**COMPANY PROFILE**

TVAX Biomedical is a clinical stage biotechnology company testing TVAX Immunotherapy™, a unique vaccine-enhanced adoptive T cell therapy. TVAX Immunotherapy uses vaccination combined with *ex vivo* T cell activation to maximize the number and effect of cancer neoantigen-specific effector T cells in cancer tissue.

**A key distinction** between TVAX Biomedical and other immunotherapy companies that use effector T cell-based treatments is that TVAX Immunotherapy could potentially be used to safely and effectively treat any patient’s cancer and is able to be delivered with only transient inflammatory-type side effects and no long-term toxicity.

**CLINICAL PLATFORM**

**TVAX Immunotherapy**

1. Vaccinate the patient with their own cancer cells combined with a powerful immunological adjuvant (GM-CSF).
   
   **Rationale:** Vaccination generates an immune response that produces high numbers of cancer neoantigen-specific effector T cell precursors in the body.

2. Collect immune cells by leukapheresis from vaccinated patient’s blood and stimulate to differentiate into effector T cells and multiply *in vitro* using T cell activating agents.
   
   **Rationale:** Generates large numbers of fully activated effector T cells that does not occur efficiently in vivo.

3. Adoptively transfer effector T cells into the patient by IV infusion.
   
   **Rationale:** Effector T cells are carried to cancer tissue throughout the body, enter cancer tissue and initiate a cascade of immunological events that produce killing of significant numbers of cancer cells, and, sometimes, complete elimination of the patient’s cancer.

4. Treat patient with a course of interleukin 2 (IL-2).
   
   **Rationale:** IL-2 stimulates continued multiplication of infused effector T cells thereby increasing effect of T cells.

**Benefits of Combining Vaccination and Adoptive T cell Therapy:**

Vaccination enhances adoptive T cell therapy by greatly increasing numbers of neoantigen-specific T cells in the body. Adoptive transfer of *ex vivo*-activated cancer neoantigen-specific effector T cells delivers high numbers of effector T cells into cancer tissue to attack and kill cancer cells.

**TVAX Immunotherapy**

- Unique, proprietary, cancer type-agnostic immunotherapy platform combining vaccination & adoptive T cell therapy
- Highly positive (curative) preclinical outcomes with wide range of syngeneic rodent cancers, including brain cancer and other cancers growing in the brain
- Highly positive outcomes in canine metastatic osteosarcoma (model for all metastatic cancers)
- Highly positive human adult and pediatric high-grade glioma outcomes
- Clinical data establishing benign safety profile for all treatment components
- Currently active IND-13135 on file with Food and Drug Administration with phase 2b pediatric high-grade glioma protocol
- cGMP compliant in-house manufacturing – highly portable and expandable
- Phase 2b clinical trial ready program in adult and pediatric high-grade glioma
- Broad intellectual property portfolio

**Advantages relative to other immunotherapies:**

- Potentially curative – T cells can kill all cancer cells
- Acceptable safety profile – no long-term toxicity
- Cancer type agnostic – all cancers are immunogenic and susceptible to T cell killing
- Complementary – can be combined with standard therapy to eliminate minimal residual disease
- Complementary – can potentially be combined with other immunotherapies to increase efficacy
- **Unique** – no companies currently pursuing development of comparable therapy

**WORLDWIDE MARKET OPPORTUNITY**

- Potential annual market for lead program - High-grade glioma = $1.5 billion
- Potential use of TVAX Immunotherapy in multiple other cancer indications including bladder, breast, colon, kidney, leukemia, lung, lymphoma, melanoma, ovary, pancreas and prostate
- Anticipated treatment price in line with current immunotherapies, e.g., checkpoint inhibitors
Rationale:
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.

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. TVAX Immunotherapy is effective against high-grade gliomas.

Clinical trial rationale:
Our current 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.