WRITTEN TESTIMONY

DATE: October 8, 2019

WITNESS: Tammie Wahaus, Chief Executive Officer of ELIAS Animal Health, LLC; Chief Financial Officer of TVAX Biomedical, Inc.

SUBJECT: Committee on Small Business field hearing titled, "Silicon Prairie: Tech, Innovation, and a High-Skilled Workforce in the Heartland"

TESTIMONY: Good morning. My name is Tammie Wahaus. I am the Chief Executive Officer of ELIAS Animal Health, LLC and the Chief Financial Officer of TVAX Biomedical, Inc.

I would like to thank the Committee on Small Business and U.S. Representative Sharice Davids for this opportunity to share my perspective on Technology, Innovation, and a Highly-skilled Workforce in the Heartland.

ELIAS and TVAX are great examples of the translational research being conducted in the Silicon Prairie. Together, we are advancing a vaccine enhanced adoptive T cell therapy as a treatment for cancer in both human and companion animals. Collectively, our data demonstrate the potential applicability of our innovative technology to any type of cancer in humans and in dogs.

In developing our technology, we have worked with many of the great research institutions in the region. Scientists, researchers, and clinicians (including MD's and DVM's) have all participated in laboratory research, preclinical studies, and clinical trials in both humans and in companion animals.

ELIAS Animal Health Overview

First, I would like to focus on ELIAS Animal Health. ELIAS Animal Health is a medical biotechnology company that is commercializing a novel targeted T cell-based immunotherapy (ECI®, or ELIAS Cancer Immunotherapy) for the treatment of cancer in the veterinary sector. The company's proprietary and patented therapeutic approach offers the potential for improved clinical outcomes with low toxicity, changing the way cancer is fundamentally treated in the companion animal market.

ELIAS was founded in 2014 as a spin-off of TVAX Biomedical, discussed later, in recognition of the market potential for innovation in the companion animal oncology space. In 2019, just five years later, we are commercializing our novel, and patented, targeted T cell-based immunotherapy (marketed as ECI®) for the treatment of cancer in the veterinary sector that uses the pet's own immune system to kill cancer cells. This is a platform technology with potential for all cancer types - solid tumors and blood cancers.

Over the past five years, clinical studies in key canine cancers have been conducted evaluating ECI in multiple canine cancer types, including osteosarcoma, B cell lymphoma, and hemangiosarcoma. To date, nearly 100 dogs diagnosed with cancer have been treated with ECI and the results have included

complete and partial responses, with many achieving improved survival times compared to traditional treatments such as chemotherapy and radiation.

Results of our studies in canine osteosarcoma have been reported at several scientific conferences. In that study, more than half of the dogs treated with ECI survived 3.2 times as long as historically achieved with amputation alone and 1.6 times as long as historically achieved with amputation plus chemotherapy, with minimal adverse events. In the most current analysis, fifty percent of the dogs in the study were reported as disease-free for periods ranging between 4-6 times as long as amputation alone, and 2-3 times as long as amputation plus chemotherapy. In addition to improved median survival times, regression of metastatic disease and slowed disease progression were also observed, highlighting the promise of this therapeutic approach for treating cancer in dogs. An application for conditional licensure has been submitted to USDA-Center for Veterinary Biologics ('USDA-CVB').

ELIAS Animal Health Manufacturing Facilities and Workforce

Our manufacturing facility is currently located in the Olathe, Kansas. The Company manufactures following the regulatory requirements of the U.S. Department of Agriculture – Center for Veterinary Biologics. We have in place a team who, together, have more than 20 years of experience in the animal health industry, and more than 30 years of experience in cGMP vaccine manufacturing and cell culture processes.

Commercial scale-up plans have already been designed for a facility with the capability to rapidly expand production. Our manufacturing facility can be replicated at a low cost, thereby enabling an efficient distributed manufacturing model. At scale, we estimate that could create manufacturing jobs for more than 100 microbiologists and scientists, along with quality assurance personnel.

Commercializing a companion animal cancer treatment that offers greater effectiveness and a better safety profile than those currently available, creates a projected U.S. revenue opportunity in excess of $100 million and has the potential to significantly expand the currently projected revenue opportunity with expansion to markets outside the U.S., expansion to the equine and feline species, and expansion of the referrals by general practitioners to the veterinary specialty hospitals.

ELIAS is initially targeting canine cancers being treated by veterinary specialty hospitals specializing in cancer treatment, where, an estimated 372,000 of the 6 million dogs diagnosed annually are provided care. Independent, company-sponsored, market research confirmed that these veterinarians are seeking newer, better treatments for their clients and their pet dogs. This research was instrumental in the development and validation of the company's marketing and pricing strategies. Leveraging the results of our clinical studies conducted at both private and academic veterinary clinics, as well as the experience gained by those clinicians, Commercial sales of our first product were initiated in early 2019.

Through veterinary specialty hospitals trained and certified as ECI® treatment centers, coupled with positive clinical outcomes in more than one cancer type, ELIAS intends to build market share of at least 37,000 patients per year within five years, generating revenue in excess of $100 million per year. Further growth can be achieved through the expansion to markets outside the U.S. and other species

(feline and equine), and growth in the referrals by general practitioners to the veterinary specialty hospitals for pet owners seeking safe, more effective treatment options.

ELIAS Animal Health - Capital Requirements

To date, ELIAS has raised just over $5 million in equity capital, primarily from regional investors. By putting that capital to work we have employed a multi-disciplinary team that includes expertise in cancer immunology, veterinary medicine, microbiology, clinical trial oversight, and regulatory compliance, to bring this product to market. The progress that we have made in just 5 years and with only $5.5 million dollars is rare in this industry.

A funding round of up to $5 million is currently being pursued to support the expansion of our commercial launch for ECI® as a treatment for canine osteosarcoma, clinical studies in additional cancer types, and facilities, equipment, and staff to support commercial expansion.

The Small Business Innovation Research program is another potential source of funding for early stage life science technologies like ours. The SBIR provides an opportunity for businesses like ELIAS Animal Health to pursue grant funding that is additive to the capital raised from investors. We currently have a grant application under consideration by reviewers for the National Cancer Institute for a translational clinical trial in companion animals, specifically dogs, that could provide critical information supporting the further development of this treatment by TVAX Biomedical for use in humans.

Raising adequate capital to support the rapid development and commercialization of this cancer treatment is critically important to the overall success of the business. Speed to market is a key differentiator for innovative technologies.

TVAX Biomedical Overview

As discussed above, TVAX Biomedical is a clinical stage biotechnology company testing TVAX Immunotherapy, a unique, proprietary, cancer type-agnostic immunotherapy platform combining vaccination and adoptive T cell therapy.

TVAX has tested TVAX Immunotherapy in >200 patients with various types of cancer, including high-grade glioma. Surrogate outcomes demonstrated that ~90% of patients developed neoantigen-specific immune responses, thereby demonstrating all cancers' potential susceptibility to neoantigen-specific effector T cells. The basis for use of neoantigen-specific effector T cells in TVAX Immunotherapy is similar to use of these cells in highly effective checkpoint inhibitor and tumor infiltrating lymphocyte therapies.

Our plan is to conduct a single armed, multi-institutional 75-patient phase 2b clinical trial to assess TVAX Immunotherapy as a treatment for newly diagnosed pediatric and adult high-grade glioma patients. TVAX Immunotherapy will be integrated with standard therapy such that immunity is generated prior to chemoradiotherapy-induced immune suppression and effector T cells are delivered after chemoradiotherapy reduces cancer tissue-associated immune suppression and patients have minimal residual disease.

TVAX Biomedical Manufacturing Facilities and Workforce

Similar to ELIAS Animal Health, manufacturing this personalized cancer treatment for humans in accordance with the regulatory requirements of the Food & Drug Administration requires a workforce skilled in cancer immunology, microbiology, clinical trial management, and regulatory affairs. It is anticipated that a 5,000 square-foot facility will be needed initially for manufacturing and that footprint will need to grow as the manufacturing volumes increase over time.

TVAX Biomedical - Capital Requirements

TVAX is currently pursuing funding of $12 million for the 75-patient phase 2b clinical trial. Investors both inside and outside of the Heartland are being approached to support this very important work.

High-grade glioma patient prognosis is dismal; current therapies are not delivered with curative intent and provide only a few months additional survival. There is a serious unmet medical need for safer and more effective treatments for adult and pediatric high-grade glioma patients. In clinical trials, TVAX Immunotherapy has been shown to be effective against high-grade gliomas.

Summary Statement – ELIAS Animal Health and TVAX Biomedical

ELIAS Animal Health and TVAX Biomedical are focused on changing the way cancer is fundamentally treatment. Our mission is to provide a safer, more effective treatment option for cancer patients. To achieve that goal, we will need increasing access to a workforce skilled in biologics manufacturing, clinical trial oversight, cancer immunology, human and veterinary medicine, and regulatory compliance.

Bringing a life sciences product to market takes years of scientific and clinical development, and costs millions of dollars. From early stage development through to regulatory approval and marketing is a significant financial undertaking because it takes 5-7+ years to bring a product to that stage.

Along with the great work being done by ELIAS Animal Health and TVAX Biomedical, there are many other important innovations being created in the Silicon Prairie. In my experience, we have a robust angel investor community, but it is critical that venture funds, institutional investors, and granting agencies become more robust in their support of emerging businesses in the Heartland.

We have great universities that are building critical educational programs to train workers that will support the life sciences industry. Expanded support from the broader investment community would provide the capital needed to bring our cancer treatment and other innovations to market.

Thank you for the opportunity to speak before the Committee.