

October 2023

Teralmmune BAUDAX BIO

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Highlights

Powerful Combined Team

Baudax Bio: Development and Commercialization

Teraimmune: Discovery Platform and Research

- IND cleared for TCR Treg, expected "once and done" treatment to eradicate "inhibitors/auto-antibodies" interfering with Factor VIII therapy for Hemophilia A.
- Q1 '24 target for first ever human TCR Treg study for any product – will be an open Phase 1/2a study of TI-168 in Hemophilia A with inhibitors. Results for early patients could confirm early tolerability and efficacy.

Senior Leadership Team

Gerri Henwood - President & CEO

Founder, President, CEO Baudax, Recro

President of Malvern Consulting Group

Founder, Pres., CEO Auxilium (NASDAQ: AUXL)

Founder, CEO IBAH (NASDAQ: CRO)

>10 years at SK&F (now GSK)

Yong Chan Kim, PhD - CSO

Former President & CEO, TeraImmune

Res Assis Prof., Uniformed Services University

Post-Doctoral Fellow, NIAID, NIH

Stewart Mc Callum, MD - Consulting CMO

EVP Medical Affairs, Baudax, Recro

Medical Director, GSK

Assistant Professor of Urology Stanford University

Staff Surgeon, Stanford University & Palo Alto VA Medical Center

Natalie McAndrews, CPA – PT CFO/PFO

Past Senior Finance roles with Tmunity,

Spark Therapeutics (startup through merger)

Renmatrix, Tengion

What is the opportunity?

Commercial opportunity could produce peak year sales of $50-100 Million, assuming TPP met.

- Expected Q1 ‘24 open and begin enrollment of Phase 1/2a TI 168 trial in Hemophilia A patients with inhibitors.
- Clinical trial for an orphan drug complication. Treatment expected to be “once and done” administration of patient’s own targeted Tregs (modified to block production of Factor VIII inhibitors in Hemophilia A).
- We believe a TCR Treg autologous product for elimination of the Factor VIII inhibitor in Hemophilia A patients can be developed and commercialized in a timely and cost-efficient manner.

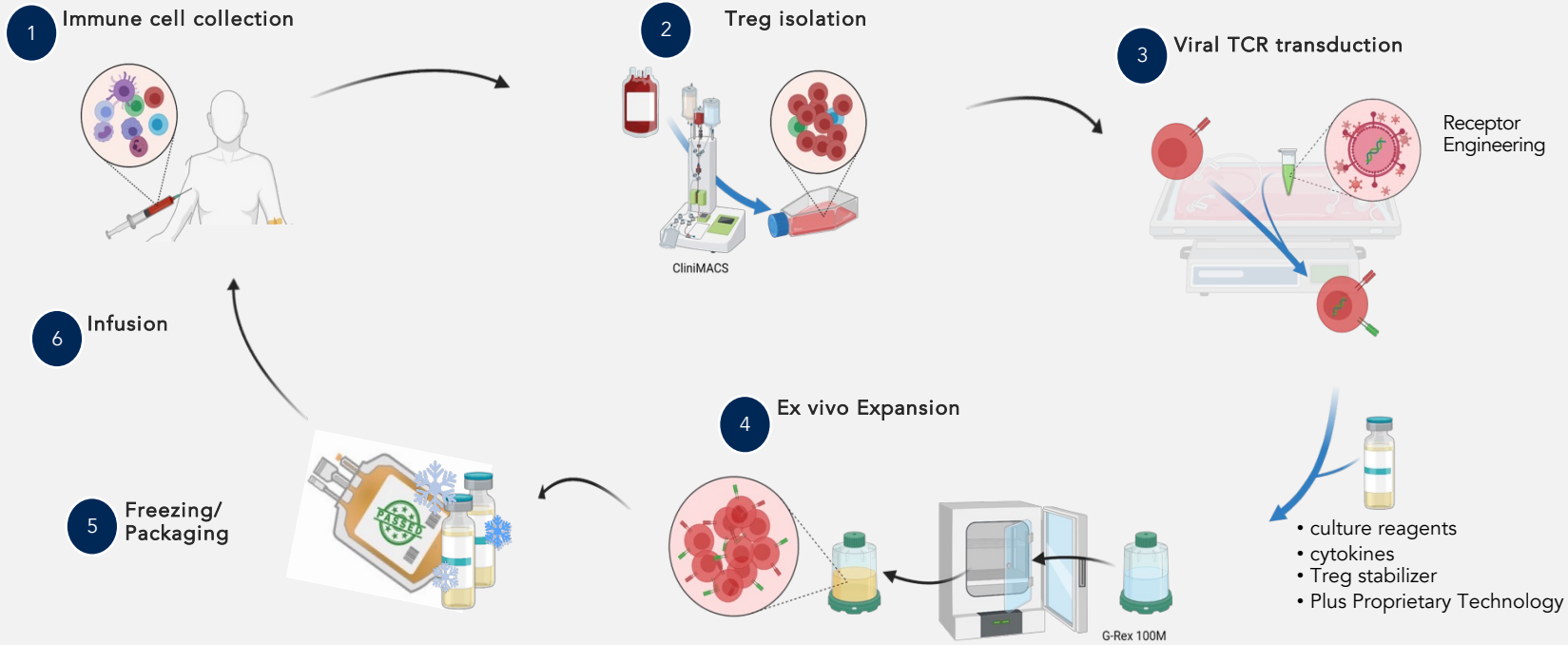
Hemophilia A with Inhibitors

- Estimated 180,000 Hemophilia A patients in the developed world
- Hemophilia A patients do not make Factor VIII, needed for normal blood clotting
- About 30% of the Hemophilia A patients develop antibodies to Factor VIII, called inhibitors that make it hard to use Factor VIII medicine for successful treatment

Source: The report on the WFH Annual Global Survey 2021; Facts about inhibitors, National Hemophilia Foundation, www.hemophila.org; Grandview research: Hemophilia Market Size, 2020

Fortune Bus. Insights.com/Hemophila; FDA.gov, Roctavian prescribinbg information, 2023, sec. 8.7.

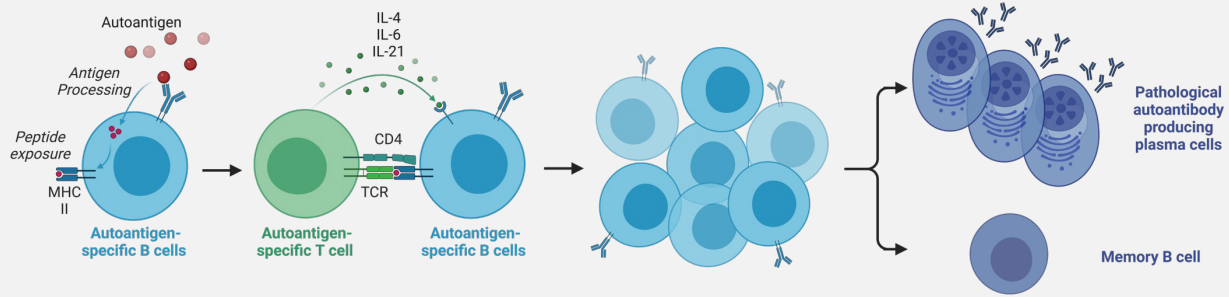
Proprietary First-In-Class Platform for Manufacturing TCR Tregs



- IP Protected and FDA IND cleared, TCR Treg manufacturing platform technology for the production of highly stable, pure, and select TCR Tregs are anticipated to treat multiple autoimmune conditions
- These unique TCR Tregs are intended to act to clear pathologic autoantibodies by inducing tolerance to a specific protein without systemic immune suppression (does not reduce systemic IgG)

TCR Treg Mechanism of Action in Autoimmune Disease

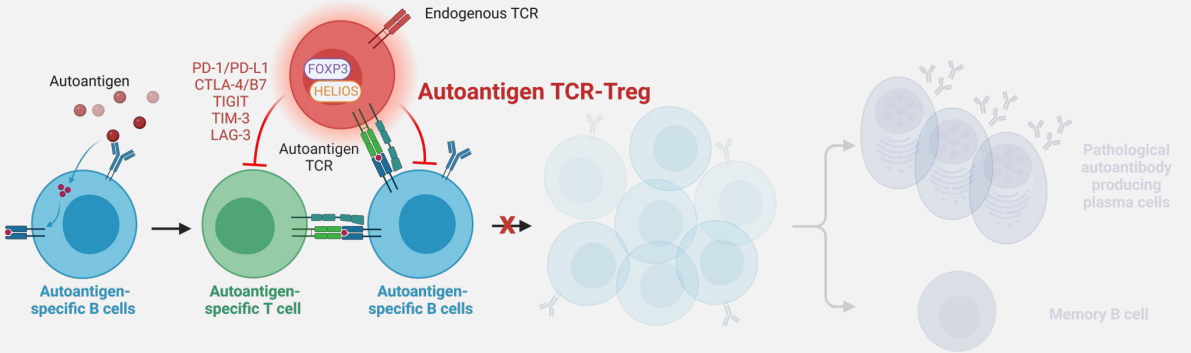
Autoimmune Disease



Antigen recognition induces expression of effector T cells, activating B cells

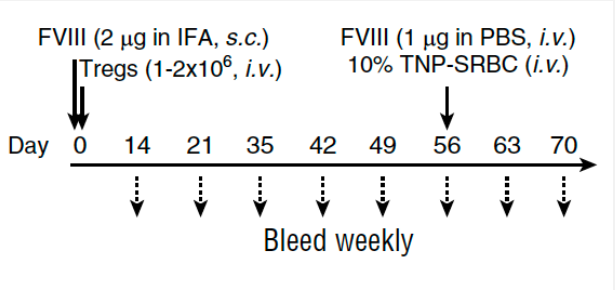
B cells proliferate and differentiate into autoantibody- secreting cells

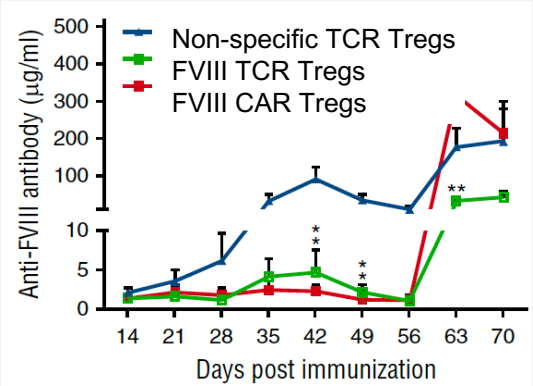
Treatment with TCR Tregs

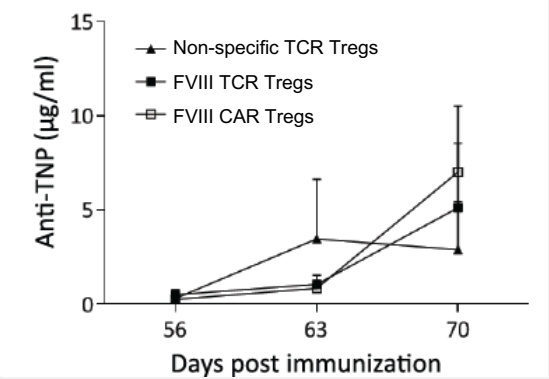


TCR Tregs block pathologic Autoantigen-specific B cells activation and differentiation

FVIII TCR-Tregs Suppress anti-FVIII Antibody Formation in HA* Mice







Study protocol

- Hemophilic mice were subcutaneously immunized with FVIII on day 0
- 4h after immunization, mice were infused with Control, TCR Tregs or CAR Tregs
- FVIII –specific antibody levels were monitored weekly, and mice rechallenged with FVIII on day 56

* HA =Hemophilia A

Time course of anti-FVIII antibody response

- FVIII Engineered Tregs (TCR and CAR) show significant FVIII-specific immunosuppressive efficacy
- TCR Tregs outperformed CAR Tregs in suppressing FVIII-specific antibodies
- Human Tregs not detectable after 14 days due to immunocompetent mouse model
- TNP antibodies did not differ between groups (antigen-specific suppression)
- Data strongly implies that FVIII TCR Tregs could provide a therapeutic option in controlling anti-FVIII antibody formation in refractory HA* patients

Source: Yoon, *et al.*, Blood 129(2): 238–245 2017; Anti-TNP data on file, TI.

TCR Treg Program

NEXT STEPS: Initiate TI-168 Clinical Program for treatment of Hemophilia A inhibitors

- TI-168 IND with associated preclinical and manufacturing data as well as clinical study protocol have been cleared.
- Initiating clinical study process
- Study site selection (specially qualified sites)
- IRB approval process – at specialized sites can be extended, but we believe 1 or more sites will be open in Q 1 2024
- Open study sites and enrollment of first patient
- First cohort of 3 patients – anticipate enrollment and early results in 1H ‘24
- Evaluate safety/tolerability and dosing/effect on inhibitor production

Research Program Priorities

Multiple Sclerosis (MS) TCR Treg research to target CNS auto-immunity

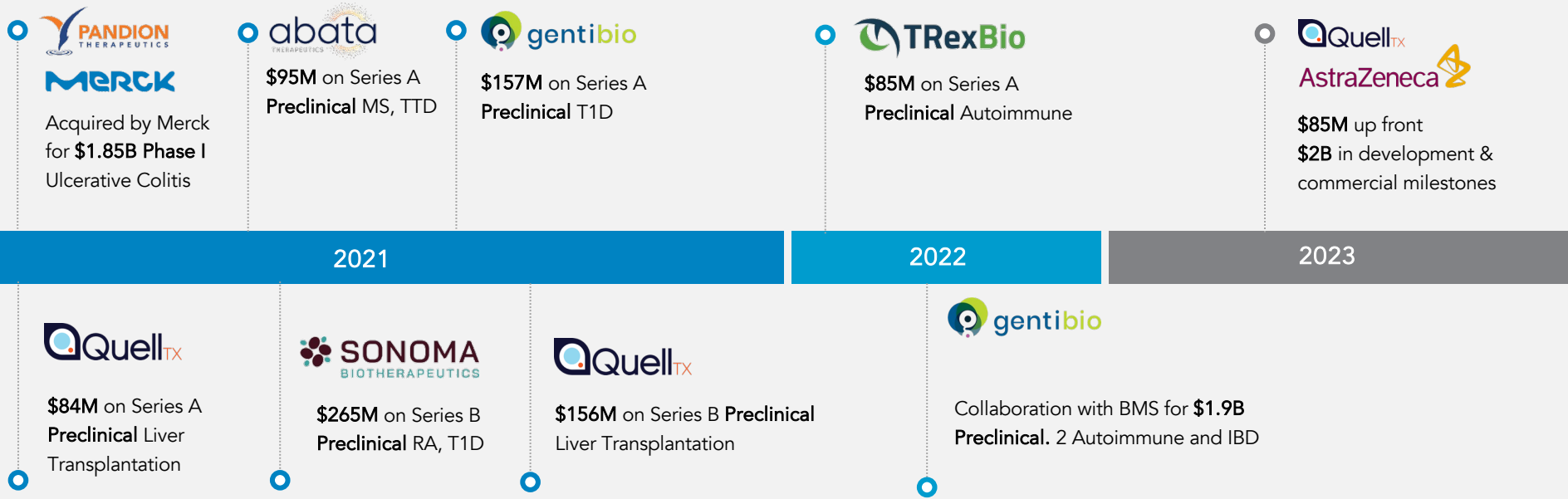
- Preclinical model development and qualification is completed
- CMC and preclinical model studies preparatory work for IND
- IND filing target : 2025

Myasthenia Gravis (MG) TCR Treg research to target anti-AChR* auto-antibody

- Develop AChR* TCR Treg
- Verify the TCR as appropriate for the target
- Preclinical model development and qualification of proposed TCR Treg
- CMC and preclinical model studies preparatory work for IND
- IND filing target : 2025

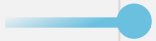
* Acetylcholine receptor (AChR)

Strong Interest in Treg Cell Therapies Companies

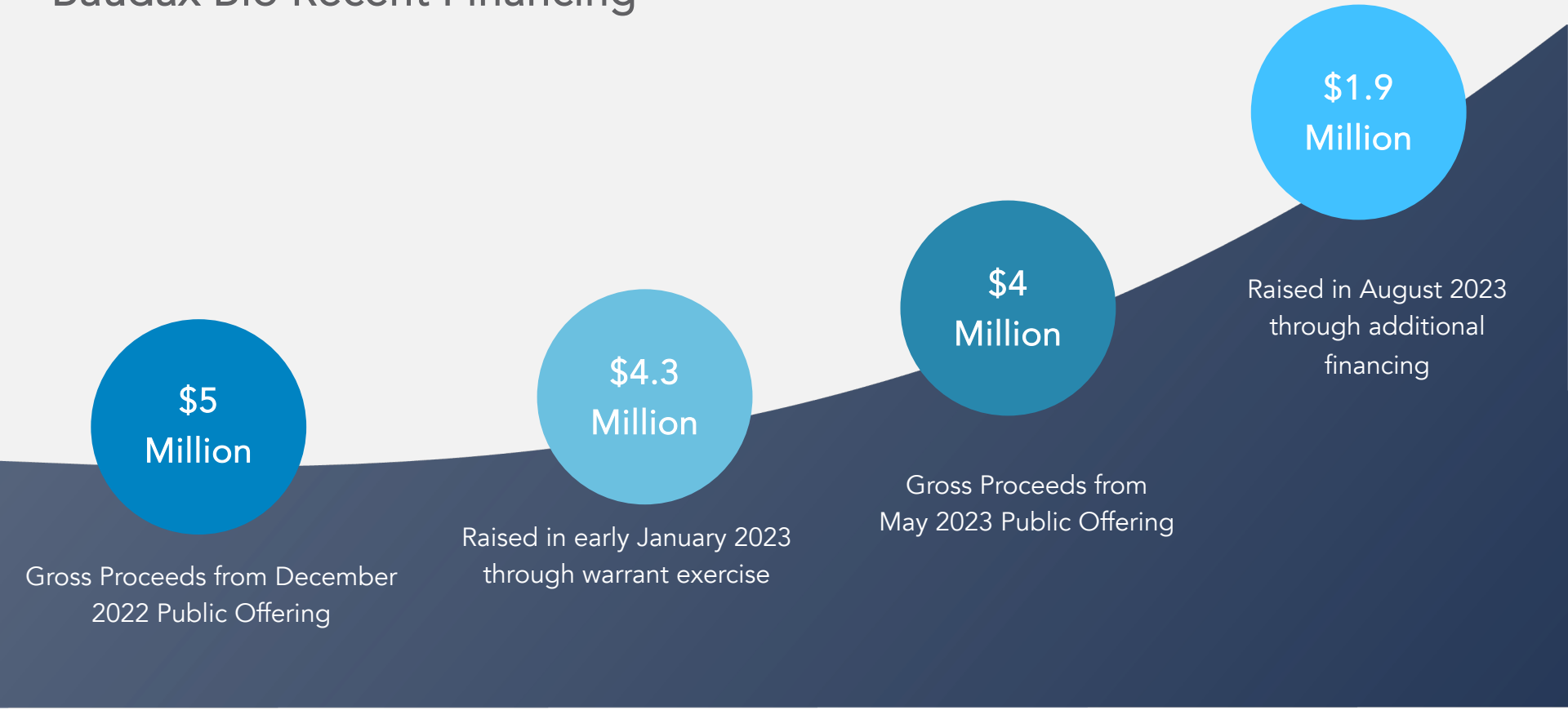


NMB Portfolio

NMB – Anesthesia Pipeline
Continue at modest, sustainable pace

	Pre-clinical	Phase 1	Phase 2	Phase 3	Milestones
NEUROMUSCULAR BLOCKING AGENTS (NMBs)					
IV Intermediate-action (BX1000)					Top-line data reported/Q2 2023
IV Ultra-short action (BX2000)					Last patient dosed/end ‘24
NMB REVERSAL (ANESTHESIA)					
BX3000					IND and combo study reversing BX1000 2024.

Baudax Bio Recent Financing



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