Therapeutics

Engineering space and time for next-generation immunotherapy
TEAM: Diverse and talented team of founders and advisors

**Leadership Team**

**Colin Foster, MBA – Executive Chairman**
Former CEO of Bayer Pharmaceuticals North America. Over 30 yrs experience as Chairman, CEO, and entrepreneur with leadership experience across the R&D-commercial continuum.

**Owen Yang, MBA – Chief Executive Officer**
Passionate Healthcare Entrepreneur with an MBA from Yale University; 7+ years experience in large healthcare technology and medical device companies; oversaw product development and business strategy.

**Philip Kong, PhD – Chief Scientific Officer**
Chief Inventor of Statera’s Core IP. Expert in immunology and nanotechnology with PhD from Yale University and B.S. from Caltech. Published several papers in Science, Cell Host & Microbes, and JCI. 4+ years of buy-side experience in biotech hedge funds.

**Usha Pillai, PhD, PMP – Development Lead**
Over three decades of combined experience in pharmaceutical industry, academia, and biotech consulting. Deep knowledge of the industry, preclinical R&D, alliance management & program management with a passion for enabling entrepreneurship.

**Scientific/SBIR Advisors**

**Dan Littman, PhD**
World-recognized T cell expert; discovered CD4/CD8 T cells
New York University

**Michael Levy, MD**
Foremost expert in MOG Antibody disease and NMO. Research director in Neuroimmunology at Mass General Hospital

**David Hafler, MD**
Prominent physician in neurodegenerative autoimmune diseases
Yale University

**Manufacturing**

**Prabu Nambiar, PhD, RAC, MBA**
CMC expert with 25+ years of experience in CMC, quality and compliance

**Patrick Han, PhD**
Distinguished scientist and engineer specializing in biodegradable nanoparticles & drug delivery

**Nanoparticle Engineering**

**Scientific/SBIR Advisors**

**David Hafler, MD**
Prominent physician in neurodegenerative autoimmune diseases
Yale University

**Biotech Advisors**

**Usha Pillai, PhD, PMP – Development Lead**
Over three decades of combined experience in pharmaceutical industry, academia, and biotech consulting. Deep knowledge of the industry, preclinical R&D, alliance management & program management with a passion for enabling entrepreneurship.
What if…

we can tune the delivery of combinatorial therapeutics to the same target cell AND at the right time to improve precision?

Novel therapeutics are often delivered in combination.

Autoimmune diseases

Cancer Immunotherapy

Allergy

Antigen and adjuvants

Checkpoint inhibitors

ADCs

Neutralizing antibodies and immunosuppressants

Current immunotherapies are often variable in efficacy & safety and less predictable.
**RATIONALE:** Spatiotemporal Tuning elicits a consistent tolerogenic outcome by synergizing with the immune system.

**Scenario A.** Heterogeneous delivery of antigen(s) and immunosuppressant to target cells leads to **partial** antigen-specific tolerance:

Scenario B. Homogenous delivery of antigen(s) and immunosuppressant to target cells leads to **consistent** antigen-specific tolerance:

**Statera’s Discovery:** Co-delivery of immunosuppressant and antigen(s) to the same APC (spatial) and priming with immunosuppressant prior to antigen presentation (temporal) can enable the bioagents to work *in sync* with the immune system.
**STATERA SOLUTION: Spatiotemporally Tuned Particles (STPs)** achieve space and time optimized delivery to orchestrate therapeutics in harmony

Our technology is a single therapeutic that can deliver multiple payloads to the same cell in the optimal time sequence

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**General Properties**

- Encapsulates and delivers multiple agents to target APCs and in optimal order

- Novel biodegradable composition built with FDA approved materials [poly lactic-co-glycolic acid (PLGA)].

- Encapsulants are not limited and can be generalized to:
  - Small molecule drugs on the outer layer
  - Multiple antigens, proteins, or drugs in the inner layer
  - Potential to expand to antibodies

- STP can be further tuned to modify time of release and targeting to cell types

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**Diagram:**

- **Immunosuppressive Drug**
- **Target Antigen(s)**
- **PLGA Nanocarrier**
- **Payload A (small molecule drugs)**
- **Payload B (antigens, proteins, and drugs)**

Note that known immunosuppressive drug is on outside of nanocarrier so that it is processed by the APC in advance of the encased antigen(s)
A single injection (i.p.) of our technology shows significant efficacy in both prevention and treatment in a gold standard animal disease model.

**Prevention**

- Control
- RAPA
- Antigen (MOG)
- CO (MOG/RAPA)
- STP

**Treatment**

- Control
- RAPA
- Antigen (MOG)
- CO (MOG/RAPA)
- STP

*Han, P., Kong, P., et al. Spatio-Temporal Programming of Combinatorial Delivery Tunes the Amplification of Synergistic Therapeutic Response. (In revision)*
MOG-Antibody Disease (MOGAD)

Selected as lead indication due to the demonstrated efficacy of STP in MOGAD representative disease model (EAE by MOG), and a high unmet need in stand of care

Disease Phenotype and symptoms

Epidemiology: 25K patients in the US and EU

Optic Neuritis

Longitudinally Extensive Transverse Myelitis (LETM) 14%
Acute Disseminated Encephalomyelitis (ADEM) 18%
Optic Neuritis (ON) + Transverse Myelitis (TM) 9%
Short TM 4%
Bilateral ON 24%
Unilateral ON 31%

Our Strategy (STP001)

- Auto-Antibodies
  - Non-activated microglia/meningeal macrophage
  - Activated microglia/meningeal macrophage
  - MOG-specific auto-antibody

+ Auto-Antibodies
  - Non-activated antigen-specific T cell
  - Weakly activated antigen-specific T cell
  - Highly activated antigen-specific T cell
  - Antigen
Candidate therapeutics are identified through academic and clinical research.

Candidate therapeutics are screened for optimal spatiotemporal configuration.

STPs are manufactured with their optimal spatiotemporal conditions.

STPs are validated for their immunogenic efficacy in cancer, autoimmune diseases, and allergies.
PRODUCT DEVELOPMENT TIMELINE

INTERNAL PIPELINE

MOGAD (MOG Antigen) STP001

Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1

IND-enabling studies Phase 1 Clinical Phase 2 Clinical Phase 3 Clinical

Manufacturing scale-up and CMC development Stability Studies, Scale-up

STP002

Discovery in cancer, autoimmune disease, or allergy

IND-enabling studies Phase 1 Clinical Phase 2 Clinical Phase 3 Clinical

Non-GMP Manufacturing CMC development to GMP Stability Studies, Scale-up

YEAR 1 YEAR 2 YEAR 3 YEAR 4

Non-dilutive funding

Pemphigus Vulgaris, Type 1 Diabetes, Myasthenia Gravis, Peanut Allergy, MS, Cancer

Business Development

Biz Dev Engagements

Series A Financing
Future Financing
Value Inflection

YEAR 1
YEAR 2
YEAR 3
YEAR 4
EXECUTIVE SUMMARY

• Statera Therapeutics’ Mission:
  ▪ To develop next generation immunotherapies for autoimmune disease, allergy, and cancer through synergistic targeted delivery of immunosuppression and antigen using our Spatiotemporally Tuned Nanoparticles ("STP").

• Product/Platform:
  ▪ A novel nanocarrier platform that establishes spatial and temporal control to antigen/drug delivery, ensuring appropriate priming of APCs and expansion of Tregs to repair immune dysregulation.

• Proof of Concept:
  ▪ Demonstrated in vitro and in vivo that space (co-delivery) and time (sequencing) are each and together critical in immune modulation.
  ▪ Proof-of-concept established in animal model of myelin oligodendrocyte glycoprotein (MOG) antibody disease (EAE)

• Funding Objective:
  ▪ $14M in financing to take lead STP candidate in MOGAD to IND in ~21 months post funding, and to complete POC & non-GMP manufacturing of lead STP candidate in a secondary indication.