
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): July 17, 2023

Baudax Bio, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania
(State or other jurisdiction of
incorporation or organization)

001-39101
(Commission
File Number)

47-4639500
(I.R.S. Employer
Identification No.)

490 Lapp Road, Malvern, Pennsylvania
(Address of principal executive offices)

19355
(Zip Code)

Registrant's telephone number, including area code: (484) 395-2470

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of Each Class | Trading Symbol | Name of Exchange on Which Registered |
|--------------------------------|-------------------|---|
| Common Stock, par value \$0.01 | BXX | Nasdaq Capital Market |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On July 17, 2023, Baudax Bio, Inc. (the “Company”) updated information reflected in a slide presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. The Company will use the updated presentation in various meetings with investors from time to time.

Important Additional Information and Where to Find It

Baudax Bio, Inc., its directors and certain of its executive officers are deemed to be participants in the solicitation of proxies from Baudax Bio’s shareholders in connection with the matters to be considered at Baudax Bio’s 2023 Special Meeting of Shareholders. Information regarding the names of Baudax Bio’s directors and executive officers and their respective interests in Baudax Bio by security holdings or otherwise can be found in Baudax Bio’s proxy statement for its 2023 Annual Meeting of Shareholders, filed with the SEC on April 28, 2023. To the extent holdings of Baudax Bio’s securities have changed since the amounts set forth in Baudax Bio’s proxy statement for the 2023 Annual Meeting of Stockholders, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. These documents are available free of charge at the SEC’s website at www.sec.gov. Baudax Bio intends to file a proxy statement and accompanying proxy card with the SEC in connection with the solicitation of proxies from Baudax Bio shareholders in connection with the matters to be considered at Baudax Bio’s 2023 Special Meeting of Shareholders. Additional information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, will be set forth in Baudax Bio’s proxy statement for its 2023 Special Meeting, including the schedules and appendices thereto. **INVESTORS AND SHAREHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH PROXY STATEMENT AND THE ACCOMPANYING PROXY CARD AND ANY AMENDMENTS AND SUPPLEMENTS THERETO AS WELL AS ANY OTHER DOCUMENTS FILED BY BAUDAX BIO WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION.** Shareholders will be able to obtain copies of the proxy statement, any amendments or supplements to the proxy statement, the accompanying proxy card, and other documents filed by Baudax Bio with the SEC for no charge at the SEC’s website at www.sec.gov. Copies will also be available at no charge at the Investor Relations section of Baudax Bio’s corporate website at <https://www.baudaxbio.com/news-and-investors.com> or by contacting Baudax Bio’s Investor Relations at Baudax Bio, Inc., 490 Lapp Road, Malvern, PA 19355 or by calling Baudax Bio’s Investor Relations at (484) 395-2440.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

| <u>Exhibit No.</u> | <u>Document</u> |
|--------------------|---|
| 99.1 | Investor Presentation of Baudax Bio, Inc., dated July 17, 2023. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: July 17, 2023

Baudax Bio, Inc.

By: /s/ Gerri A. Henwood

Name: *Gerri A. Henwood*

Title: *President and Chief Executive Officer*



Overview

Forward Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding: uses of proceeds; projected cash runways; future product development plans; and stockholder approval of the conversion rights of the Series X Preferred Stock, in each case, that involve risks and uncertainties. Such forward-looking statements reflect Baudax Bio's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "may," "upcoming," "plan," "target," "goal," "intend," and "expect," and similar expressions, as they relate to Baudax Bio or its management, and TeraImmune or its management, are intended to identify such forward-looking statements. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on Baudax Bio's current beliefs, expectations and assumptions regarding the future of its business, future plans and strategies, clinical results and other future conditions. There are a number of important factors that could cause Baudax Bio's actual results to differ materially from those indicated or implied by such forward-looking statements including, without limitation: whether Baudax Bio will be able to successfully integrate the TeraImmune operations and realize the anticipated benefits of the acquisition of TeraImmune; whether Baudax Bio's shareholders approve the conversion of the Series X Preferred Stock and the required cash payment of the then-current fair value of the Series X Preferred Stock if such approval is not provided; whether Baudax Bio's cash resources will be sufficient to fund Baudax Bio's continuing operations and the newly acquired TeraImmune operations, including the liabilities of TeraImmune incurred in connection with the completion of the Merger; whether Baudax Bio's collaborations will be successful; whether Baudax Bio will be able to advance its current product candidate pipeline through pre-clinical studies and clinical trials, that interim results may not be indicative of final results in clinical trials, that earlier-stage trials may not be indicative of later-stage trials, the approvability of product candidates; whether Baudax Bio will be able to comply with the financial and other covenants under its credit facility; and whether Baudax Bio will be able to maintain its listing on the Nasdaq Capital Market. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Baudax Bio may not actually achieve the forecasts disclosed in such forward-looking statements, and you should not place undue reliance on such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to those set forth under the caption "Risk Factors" in Baudax Bio's most recent Annual Report on Form 10-K filed with the SEC, as well as discussions of potential risks, uncertainties, and other important factors in its subsequent filings with the SEC. Any forward-looking statement speaks only as of the date on which it was made. Neither Baudax Bio, nor any of its affiliates, advisors or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing Baudax Bio's views as of any date subsequent to the date hereof.

Important Additional Information and Where to Find It

Baudax Bio, Inc., its directors and certain of its executive officers are deemed to be participants in the solicitation of proxies from Baudax Bio's shareholders in connection with the matters to be considered at Baudax Bio's 2023 Special Meeting of Shareholders. Information regarding the names of Baudax Bio's directors and executive officers and their respective interests in Baudax Bio by security holdings or otherwise can be found in Baudax Bio's proxy statement for its 2022 Annual Meeting of Shareholders, filed with the SEC on April 28, 2023. To the extent holdings of Baudax Bio's securities have changed since the amounts set forth in Baudax Bio's proxy statement for the 2023 Annual Meeting of Stockholders, such changes have been reflected on Initial Statements of Beneficial Ownership on Form 3 or Statements of Change in Ownership on Form 4 filed with the SEC. These documents are available free of charge at the SEC's website at www.sec.gov. Baudax Bio intends to file a proxy statement and accompanying proxy card with the SEC in connection with the solicitation of proxies from Baudax Bio shareholders in connection with the matters to be considered at Baudax Bio's 2023 Special Meeting of Shareholders. Additional information regarding the identity of participants, and their direct or indirect interests, by security holdings or otherwise, will be set forth in Baudax Bio's proxy statement for its 2023 Special Meeting, including the schedules and appendices thereto. INVESTORS AND SHAREHOLDERS ARE STRONGLY ENCOURAGED TO READ ANY SUCH PROXY STATEMENT AND THE ACCOMPANYING PROXY CARD AND ANY AMENDMENTS AND SUPPLEMENTS THERETO AS WELL AS ANY OTHER DOCUMENTS FILED BY BAUDAX BIO WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE AS THEY WILL CONTAIN IMPORTANT INFORMATION. Shareholders will be able to obtain copies of the proxy statement, any amendments or supplements to the proxy statement, the accompanying proxy card, and other documents filed by Baudax Bio with the SEC for no charge at the SEC's website at www.sec.gov. Copies will also be available at no charge at the Investor Relations section of Baudax Bio's corporate website at <https://www.baudaxbio.com/news-and-investors.com> or by contacting Baudax Bio's Investor Relations at Baudax Bio, Inc., 490 Lapp Road, Malvern, PA 19355 or by calling Baudax Bio's Investor Relations at (484) 395-2440.

Baudax Bio + Teralmmune : Summary

“Sign and Close” Structure

- Structured as a stock-for-stock transaction, signed/closed 6/29/23
- Baudax equity holders owned ~18% (fully diluted) of combined company
- Balance of consideration in convertible-preferred, non-voting stock
- Baudax to seek stockholder approval of the conversion of the newly issued shares of preferred stock into common stock
- Shareholder proxy for conversion vote will require SEC submission

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 , Ph D - CSO

Former President & CEO, Teralmmune
Res Assis Prof., Uniformed Services University
Post-Doctoral Fellow, NIAID, NIH

Stewart Mc Callum, MD -Consulting CMO

EVP Medical Affairs, Recro
Medical Director, GSK
Assistant Professor of Urology Stanford University
Staff Surgeon, Stanford University & Palo Alto VA Medical Center

Jillian Dilmore, Principal Accounting Officer

Director of Accounting, Recro
Assistant Controller, Royal DSM
Senior Auditor, Deloitte & Touche

R & D Leadership

Significant discovery and drug development expertise

Yong Chan Kim, Ph D, CSO

Former President & CEO, Teralmmune

Res Assis Prof., Uniformed Services University

Post-Doctoral Fellow, NIAID, NIH

Jay Park, PhD, VP Strategy

Co-Founder, Former COO

Former VP Finance, Teralmmune

Postdoctoral Fellow, NHLBI, NIH

Jeong Heon Yoon, PhD - VP Research

Post-Doctoral Fellow, NCI, NIAID,USUHS

Stewart Mc Callum, MD, PT-EVP, Medical Affairs

EVP Medical Affairs, Recro

Medical Director, GSK

Assistant Professor of Urology Stanford University

Staff Surgeon, Stanford University & Palo Alto VA Medical Center

Randall Mack, PT-EVP, Development & Operations

EVP Development, Recro

VP Development & Operations, Adolor

VP Development, Auxilium

Director Venture Development, Abbott Labs (now Abbie)

Diane Myers, SVP Regulatory & Quality

SVP Regulatory & Quality, Recro

SVP Regulatory Affairs & Quality Assurance, MCG

VP Regulatory Affairs & Quality, Auxilium

>15 years at GSK



OVERVIEW

About Teralmmune

Clinical stage company focused on autoantibody disorders by harnessing the power, innovation, and specificity of TCR Treg Cell therapies

Regulatory T cells (Tregs) focused on diseases with known pathological autoantibody, with potential to provide possible "One-and Done" functional cure

We believe this is a « best in class » manufacturing platform for highly stable, pure and select TCR Tregs

Lead TCR Treg against FVIII autoantibodies in hemophilia A, with a cleared IND and poised to begin a Phase 1/2a trial. Value inflection point with proof of concept data expected within 12-15 months, on first 3 patients.

IP – Patents issued and filed on the platform technology and individual TCR constructs

Substantial commercial opportunity across multiple orphan indications with autoantibodies HA¹, MG², MN³, PV⁴, BP⁵, NMO⁶

Compelling valuation (relative to Treg comps)

First Indication

Hemophilia A With Inhibitors

Hemophilia A is significant bleeding disorder characterized by impaired clotting as a result of deficiencies in the production or coagulation factor VIII. Annual treatment cost can exceed \$1M USD.

Hemophilia patients have a tendency for **bleeding in joints, muscles, soft tissues, and within mucous membranes**, which can be either spontaneous or due to internal or external trauma, depending on the severity of the disease. **Lifelong condition** with limited treatment options. Hemophilia thereby affects the entire family.

30% of patients develop Inhibitors to FVIII¹. This adds complexity as patients do not respond to FVIII treatments. **Treating inhibitors is difficult and expensive.**

Inhibitors must be dealt with before a hemophilia A patient can be a candidate for hemophilia A gene therapy.

Unmet Treatment Needs



Curative Treatment



Decreased Treatment Costs



Treatment for Inhibitors



More Convenient Treatments

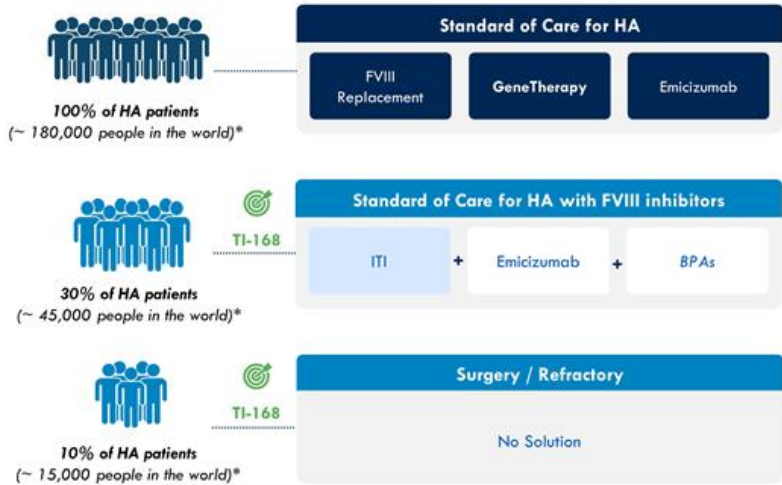
"Having a son with hemophilia and then, the added challenge of an inhibitor, is not always easy. As a parent, I would love to fix things and make everything better. The inhibitor has taken away a lot of the control that parents have in effectively managing hemophilia"

-Parent of a hemophilia patient

TI-168, an Inhibitor-Eradicating Therapy for Hemophilia A Patients with Inhibitors

Hemophilia A – estimated to be a \$9-10.5 Billion Market

30% of Hemophilia A Patients develop Inhibitors

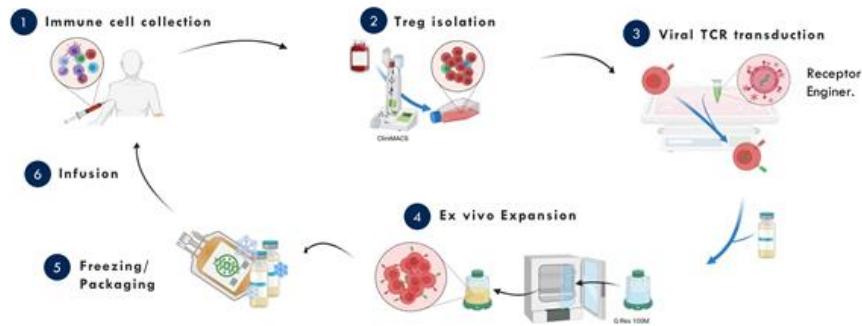


TI-168, an **Autologous TCR Treg** therapy for the management of Hemophilia A with inhibitors

- TI-168 is a **Replacement for ITI** – NOT competitive with FVIII replacements or emicizumab
- **Complementary therapy** to FVIII Therapeutics – Therapeutically for Hemophilia A products from Shire, CSL, Pfizer, Bayer, Novo N, Sanofi, and others as these patients currently cannot receive FVIII (30% of patients)
- Intended to be **“One-and-Done”** solution with **functional cure** potential for treatment of FVIII inhibitors
- Intended to improve treatment outcomes, economics, convenience
- May result in **lower use of bypass agents (BPAs)** such as FVIIa and aPCC

Inhibitors are contraindicated for gene therapy ; TI-168 could be a complementary therapy

Proprietary First-In-Class Platform for Manufacturing TCR Tregs



Platform for Autologous T Cell Therapy

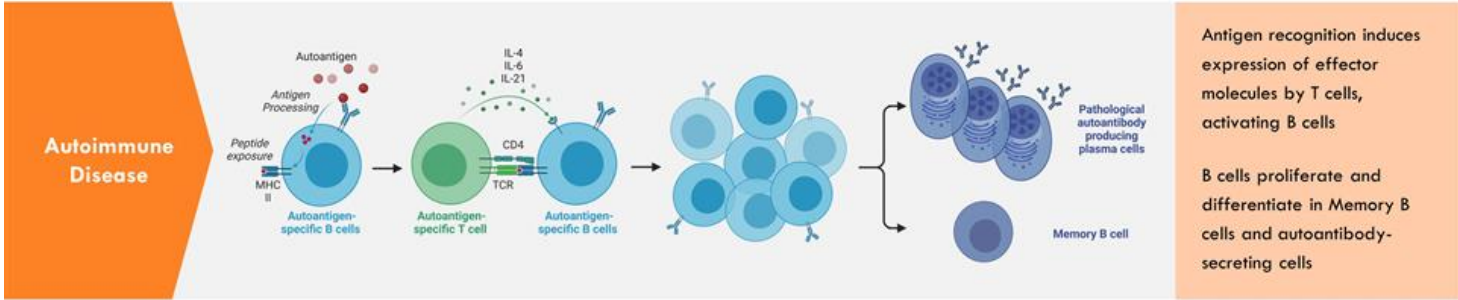
- **IP Protected and FDA IND cleared, TCR Treg** manufacturing platform technology for the production of highly stable, pure, and select TCR Tregs are anticipated to treat **multiple** autoimmune conditions
- These **unique** TCR Tregs are intended to act to clear pathologic autoantibodies by inducing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

Manufacturing optionality

(Academic institutions /and TI facility– in process to be GMP ready)

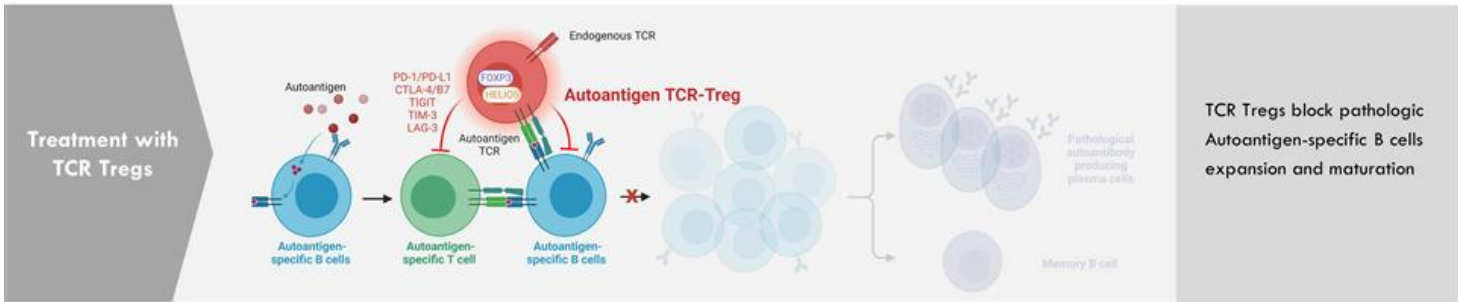
- Foxp3⁺Helios⁺ Tregs, we believe “**best-in-class**” clinical-grade Treg cells
- Consistent Treg production **without lot-to-lot variation**
- Standard cGMP Treg production **without gene modification**
- **Universal** target-specific Treg production platform

TCR Treg Mechanism of Action in Autoimmune Disease



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

B cells proliferate and differentiate in Memory B cells and autoantibody-secreting cells



TCR Tregs block pathologic Autoantigen-specific B cells expansion and maturation

TCR Treg Program

NEXT STEPS: Initiate TI-168 Clinical Program

- TI-168 -Initiate clinical study process
- Study site selection (specially qualified sites)
- IRB approval process –at specialized sites can be extended, est. 6-12 months

- Open study sites and enrollment of first patient
- First cohort of 3 patients –anticipate enrollment and POC within 12-15 months
- Evaluate safety/tolerability and dosing/effect on inhibitor production

Research Program Priorities for 2023/2024

- Develop AChR TCR Treg
 - Verify the TCR Treg as appropriate for the target
 - Preclinical model development and qualification
 - CMC and preclinical model studies preparatory work for IND
 - IND filing target : late 2024/early 2025
-
- Preclinical model development and qualification is completed.
 - CMC and preclinical model studies preparatory work for IND
 - IND filing target : 2025

Teralmmune is a Leading Developer of First-in-Class TCR Treg Cell Therapies Targeting Autoimmune Disease

Teralmmune's TCR approach in autoimmune diseases is more specific than CAR-Treg and is designed to minimize off-target effects

CAR-Treg – Engineering company in autoimmune disease



Cell surface antigens only

MHC-independent

Intracellular signaling domains

100+ target molecules required for activation

TCR Treg cell therapy in autoimmune disease



TCR Highly targeted and designed to minimize the risk for off target organ biodistribution. Teralmmune has the only cleared TCR Treg

IND for use in Hemophilia A patients with inhibitors.



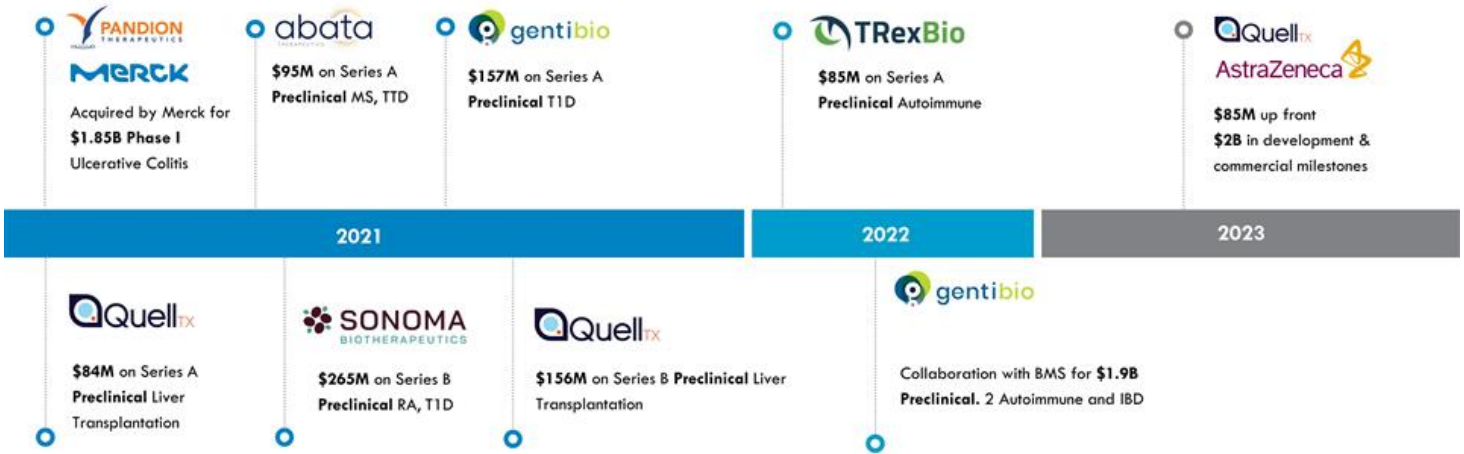
Cell surface and Intracellular antigens

MHC-dependent (genetic restriction)

Proximal signaling molecules/ coreceptors

Only 1 target molecule required for activation

Strong Interest in Treg Cell Therapies Companies





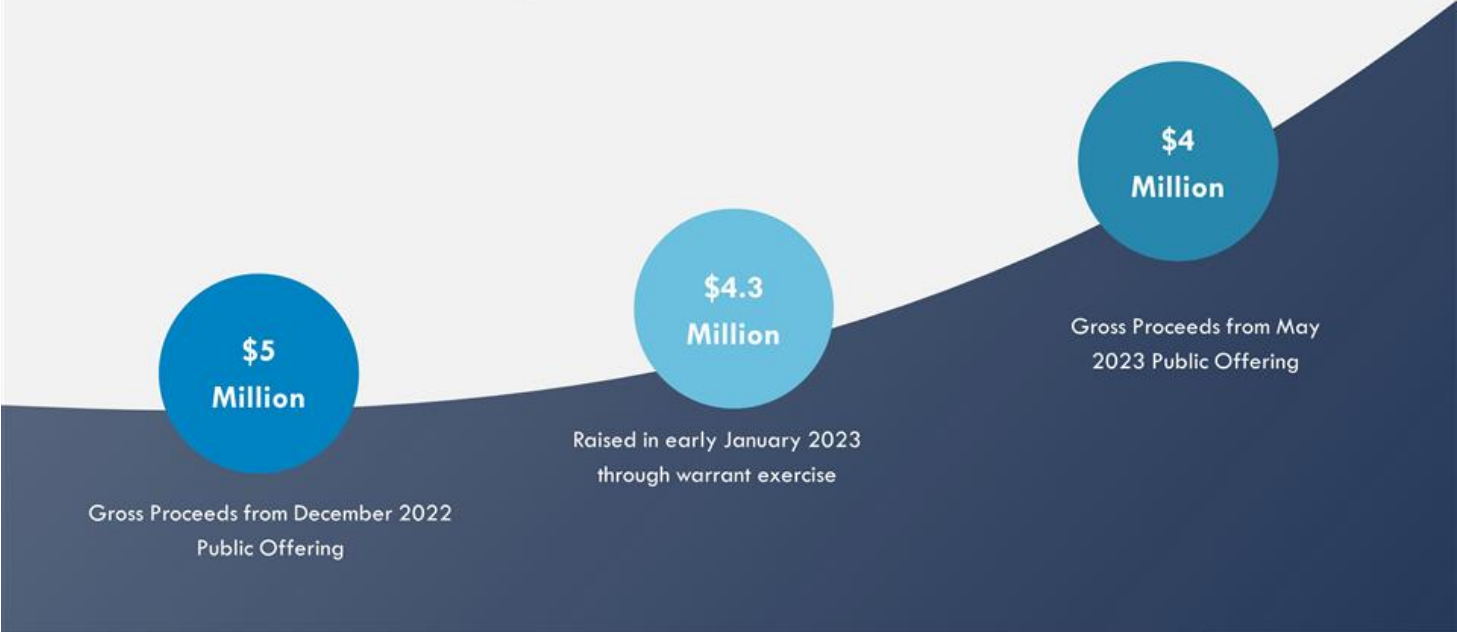
NMB Portfolio

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 filing Q4 2023. Combo study reversing BX1000 end 1H 2024. |

Baudax Bio Recent Financing



About Teralmmune

Clinical stage company focused on autoantibody disorders by harnessing the power, innovation, and specificity of TCR Treg Cell therapies

Regulatory T cells (Tregs) focused on diseases with known pathological autoantibody, with potential to provide possible "One-and Done" functional cure

We believe this is a « best in class » manufacturing platform for highly stable, pure and select TCR Tregs

Lead TCR Treg against FVIII autoantibodies in Hemophilia A, with a cleared IND and poised to begin a Phase 1/2a trial. Value inflection point with Proof of Concept data expected within 12-15 months, on first 3 patients.

IP – Patents issued and filed on the platform technology and individual TCR constructs

Substantial commercial opportunity across multiple orphan indications with autoantibodies HA¹, MG², MN³, PV⁴, BP⁵, NMO⁶

Compelling valuation (relative to Treg comps)



Contact Information

Mike Moyer
LifeSci Advisors
mmoyer@lifesciadvisors.com

APPENDIX

Inhibitor Eradication Remains The Goal of Treatment for HA with Inhibitors

EXPERT REVIEW OF HEMATOLOGY
2021, VOL. 14, NO. 2, 143–148
<https://doi.org/10.1080/17474096.2021.1875817>

Taylor & Francis
Taylor & Francis Group

SPECIAL REPORT

OPEN ACCESS

Check for updates

Key questions in the new hemophilia era: update on concomitant use of FVIII and emicizumab in hemophilia A patients with inhibitors

Manuel Carcao^a, Maria Elisa Mancuso^a, Guy Young^a and Victor Jiménez-Yuste^a

^aDivision of Thrombotic and Hemostatic Disorders, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, Torrance, CA, USA

UpToDate[®] Official reprint from UpToDate[®]
www.uptodate.com © 2023 UpToDate, Inc. and/or its affiliates. All Rights Reserved.

Wolters Kluwer

Inhibitors in hemophilia: Mechanisms, prevalence, diagnosis, and eradication

Authors: W Keith Hoops, MD, Amy D Shapiro, MD
Section Editor: Lawrence LK Leung, MD
Deputy Editor: Received: 23 September 2021 | Revised: 12 November 2021 | Accepted: 29 November 2021
All topics: DOI: 10.1111/hae.14470
Literature

ORIGINAL ARTICLE

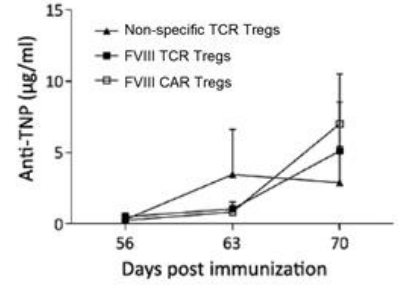
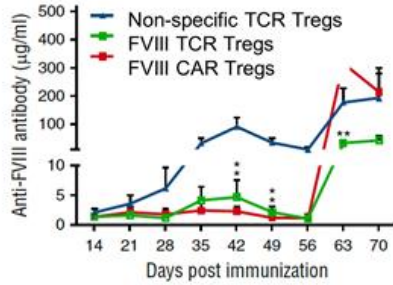
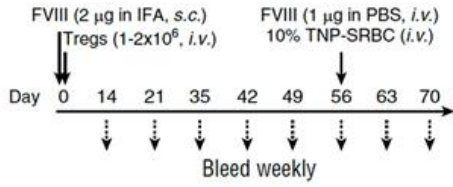
Haemophilia WILEY

Immune tolerance induction in the era of emicizumab – still the first choice for patients with haemophilia A and inhibitors?

Katharina Holstein¹ | Sandra Le Quellec² | Robert Klamroth³

- Inhibitor eradication remains the clinical goal
- ITI is the primary therapeutic strategy
- All patients should be offered at least one attempt at ITI
- Emicizumab monotherapy is an option for inhibitor patients who must delay or are unable/unwilling to undergo ITI, and those who fail ITI

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 antibody levels were monitored weekly, and mice rechallenged with FVIII on day 56

Time course of anti-FVIII antibody response

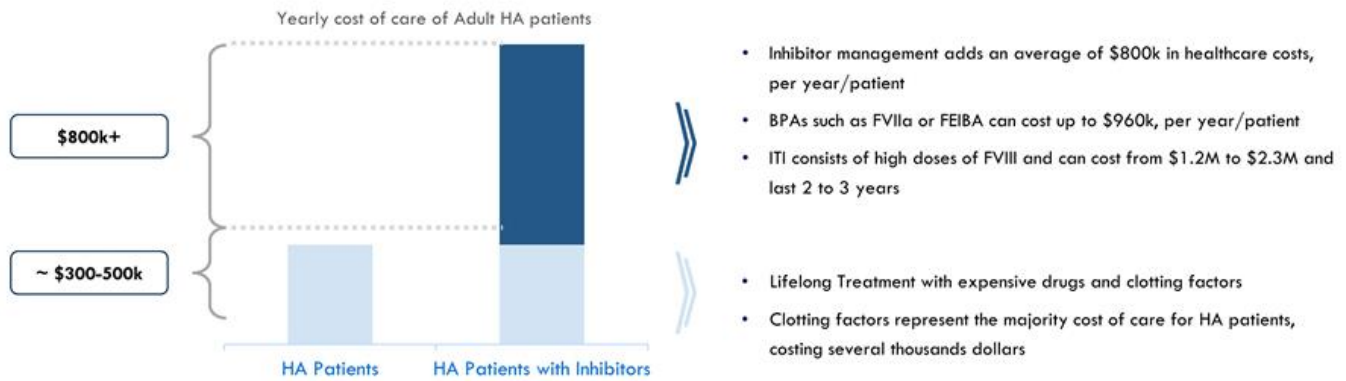
- FVIII Engineered Tregs (TCR and CAR) show significant FVIII-specific immunosuppressive efficacy
- TCR Tregs outperformed CAR Tregs in suppressing FVIII-specific antibodies
- Human Tregs not detectable after 14 days due to immunocompetent mouse model
- TNP antibodies did not differ between groups (antigen-specific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

Limitations of Currently Available Therapies for HA with Inhibitors

TI-168 is designed to overcome limitations of existing therapeutics by providing a durable solution for the management of inhibitors

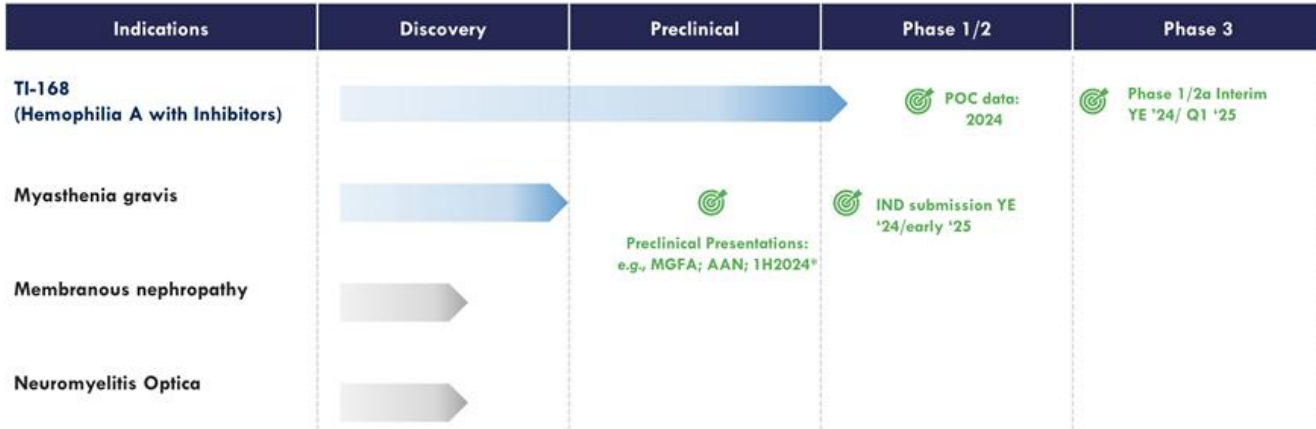
| | Immune Tolerance Induction (ITI) | Products that Mimic Factor VIII (emicizumab) | Bypassing Agents (BPAs) (Factor VIIa and aPCC) |
|-------------|---|---|--|
| MoA | Elimination of inhibitors: repeat administration of FVIII until the body is trained to accept it (tolerized) | <ul style="list-style-type: none"> Bleeding prophylaxis Replaces the function of Factor VIII without being affected by inhibitors Can be used to prevent bleeding prophylaxis episodes in people with Hemophilia A | <ul style="list-style-type: none"> Spontaneous and breakthrough bleeding Helps the blood form normal clots Does not replace missing clotting factor Correct the clotting process by going around (or bypassing) ineffective factor |
| Limitations | <ul style="list-style-type: none"> 60% of patients do not respond to ITI Recurrence in 29% of patients Expensive, inconvenient, time consuming (spans years) Patients not eligible for gene therapy given history of inhibitor and risk of recurrence | <ul style="list-style-type: none"> Still need to treat spontaneous and traumatic bleeds with BPAs Risk of thrombosis when aPCC is used with emicizumab for spontaneous or traumatic bleeds | <ul style="list-style-type: none"> Lacks universal standards or tests to stem bleeding Multiply dose adjustments and sequencing of drugs Associated with thrombotic events Lower efficacy, very expensive |
| | TI-168 replaces ITI | | |

Pressing Need for Novel Cost-Effective Therapies for HA Patients with Inhibitors







- TI-168, HA patients would avoid the cost, inconvenience, and limited efficacy of ITI and get a convenient One-and-Done solution.
- Immune tolerance established with Treg therapy, patients would get prophylactic factor VIII (such as long acting Altuviiio) or emicizumab
- Ability to receive FVIII for breakthrough / traumatic bleeds which would reduce the spend on NovoSeven (>\$1Bn of sales) and FEIBA (>\$330M of sales)
- TI-168 patients with FVIII tolerance would be candidates for gene therapy (today any patient with inhibitor history is excluded due to the risk of severe autoimmune reaction to the liver)

Positive TI-168 Readout Paves the Way for Follow-on Indications with Well-Characterized Pathological Autoantibodies

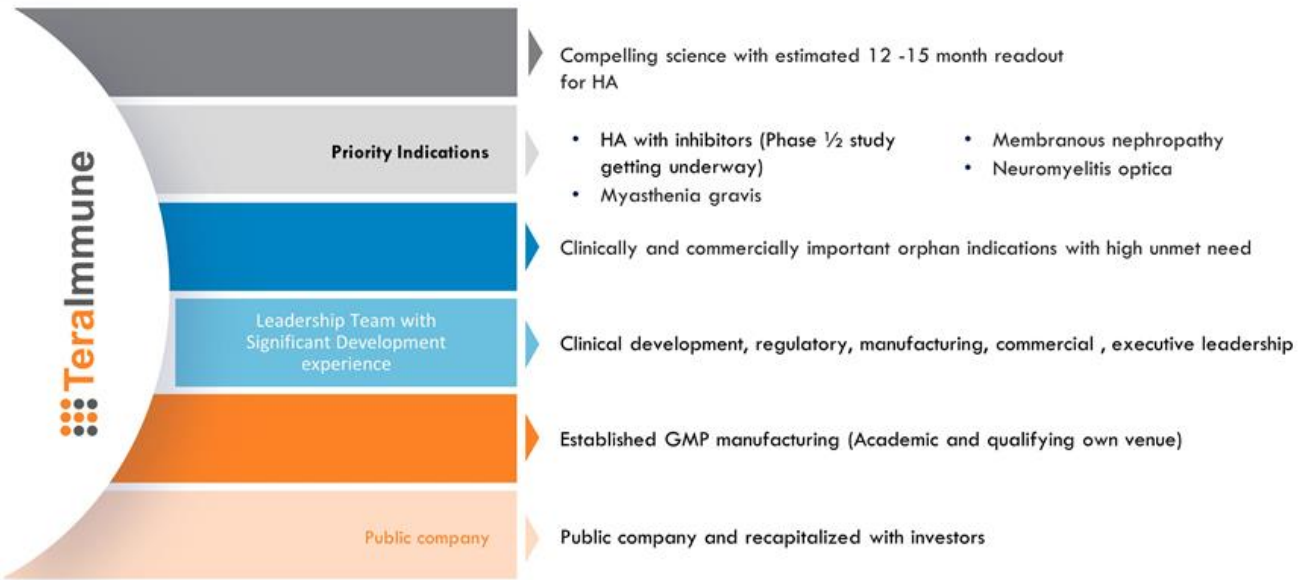


Mid -2024: FPI in hemophilia A with inhibitors
 2H 2024: POC first cohort **provides proof of clinical utility** through Factor VIII antibody titer reduction
 2025: **Target for IND Submission in MG**

TeralImmune's Competitive Edge Compared to its Closest Peers

| |  TeralImmune |  SONOMA BIOTHERAPEUTICS |  gentibio |  Quell ^{rx} |
|--|---|--|--|--|
| Funding History | Pre-A: \$10M | Series A: \$70M Series B: \$265M | Seed: \$20M Series A: \$157M | Series A: \$83.5M Series B: \$156M |
| Dev. Stage | IND approved (2022) | Pre-clinical | Pre-clinical | Phase 1/2 in UK |
| Product | TCR Treg | Teff debulking biologics, CAR Treg | CAR Treg, TCR Treg | CAR Treg |
| Virus | 1 virus: TCR | 1 virus: CAR | 3 viruses: CAR; Foxp3; IL-2R | 1-3 viruses: CAR; Foxp3; safety switch |
| Manufacturing: | receptor only | combination of Teff debulking biologic with CAR Treg | multiple virus transduction | multiple gene transduction |
| Vein to vein Time | 15 days | >14 days | 2-4 weeks | ~14 days |
| Manufacturing: Lot-to-lot variation | high number of Tregs with high purity by non-viral expansion Expected variability lo | ___no data | Possible generation of non-functional Treg, or Treg transduced with only 1-2 genes | Possible generation of non-functional Treg, or Treg transduced with only 1-2 genes |
| Possible Safety issues | We believe-minimal risk of vector insertional mutagenesis in final products (use of a single virus) | N/A: Teff debulking strategy to be defined prior to treatment combination. Potentially higher when combined with CAR Treg | increased risk of vector insertional mutagenesis in final products (virus with long genome size or multiple viruses) possible | increased risk of vector insertional mutagenesis in final products (virus with long genome size or multiple viruses) possible |

Addressing High Unmet Need Orphan Conditions in Established Markets with Demonstrated Investor Interest



NMB portfolio offers potential to improve anesthesia patient management

Rapid onset/offset may increase procedure capacity, reduce costs

| AGENT | DURATION OF ACTION | TARGET PROFILE |
|--------|---|---|
| BX1000 | Intermediate duration of action (est. 30-45 mins) | Rapid onset Predictable offset without reversal |
| BX2000 | Ultra short acting (est. 10-15 mins) | Rapid onset Predictable offset without reversal |
| BX3000 | Rapid offset (2-5 min) | Specific for BX1000 and BX2000. Rapid Chemical reversal of neuromuscular blockade from any depth. Predictable dosing for rapid reversal |

Baudax NMB Portfolio

Added value at very modest, sustainable pace

BX1000

Positive topline results reported Phase 2 in Q2 2023

BX2000

Phase 1 Dose escalation in progress, completion expected late 2024

BX3000

IND filing expected early Q4 2023

Combination BX1000/ BX3000

Small cohort study anticipated end of 1H 2024



NMB Overview

~400 million patients receive NMB agents annually*

Used to induce rapid total paralysis to permit intubation and muscle relaxation during surgery or in ventilated patients

Used in the operating room/ASC to optimize surgical conditions

Additional use in ICU to facilitate mechanical ventilation

Procedural use increasing with growth of laparoscopic abdominal procedures