



Business Summary: Tolera is a Kalamazoo, Michigan based clinical stage company with a highly specific T-cell targeting monoclonal antibody technology (anti-TCR) for immune modulation with broad application potential in T-cell mediated disease such as transplant rejection, autoimmune disease (e.g. type 1 diabetes and multiple sclerosis) and hematological malignancies (e.g. pediatric ALL).

Management: *Tolera is managed by an experienced biotech team and supported by an extensive network of development and clinical experts. The CEO, John Puisis has experience as CEO of a publicly traded biotech company and has over 20 years experience in biotech. Tolera has the support of the Cleveland Clinic, the University of Michigan, and Northwestern University, advising on the market's unmet needs and clinical development strategies.*

Unmet Medical Need: Current T-cell antagonists operate as either overly broad spectrum, toxic agents, or as overly specific and less effective immune inhibitors. As a result, clinicians are seeking safer alternatives for T-cell modulation with an improved therapeutic index. Extensive research dollars and development efforts have been expended in search of a more selective and safer means of modulating T-cell function without triggering dangerous inflammatory responses or opportunistic infections; such as those seen in currently available therapies.

Product: *Tolera has a proven, T-cell specific, monoclonal antibody, ready for later stage trials (TOL101). It has been successfully manufactured and purified to GMP standards for clinical investigation.*

Target Market: The initial target market will be the solid organ transplant market where the MAb has shown clinical efficacy and superior safety in over 100 patients. The anti-T-cell technology has an attractive product profile for the autoimmune market as well, where its anti-CD3 properties make it an ideal candidate for T-cell mediated diseases like diabetes and multiple sclerosis. As a result, Tolera is well positioned with a novel T-cell modulator and plans to develop a deep pipeline to address valuable therapeutic opportunities.

Customers: *Transplant surgeons, immunologists and oncologists who have experience with the MAb, have expressed strong interest in seeing it commercialized. These physicians are not satisfied with the current array of therapeutic agents and their untoward effects.*

Business Model / Marketing Strategy: Develop safer, more targeted, T-cell therapy – TOL101 – with an improved therapeutic index over current therapies. Obtain FDA market approval for first indication (solid organ transplant) within 3 years. Address the highly concentrated market of transplant practitioners with a safer, more targeted T-cell modulator. Parallel track development of T-cell therapies to address autoimmune applications to expand the pipeline (i.e. potential for partnering).

Competitive: *T-cell antagonists while often proven effective, create clinical concerns over inflammation, opportunistic infections, and cancers resulting from their use. Tolera's MAb profile offers the potential efficacy of the market leading agents with an improved therapeutic index. Tolera intends to displace the antibody induction market leader (used off-label) once approved for transplant rejection. In autoimmune and oncology, there are no approved anti-CD3 T-cell mediators which combine strong efficacy with low risk of adverse event.*

Profile:

Founded: 2007

Management:

John J. Puisis, *President and CEO*
Maria Siemionow, MD, PhD, DSc, CSO
Jim Herrmann, *Chief Operating Officer*

Investors:

SWMF Life Sciences Fund
Triathlon Medical Ventures
Hopen Therapeutics
Michigan Economic Development Corp.

Board of Directors:

Suzette Dutch *Triathlon Medical Ventures*
Douglas R. Morton, Jr. PhD *SWMF Life Sciences*
Mark Olesnavage *Hopen Therapeutics*
Donald R. Parfet *Apjohn Group*
John J. Puisis, *CEO*

Advisors:

Steve Miller, PhD
Northwestern University
Dr. John Thompson
University of Kentucky
Dr. Ellen Cooper
ClinReg Solutions
Casimir, Jones - *IP counsel*

Clinical Advisors:

Renal transplant:
Dr. Stuart Flechner, *Cleveland Clinic*
Dr. Diane Cibrik, *University of Michigan*
Dr. Xunrong Luo, *Northwestern University*