. The study was conducted, and successfully repeated, at the Institute of Human Virology at the University of Maryland School of Medicine. The Company further expanded its LASV vaccine development efforts through a collaboration with The Scripps Research Institute located in San Diego, CA. In October 2017, at the International Society for Vaccines, at the Institute Pasteur in Paris, France, GeoVax presented updates on efficacy data of its single dose vaccine for Lassa fever virus. In December 2017, GeoVax announced that it is collaborating with the U.S. Naval Research Laboratory (USNRL) to develop high-quality antibodies useful for detection of LASV and potentially as a treatment for Lassa Fever (LF). Because there is no vaccine currently available, LASV continues to kill more than 5,000 people each year in West African countries where the virus is endemic.

In April, 2018, GeoVax announced that it was awarded a Fast-Track Phase I/II SBIR grant by the NIAID to advance its Lassa Fever vaccine (GEO-LM01). The \$300,000 initial grant is for Phase I of the project, with an expected total project budget of up to \$1.9 million. This grant is to enable preclinical testing of the Company's vaccine candidates in preparation for human clinical trials. The work is being performed in collaboration with the Institute of Human Virology at the University of Maryland, The Scripps Research Institute, and the University of Texas Medical Branch.

A single dose of GeoVax's Ebola (EBOV) vaccine has been shown to protect 100% of rhesus monkeys against death. The Company is also developing vaccines against Sudan virus (SUDV) and Marburg virus (MARV), two other lethal hemorrhagic fever viruses for which no effective vaccine currently exists. In addition to developing the four individual hemorrhagic fever vaccines (EBOV, LASV, SUDV, MARV), GeoVax seeks to combine the vaccines into a single tetravalent vaccine to provide broad protection for individuals at-risk for these viruses.

Immuno-oncology Program

In August 2017, at the 5th Annual Meeting of Cambridge Healthtech Institute, Immuno-Oncology Summit, in Boston, MA, and in October 2017, at the 18th World Vaccine Congress Europe in Barcelona, Spain, GeoVax presented preliminary results from studies of its cancer vaccine in collaboration with ViaMune, Inc. The studies were performed by the laboratory of Dr. Pinku Mukherjee, PhD, at the University of North Carolina at Charlotte. GeoVax and ViaMune are each developing products that target an abnormal form of the cell surface-associated protein, Mucin 1 (MUC1), which is overexpressed in metastatic cancers (e.g. breast, pancreatic, lung, and ovarian cancers) and circulating tumor cells and which is often used as a diagnostic marker for cancer progression. In a human MUC1 colon adenocarcinoma mouse tumor model, groups of hMUC1 transgenic mice with established



tumors were treated with MTI (ViaMune's synthetic vaccine), MVA-VLP-MUC1 (GeoVax's viral-vectored vaccine), or a combination of both. All treatment groups received an immune checkpoint inhibitor in the form of an anti-PD-1 antibody. Results from two studies indicate that a combined vaccine approach increases the therapeutic potential of anti-PD-1 therapy, affording scientific justification to pursue additional investigation of this cancer vaccine candidate.

In January 2018, GeoVax announced that it is collaborating with Vaxeal Holding SA on the expansion of GeoVax's cancer immunotherapy program. The collaboration between GeoVax and Vaxeal will include the design, construction, characterization, and animal testing of vaccine candidates using using Vaxeal's antigens in GeoVax's MVA-VLP vaccine platform. This project is complementary to GeoVax's ongoing collaboration with ViaMune, Inc. for co-developing cancer immunotherapies. GeoVax is also collaborating with the University of Pittsburgh and their Professor, Dr. Olja Finn, to use combined technologies for abnormal MUC1 secreting tumors.

Malaria Vaccine

In January 2017, GeoVax initiated a program to develop a malaria vaccine with its MVA-VLP viral vector platform via a collaboration with The Burnet Institute in Australia. The Company has completed construction of four vaccine candidates, which have been shipped to The Burnet Institute and are being evaluated in preclinical proof-of-concept studies.

Chronic Hepatitis B (HBV) Immunotherapy

During the first quarter 2017, GeoVax added Georgia State University and Peking University as collaborators to develop a therapeutic vaccine for chronic hepatitis B infection. Preclinical proof-of-concept studies are ongoing. In February 2018, the Company announced that it is collaborating with CaroGen Corporation to develop a combination immunotherapy treatment for chronic hepatitis B virus (HBV) infection. The project will include testing GeoVax's MVA-VLP-HBV vaccine candidate in combination with CaroGen's HBV virus-like vesicles (VLVs) vaccine candidate in prophylactic and therapeutic animal models of HBV.

Human Papillomavirus (HPV) Infection

GeoVax announced at the end of July 2018 that it was collaborating with Emory University on the development of a therapeutic vaccine for human papillomavirus (HPV) infection, with a specific focus on head and neck cancer (HNC). The GeoVax/Emory collaboration is to include testing GeoVax's MVA-VLP-HPV vaccine candidates in therapeutic animal models of HPV in the laboratory of Dr. Rafi Ahmed, Director of the Emory Vaccine Center. Dr. Ahmed, a member of the National Academy of Sciences, is a world-renowned immunologist whose work during the past decade has been highly influential in shaping understanding of memory T cell differentiation and T and B cell-mediated antiviral immunity. This is important research area as there are currently no medical treatments for chronic HPV infections, which can lead to the formation of cancerous tumors.



Company Background

GeoVax Labs, Inc. is a clinical-stage biotechnology company focused on developing human vaccines—both preventative and therapeutic—against infectious diseases as well as cancer using a novel patented Modified Vaccinia Ankara-Virus Like Particle (MVA-VLP) vector vaccine platform. The Company's proprietary MVA platform, a large virus capable of carrying several vaccine antigens, expresses highly effective virus like particle (VLP) immunogens in the vaccinated individual, prompting durable immune responses while providing the safety features of a replication defective vector.

The Company's development efforts are focused on preventive vaccines within the following important areas: human immunodeficiency virus (HIV), Zika virus (ZIKV), hemorrhagic fever (HF) viruses (Ebola, Sudan, Marburg, and Lassa), and malaria. GeoVax is also developing therapeutic vaccines for chronic HBV infections and immunooncology, and is collaborating on a combination approach to developing a functional cure for HIV infection. The Company's vaccine development activities have been, and continue to be financially supported by the U.S. Government in the form of research grants awarded directly to the Company, in-kind support in terms of animal experiments, as well as indirect support for conducting human clinical trials. In particular, GeoVax's HIV program receives substantial federal support (with over \$50 million received to date from the NIH). Importantly, large pharmaceutical or biotechnology companies typically do not have a significant interest in sponsoring early-stage activity in HIV until the development at least reaches an efficacy trial. All of GeoVax's preventative vaccine trials have been sponsored by the NIH, with the NIH (through the HIV Vaccine Trials Network [HVTN]), in fact, running the Company's trials—something that is unusual within the biotechnology space.

MVA-VLP Technology Platform

GeoVax's MVA-VLP vector vaccine technology platform combines the safety of a replication-defective live vector (MVA) with the immunogenicity of VLPs and the durability of immune responses elicited by vaccinia vectors. An overview of the Company's current MVA-VLP-based technology pipeline is provided in Figure 2, followed by brief descriptions of each program. Greater details are provided within the Core Story of our base report, https://www.crystalra.com/research-library/geovax-0-0 (pages 21-52).



Source: GeoVax Labs, Inc.



Vaccines are most often made of agents (antigens) that resemble disease-causing microorganisms and are traditionally created from weakened or killed forms of the virus or from its surface proteins. Newer vaccines largely use recombinant deoxyribonucleic acid (DNA) technology to produce vaccine antigens in bacteria or cultured cells from specific portions of the DNA sequence of the target pathogen, where the generated antigens are then purified and formulated for use in a vaccine. The most successful of these purified antigens have been non-infectious VLPs, such as the hepatitis B vaccines (Merck's Recombivax[®] and GlaxoSmithKline's [GSK's] Engerix[®]) and human papillomavirus vaccine (GSKs Cervarix[®] and Merck's Gardasil[®]).

VLPs train the body's immune system to identify and kill the authentic virus should it appear. Furthermore, VLPs train the immune system to recognize and kill infected cells to control infection and decrease the length and severity of disease. Among the most challenging aspects of VLP-based vaccines is to design the vaccines in such a way that the VLPs are recognized by the immune system in the same way as would be the authentic virus. GeoVax employs the use of recombinant DNA or recombinant viruses to produce VLPs in the person being vaccinated.

When VLPs for enveloped viruses such as HIV, Ebola, Sudan, Marburg, or Lassa fever are produced *in vivo*, they include not only the protein antigens, but also an envelope consisting of membranes from the vaccinated individual's cells, where they are then highly similar to the virus generated in a person's body during a natural infection. In contrast, VLPs produced externally have no envelope or envelopes from the cultured cells used to produce them. Based on its efforts to date, GeoVax believes its technology provides unique advantages by producing VLPs that more closely resemble the authentic virus, thus enabling the body's immune system to more readily recognize the authentic virus. By producing VLPs *in vivo*, GeoVax's vaccines avoid potential purification issues related to *in vitro* VLP production.

Noteworthy is that MVA was initially developed as a safer smallpox vaccine for use in immune-compromised individuals, where it was developed by attenuating the standard smallpox vaccine by making over 500 passages of the virus in chicken embryos or chicken embryo fibroblasts. This lead to a virus with limited ability to replicate in human cells though did not compromise the ability of MVA to grow on avian cells (used for manufacturing the virus). The deletions also lead to the loss of immune evasion genes, which help the spread of wild-type smallpox infections (even in the presence of human immune responses).

Advantages

GeoVax's MVA-VLP platform has unique advantages, summarized below and further described within the report in context.

- *Safety.* GeoVax's HIV vaccines have demonstrated a remarkable safety profile in human clinical trials. Historically, safety for MVA has been shown in more than 120,000 subjects in Europe, including immunocompromised individuals during the initial development of MVA. As well, this safety profile has been shown lately in developing MVA as a safer vaccine against smallpox.
- *Durability.* The Company's technology promotes highly durable vaccine responses that are long lasting. GeoVax theorizes that elicitation of durable vaccine responses is conferred on responding B cells by the vaccinia parent of MVA, raising highly durable responses for smallpox.
- *Limited pre-existing immunity to vector.* Following the eradication of smallpox in 1980, smallpox vaccinations ended, which left everyone except for those individuals born before 1980 and selected populations (such as vaccinated laboratory workers, first responders, etc.) unvaccinated and without pre-existing immunity.
- No need for adjuvants. MVA stimulates strong innate immune responses without the use of adjuvants.
- Thermal stability. MVA is stable in both liquid and lyophilized formats (> 6 years of storage).
- *Genetic stability and manufacturability*. MVA is genetically stable when properly engineered and can be reliably manufactured in either the established chick embryo fibroblast (CEF) cell substrate or in continuous cell lines that support scalability along with consistency and efficiency.



Collaborations and Government Support

GeoVax's HIV vaccine technology was developed in collaboration with researchers at Emory University, the NIH, and the CDC. The technology is exclusively licensed to GeoVax from Emory University. The Company also has nonexclusive licenses to certain patents owned by the NIH used in developing its other vaccines. Its immunooncology program is being developed pursuant to a collaboration with ViaMune, Inc. Its ZIKV vaccine program is in collaboration with the CDC. Its HBV therapeutic program is in collaboration with Georgia State University. As well, the Company's malaria vaccine is being developed in collaboration with the Burnet Institute in Australia. A summary of the Company's current vaccine research collaborations is provided in Figure 3.



GeoVax seeks to advance and protect its vaccine platform, while using its core competences to design and develop a broad range of products. The Company seeks to move its products through to human clinical testing, and pursue partnership(s) and/or licensing arrangement(s) at the pre-commercialization stage. Furthermore, for preclinical and clinical testing, GeoVax leverages third party resources via collaborations and partnerships.

Corporate Background, Properties, and Employees

GeoVax leases roughly 8,400 sq. ft. of office and laboratory space at 1900 Lake Park Drive, Suite 380, Smyrna, Georgia under a lease agreement that expires on December 31, 2018. GeoVax currently employs nine individuals. The Company's primary business is conducted by its wholly-owned subsidiary, GeoVax, Inc., which was incorporated under the laws of Georgia in June 2001. The predecessor to its parent company, GeoVax Labs, Inc. was originally incorporated in June 1988 under the laws of Illinois as Dauphin Technology, Inc. In September 2006, Dauphin completed a merger with GeoVax, Inc. As a result of the merger, GeoVax, Inc. became a wholly-owned subsidiary of Dauphin, and Dauphin changed its name to GeoVax Labs, Inc. In June 2008, the Company was reincorporated under the laws of Delaware.



Risks and Disclosures

This Quarterly Update has been prepared by GeoVax, Inc. ("GeoVax" or "the Company") with the assistance of Crystal Research Associates, LLC ("CRA") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in GeoVax's statements on Forms 10-K, 10-Q, and 8-K as well as other forms filed from time to time.

The content of this report with respect to GeoVax has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings. GeoVax is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by GeoVax or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA has been compensated by the Company in cash of forty-eight thousand dollars for its services in creating the base report and for quarterly updates.

Investors should carefully consider the risks and information about GeoVax's business, as described in the base report, available at <u>https://www.crystalra.com/research-library/geovax-0-0</u>. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in GeoVax's SEC filings are not the only risks that the Company faces. Additional risks and uncertainties not presently known to GeoVax or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, GeoVax's business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company's shares could decline.

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Crystal Research Associates is led by Wall Street veterans, Jeffrey Kraws and Karen Goldfarb. Together, Kraws and Goldfarb have built a unique business model, capitalizing on decades of experience as an award-winning sell-side analyst team to produce institutional-quality industry and market research in a manner that is easily understood by investors and consumers. Our firm's approach has been proven successful over the years as our products are published and available on Bloomberg, Thomson Reuters/First Call, Capital IQ, FactSet, Yahoo! Finance, and scores of other popular forums.