Therapeutics

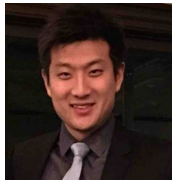
Engineering space and time for next-generation immunotherapy

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.

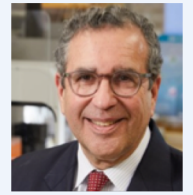
Scientific/SBIR Advisors

Dan Littman, PhD

World-recognized T cell expert; discovered CD_4/CD_8 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

Biotech Advisors

Manufacturing

Prabu Nambiar, PhD, RAC, MBA

CMC expert with 25+ years of experience in CMC, quality and compliance

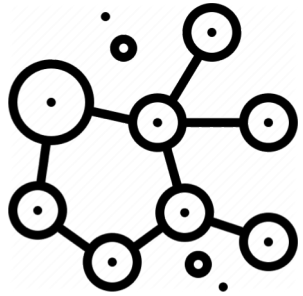
Nanoparticle Engineering

Patrick Han, PhD

Distinguished scientist and engineer specializing in biodegradable nanoparticles & drug delivery

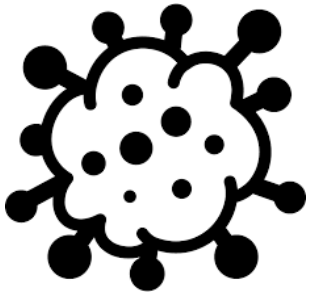
Novel therapeutics are often delivered in combination.

Autoimmune diseases



Antigen and adjuvants

Cancer Immunotherapy



Checkpoint inhibitors
ADCs

Allergy

Neutralizing antibodies and immunosuppressants

Current immunotherapies are often variable in efficacy & safety and less predictable.

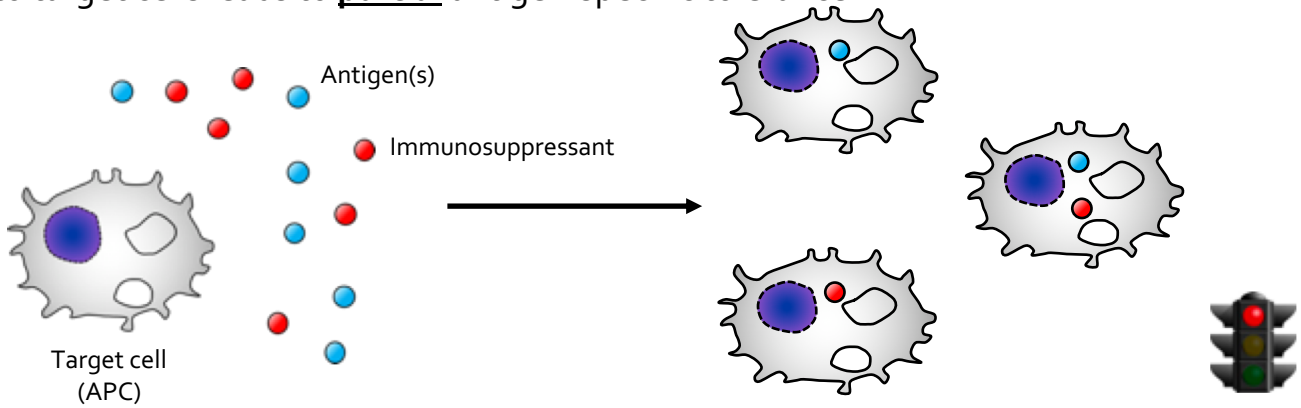
What if…

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

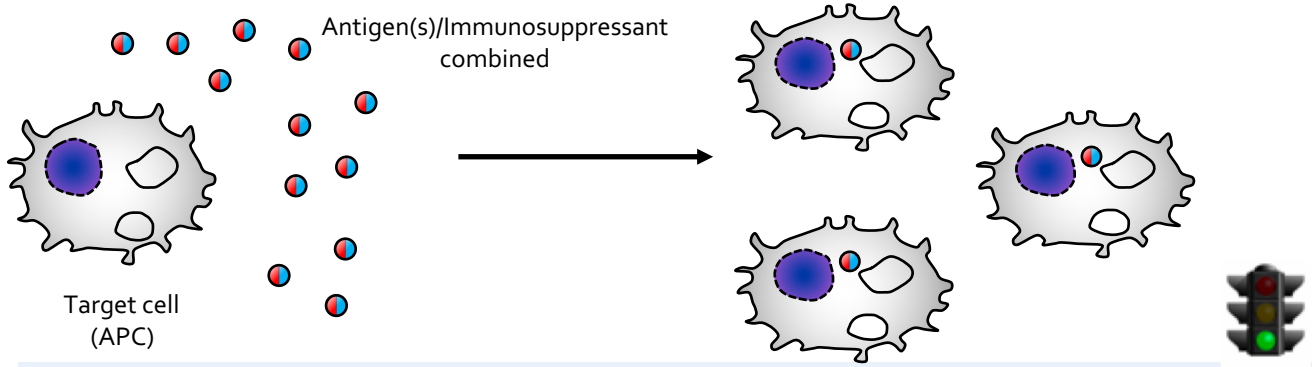
RATIONALE: Spatiotemporal Tuning elicits a consistent tolerogenic outcome by synergizing with the immune system

Space

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

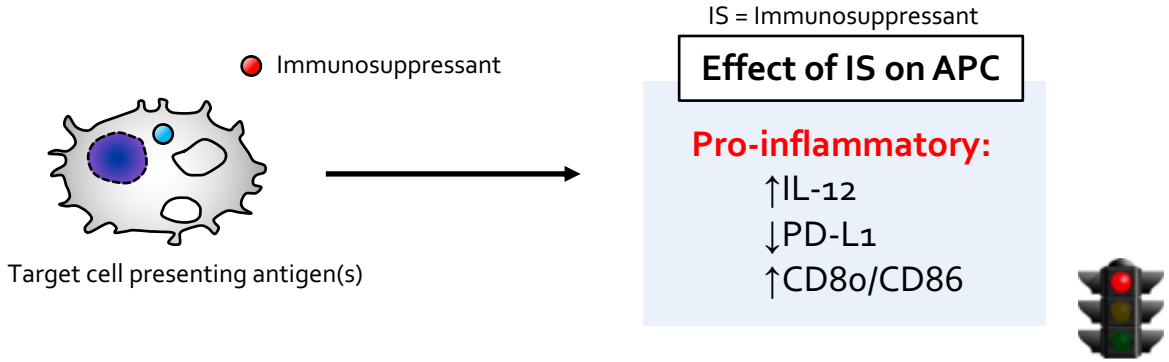


Scenario B. Homogenous delivery of antigen(s) and immunosuppressant to target cells leads to **consistent** antigen-specific tolerance:

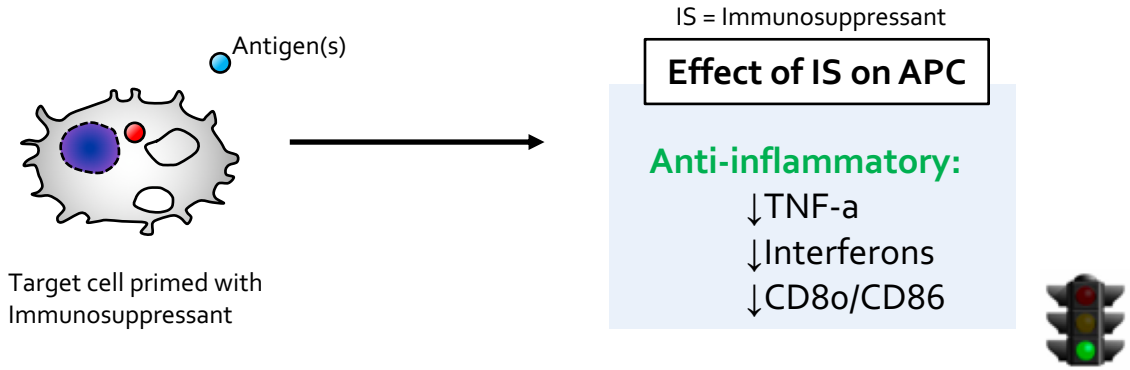


Time

Scenario A. Delivery of immunosuppressant after antigen presentation generates **pro-inflammatory cells**:



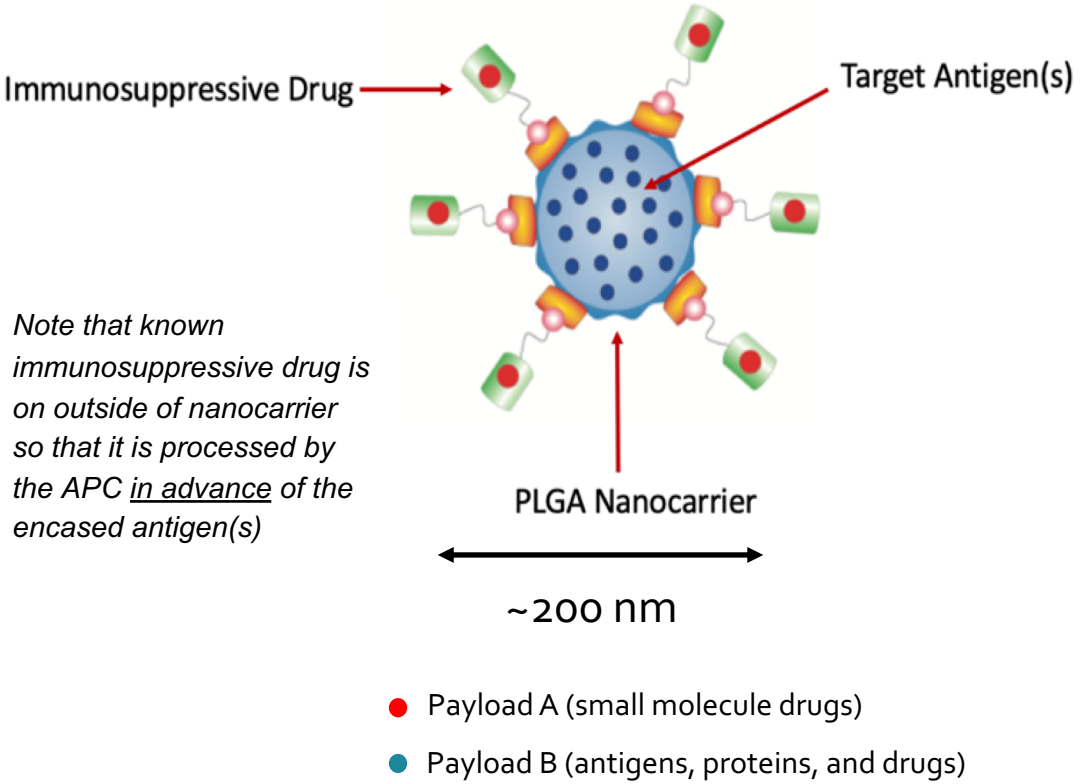
Scenario B. Delivery of immunosuppressant before antigen presentation generates **anti-inflammatory cells:**



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



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)

General Properties

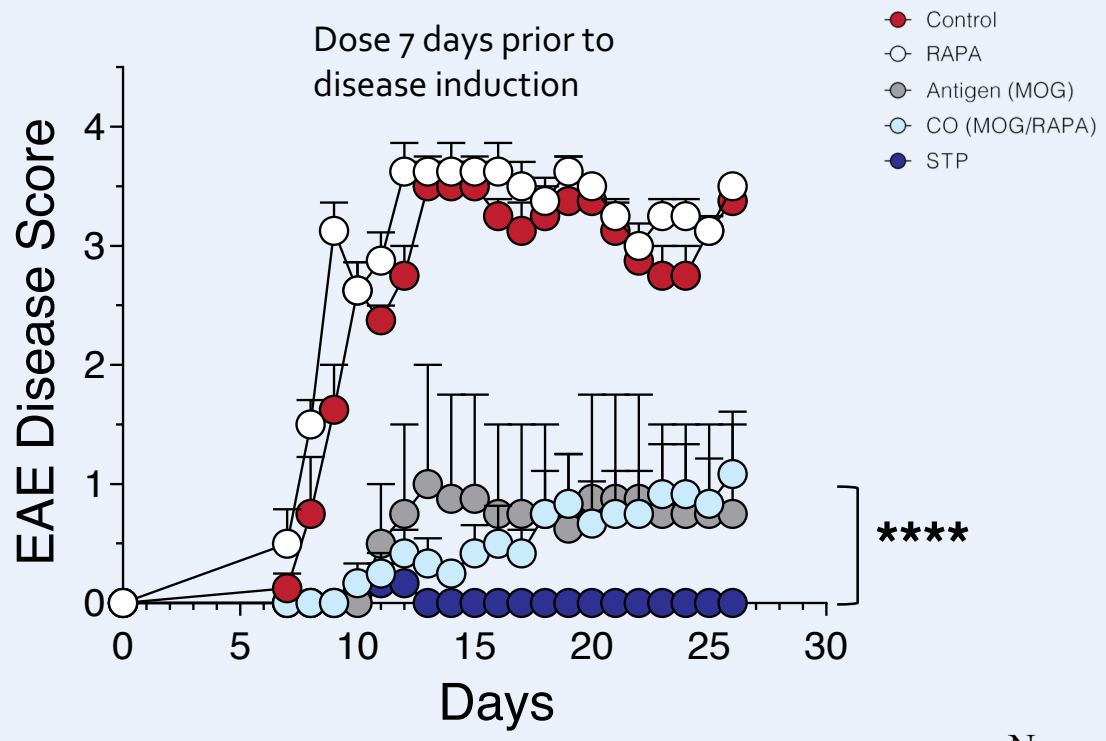
- Encapsulates and delivers multiple agents to target APCs and in optimal order
- Novel biodegradable composition built with FDA approved materials [poly lactic-co-glycolic acid (PLGA)].
- Encapsulants are not limited and can be generalized to:
  - Small molecule drugs on the outer layer
  - Multiple 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

STATERA TECHNOLOGY IN ANIMAL DISEASE MODEL: proof-of-concept in mouse model of MOG antibody disease

A single injection (i.p.) of our technology shows significant efficacy in both prevention and treatment in a gold standard animal disease model.

Prevention

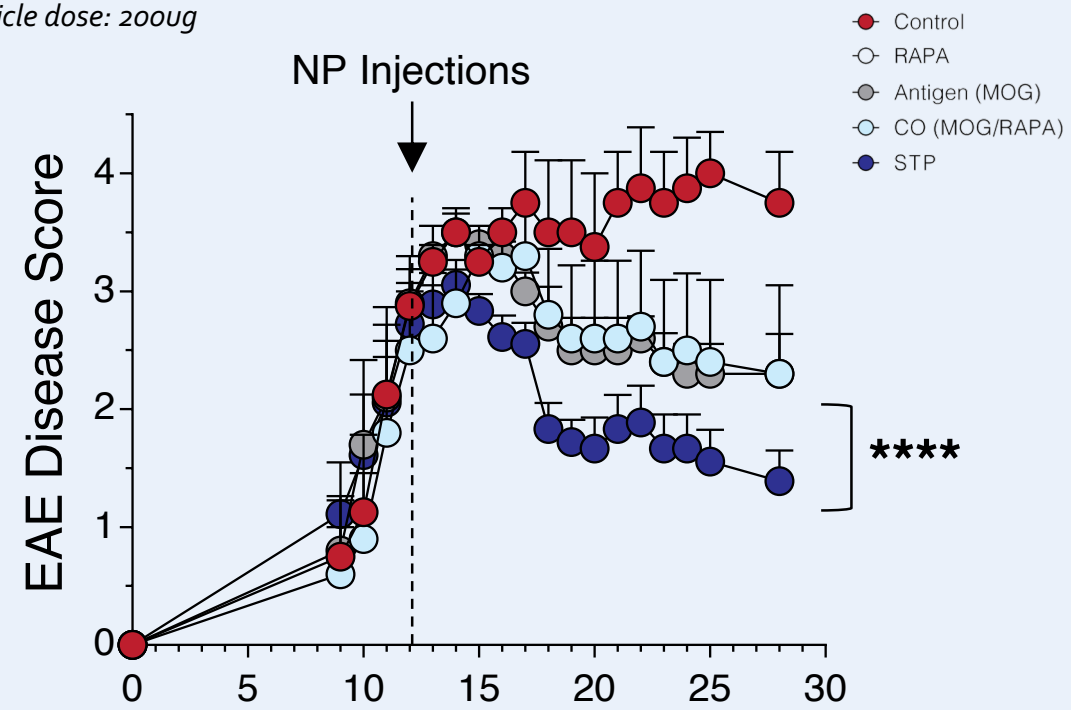
Particle dose: 200ug



$N_{STP} = 6$

Treatment

Particle dose: 200ug



$N_{STP} = 9$

Control = Empty PLGA vehicle
Antigen = PLGA particle releasing antigen from the inner core
Antigen/RAPA = PLGA particles releasing antigen and rapamycin from the inner core

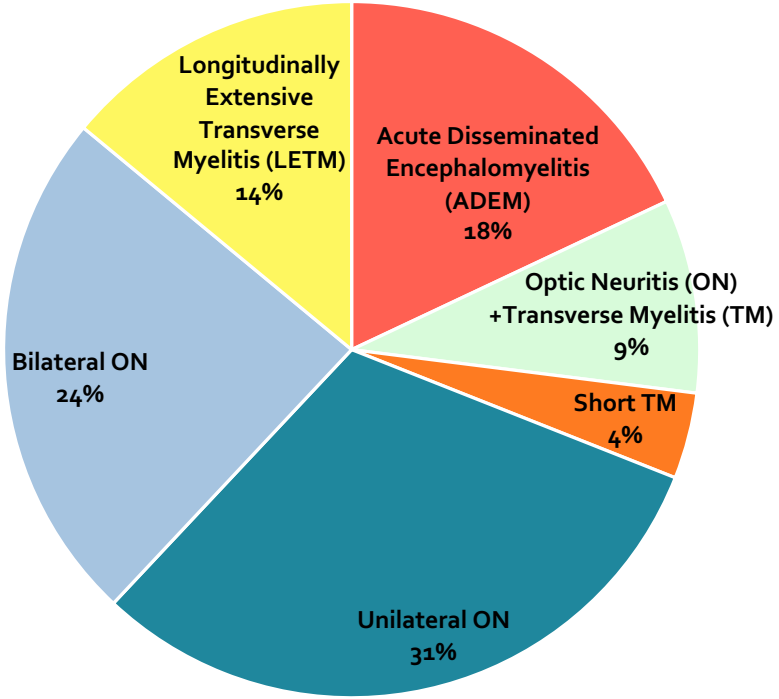
*(Han, P., Kong, P., et al. Spatio-Temporal Programming of Combinatorial Delivery Tunes the Amplification of Synergistic Therapeutic Response. (In revision)

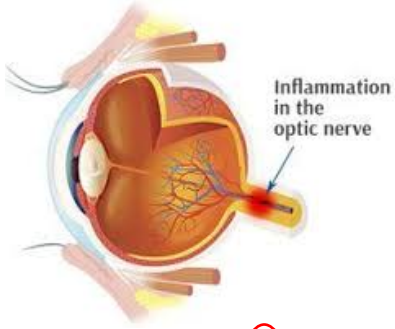
MOG-Antibody Disease (MOGAD)

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

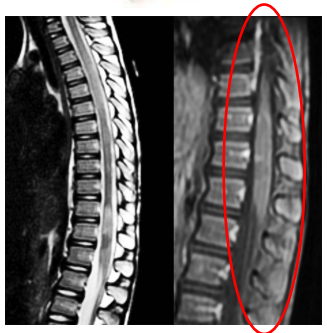
Disease Phenotype and symptoms

Epidemiology: 25K patients in the US and EU

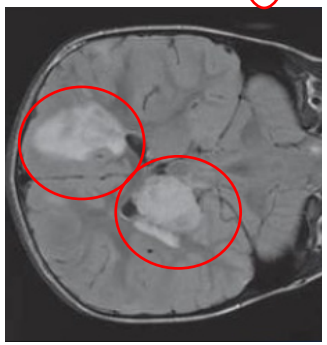




Optic Neuritis

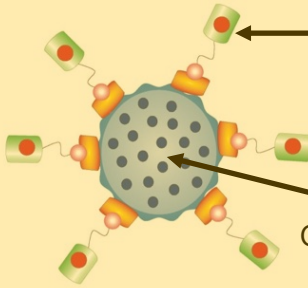


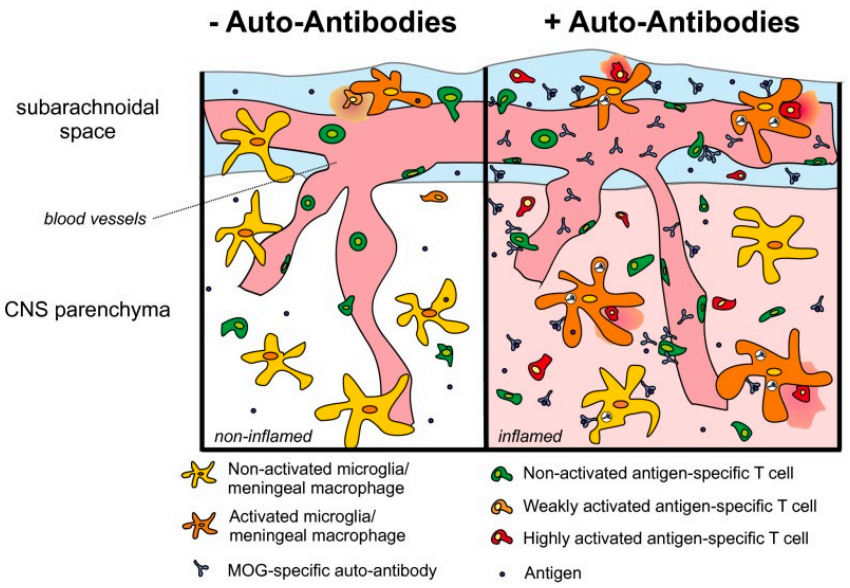
Transverse Myelitis



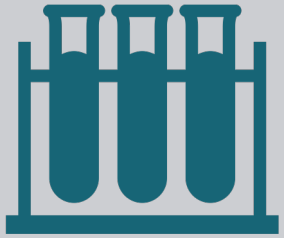
ADEM

Our Strategy (STP001)





STATERA THERAPEUTIC DISCOVERY PROCESS: ASSET EXPANSION



IDENTIFY

Candidate therapeutics are identified through academic and clinical research.

SCREEN

Candidate therapeutics are screened for optimal spatiotemporal configuration.

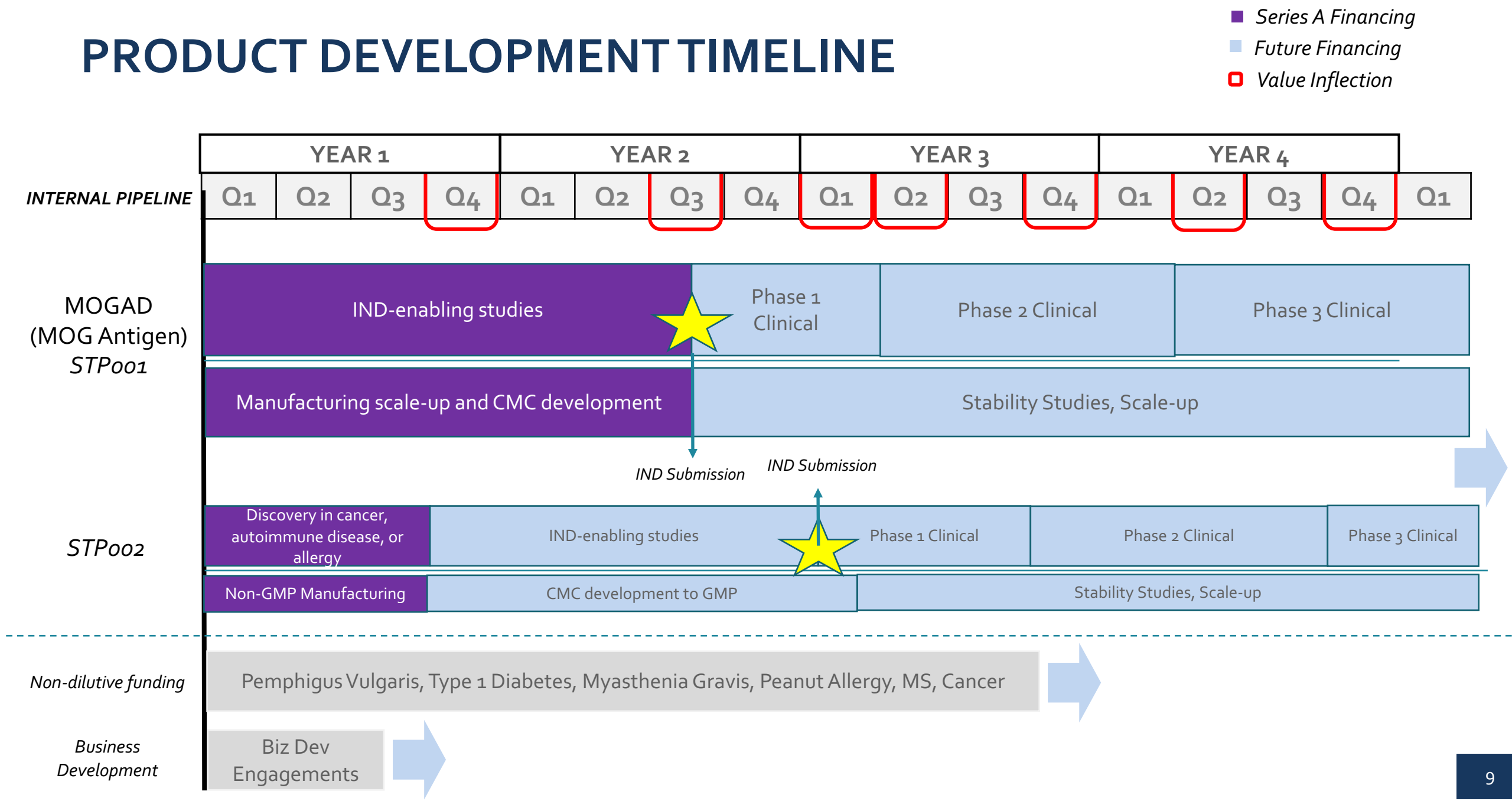
MANUFACTURE

STPs are manufactured with their optimal spatiotemporal conditions.

VALIDATE

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

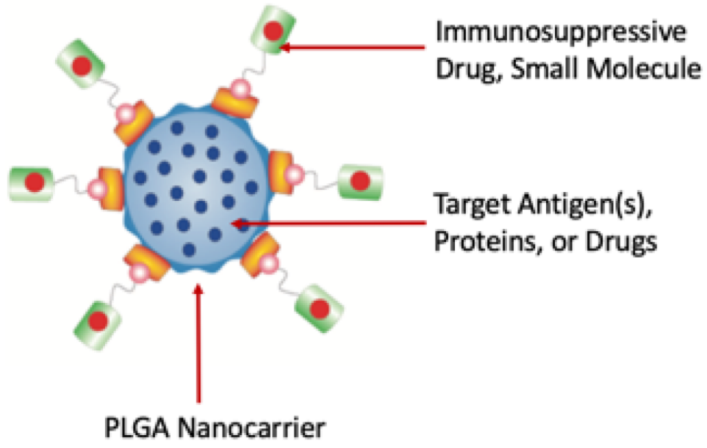
PRODUCT DEVELOPMENT TIMELINE



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.