UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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): February 7, 2023

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada	**001-36019**	**26-1434750**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

26 Main Street, Chatham,New Jersey 07928
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (862) 904-8182

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(s)	Name of each exchange on which registered
Common Stock	TNXP	The 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 7.01 Regulation FD Disclosure.

Tonix Pharmaceuticals Holding Corp. (the "Company") will present certain information regarding the Company and its product candidates at The Wall Street Conference on February 7, 2023. A copy of the presentation, which may contain nonpublic information, is filed as Exhibit 99.01 hereto and incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.01 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the United States Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the United States Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	**Description.**
99.01	The Wall Street Conference Presentation by the Company
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

Pursuant to the requirement 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.

TONIX PHARMACEUTICALS HOLDING CORP.

Date: February 7, 2023

By: /s/ Bradley Saenger
Bradley Saenger
Chief Financial Officer

Exhibit 99.01

Cautionary Note on Forward-Looking Statements

Certain statements in this presentation regarding strategic plans, expectations and objectives for future operations or results are "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. The forward-looking statements in this presentation are made as of the date of this presentation, even if subsequently made available by Tonix on its website or otherwise. Tonix does not undertake an obligation to update or revise any forward-looking statement, except as required by law. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the "SEC") on March 14, 2022, and periodic reports and current reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements.

TONIX PHARMACEUTICALS

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Who We Are

OUR MISSION

Tonix Pharmaceuticals is committed to improving population health by **inventing and developing** innovative therapies and vaccines, through **broad in-house capabilities and creative collaborations**, to help address important unmet needs.

OUR VISION

Tonix strives to be a leader in providing **novel drug therapies and vaccines** to **improve population health around the world.**

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Investment Highlights

DIVERSE PIPELINE

Tonix's core focus is on **central nervous system** disorders, but we also target unmet needs across multiple therapeutic areas including **immunology, infectious disease** and **rare disease.**

IN-HOUSE CAPABILITIES

Investment in domestic, **in-house, R&D and manufacturing** to accelerate development timelines and improve the ability to respond to pandemics.

STRATEGIC PARTNERSHIPS

Partnering strategically with other **biotech companies**, **world-class academic and non-profit research organizations** to bring innovative therapeutics to market faster.

FINANCIAL POSITION

Tonix had approximately **$120 M in cash and cash equivalents** as of 12/31/22. Tonix has no debt.

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Pipeline: Key Programs

Candidates*	Indication	Status/Next Milestone
TNX-102 SL[1]	Fibromyalgia (FM) Posttraumatic Stress Disorder (PTSD) Long COVID (PASC[2])	Mid-Phase 3 - >50% enrolled Phase 2, Targeted 2Q 2023 Start Phase 2 - enrolling
TNX-1300[3]	Cocaine Intoxication - *FDA Breakthrough Designation*	Mid-Phase 2, Targeted 2Q 2023 Start
TNX-1900[4]	Migraine, Craniofacial Pain and Binge Eating Disorder	Phase 2, Targeted 1Q 2023 Start[5]
TNX-601 ER	Depression, PTSD, Neurocognitive Dysfunction from Steroids	Phase 2, Targeted 1Q 2023 Start[6]
TNX-1600[7]	Depression, PTSD and ADHD	Preclinical
TNX-2900[8]	Prader-Willi Syndrome - *FDA Orphan Drug Designation*	Preclinical
TNX-1500[9]	Organ Transplant Rejection/ Autoimmune Conditions	Phase 1, Targeted 2Q 2023 Start
TNX-1700[10]	Gastric and colorectal cancers	Preclinical
TNX-801[11]	Smallpox and monkeypox vaccine	Phase 1, Targeted 2H 2023 Start
TNX-1850[12]	COVID-19 Vaccine (horsepox-based live virus vaccine)	Preclinical
TNX-2300[13]	COVID-19 Vaccine	Preclinical
TNX-3600[14]	COVID-19 Therapeutic Platform (fully human monoclonal antibodies)	Preclinical
TNX-3700[15]	COVID-19 Vaccine (zinc nanoparticle mRNA technology)	Preclinical
TNX-3800[16]	COVID-19 Therapeutic/Preventative (humanized monoclonal antibodies)	Preclinical

**All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*
[1]TNX-102 SL (cyclobenzaprine HCl sublingual tablets) is also in development for Agitation in Alzheimer's Disease (AAD) and Alcohol Use Disorder (AUD). Both indications are Phase 2 ready.
[2]Post-Acute Sequelae of COVID-19.
[3]TNX-1300 (double-mutant cocaine esterase) was licensed from Columbia University.
[4]Acquired from Trigemina; license agreement with Stanford University; IND cleared for the prevention of migraine indication; Planned Binge Eating Disorder study is expected to be investigator initiated.
[5]A Phase 2 trial under an investigator-initiated IND has been completed in the U.S. using TNX-1900; Phase 2 for the prevention of migraine headache expected to start 1Q 2023
[6] Phase 1 trial for formulation development was completed outside of the U.S; Phase 2 expected to start 1Q 2023
[7]Acquired from TRImaran Pharma; license agreement with Wayne State University
[8]Co-exclusive license agreement with French National Institute of Health and Medical Research (Inserm)
[9]anti-CD40L humanized monoclonal antibody
[10]Recombinant trefoil factor 2 (rTFF2) based protein; licensed from Columbia University
[11]Live attenuated vaccine based on horsepox virus
[12]Live attenuated vaccine based on horsepox virus vector, expressed SARS-CoV-2 spike protein. TNX-1850 is based on the BA.2 variant spike protein.
[13]Live attenuated vaccine based on bovine parainfluenza (BPI) virus
[14]Fully human monoclonal antibody generated from COVID-19 convalescent patients
[15]COVID vaccine based on mRNA in zinc nanoparticle (ZNP) formulation with CD40L molecular trigger
[16]Humanized monoclonal antibody generated from mice immunized with SARS-CoV02 spike protein

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TNX-1500*

Next Generation α-CD40 Ligand (CD40L) Antibody

The CD40-CD40L pathway is a pivotal immune system modulator and a well-established and promising treatment target

Differentiators: Expected to deliver efficacy without compromising safety

First Generation: Development halted due to thromboembolic (TE) complications—blood clots—traced to Fc gamma receptor (FcγR)

Second Generation: Eliminated the FcγR TE complication but potency and half life was reduced, limiting utility

Third Generation (TNX-1500): Re-engineered to better modulate the binding of FcγR while preserving pharmacokinetic properties and FcRn function

*TNX-1500 is in the pre-IND stage of development and has not been approved for any indication. Patents filed.

Prevention of Allograft Rejection

Status: Preclinical

- Collaborations ongoing with Mass General Hospital on heart and kidney transplantation in non-human primates

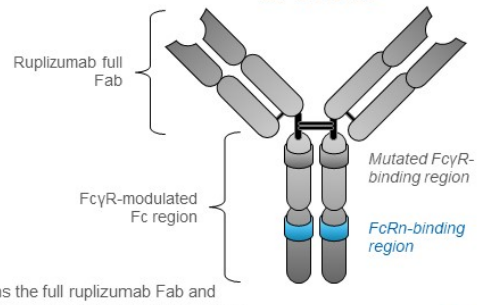
Next Steps: Initiate Phase 1 study 2Q 2023

Autoimmune Diseases

Status: Potential future indications include:
Sjögren's Syndrome, Systemic Lupus Erythematosus

- These indications require large studies, but represent large target markets

SELECTIVELY MODIFIED anti-CD40L AB



Contains the full ruplizumab Fab and the engineered Fc region that modulates FcγR-binding, while designed to preserve FcRn function.

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TNX-1500 (α-CD40L mAb): Prophylaxis of Transplant Rejection
Potential Treatment for Autoimmune Conditions

Pre-IND Candidate

Targeted as a first-line monotherapy for autoimmunity and add-on therapy for preventing and treating organ transplant rejection

- Distinct mechanism of action (MOA)—TNX-1500 blocks T cell helper function

New molecular entity, biologic

- US Patient Protection and Affordable Care Act provides 12 years of exclusivity for biologics

Patent applications directed to composition of matter

- Expected patent protection through 2039

Significant Unmet Need

Clinical evidence for anti-CD40L mAbs in the treatment of systemic lupus erythematosus (SLE), Sjögren's Syndrome (SjS), and allogeneic kidney transplant

- Several studies have shown anti-CD40L to be active in the treatment of human SLE[1-3], SjS[4,5], and transplant rejection[6,7]

[1]Huang W, et al. *Arthritis Rheum.* 2002;46(6):1554-1562.
[2]Boumpas DT, et al. *Arthritis Rheum.* 2003;48(3):719-727.
[3]Grammer AC, et al. *J Clin Invest.* 2003;112(10):1506-1520.
[4]Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary Endpoint | Horizon Therapeutics plc
[5]Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary Endpoint in the Second Study Population; Only Phase 2 Trial to Meet Primary Endpoint in Both Patient Populations | Horizon Therapeutics plc
[6]Kawai T, et al. *Nat Med.* 2000;6(2):114.
[7]Koyama I, et al. *Transplantation.* 2004;77(3):460-462.

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TNX-1500 (α-CD40 Ligand)
Market Opportunity

OPPORTUNITY

Organ transplant rejection drugs	Kidney transplants: 24,000/year/US[2]	Autoimmune Lupus: 1.5 M patients in US[4]	Autoimmune Disease
$4.7 billion[1]	**$5.54 billion[3]**	**1.87 billion[5]**	**$149.4 billion[6]**

[1]Global market as of 2018 (https://www.biospace.com/article/organ-transplant-rejection-medications-market-drug-companies-focus-on-improving-long-term-outcome-of-new-drugs/)
[2]Wang, Jeffrey H. and Hart, Allyson. *Kidney360* November 2021; 2(11) 1836-1839
[3]Global market as of 2020 (https://www.grandviewresearch.com/industry-analysis/transplantation-market)
[4]https://www.lupus.org/resources/lupus-facts-and-statistics
[5]Global market as of 2020 (https://www.globenewswire.com/news-release/2021/02/18/2177637/0/en/Global-Lupus-Therapeutics-Market-Is-Expected-to-Reach-USD-3-62-Billion-by-2028-Fior-Markets.html)
[6]Anticipated market size by 2025 (https://www.prnewswire.com/news-releases/the-global-autoimmune-disease-therapeutics-market-size-is-expected-to-reach-149-4-billion-by-2025--rising-at-a-market-growth-of-4-34-cagr-during-the-forecast-period-300902336.html)

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About CD40L (Also Called CD154)

- **CD40L is a transiently expressed T cell surface molecule and is also called CD154[1-4]**
  - Predominantly expressed by T cells and interacts with CD40 on B cells and macrophages
- **Mediates T cell helper function[1-4]**
  - Activates B cells for humoral (antibody-mediated) immune response
  - Activates macrophages and dendritic cells
  - Provides T cell help to activated CD8+ T cells
- **X-linked hyper-IgM syndrome is caused by a defective CD40L gene[5-6]**
  - Lack of T helper function with only IgM serum antibodies but no IgG or IgE because T cells are required for B cell isotype switching
  - If maintained on gamma globulin, patients are otherwise healthy
- **Member of the TNFα superfamily[4]**
  - TNFα and RANKL are other family members and are drug targets for approved products

[1]Lederman S, et al. *J Exp Med*. 1992;175(4):1091-1101.
[2]Lederman S, et al. *J Immunol*. 1992;149(12):3817-3826.
[3]Lederman S, et al. *J Immunol*. 1994;152(5):2163-2171.
[4]Covey LR, et al. *Mol Immunol*. 1994;31(6):471-484.
[5]Ramesh N, et al. *Int Immunol*. 1993;5(7):769-773.
[6]Callard RE, et al. *J Immunol*. 1994;153(7):3295-3306.

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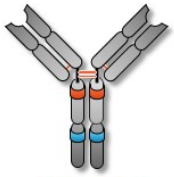
Third-Generation α-CD40L Engineered to Decrease Risk of Thrombosis

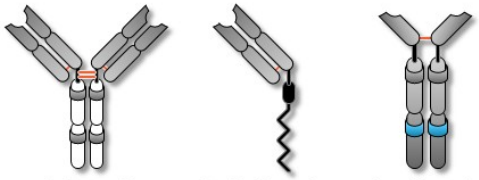
First-generation anti-CD40L mAbs



Ruplizumab

Constant fragment (Fc) domain interacted with FcγRIIA (CD32A), which suggested a mechanism for the increased risk of thrombosis.[1,2]

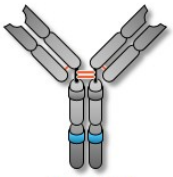
Second-generation anti-CD40L mAbs



Aglycosyl Ruplizumab *Dapirolizumab* *Letolizumab*

Second-generation anti-CD40L mAbs exhibited dramatically reduced binding to FcγRIIA[3-5] but had other issues, including , shortened half-life, anti-drug antibodies (ADAs) or decreased efficacy.[6-8]

Third-generation anti-CD40L mAbs*



TNX-1500

TNX-1500 is engineered to target CD40L therapeutically while reducing FcγRIIA binding and thereby lowering the potential for thrombosis.[1-8]

*Sanofi's frexalimab (formerly SAR441344) and Eledon's tegoprubart (formerly AT-1501) also are Fc modified

[1]Inwald DP, et al. *Circ Res*. 2003;92(9):1041-1048.
[2]Robles-Carrillo L, et al. *J Immunol*. 2010;185(3):1577-1583.
[3]Shock A, et al. *Arthritis Res Ther*. 2015;17(1):234.
[4]Xie JH, et al. *J Immunol*. 2014;192(9):4083-4092.
[5]Ferrant JL, et al. *Int Immunol*. 2004;16(11):1583-1594.
[6]ClinicalTrials.gov identifier: NCT02273960. Updated July 16, 2019. Accessed June 1, 2021. https://clinicaltrials.gov/ct2/show/results/NCT02273960?view=results
[7]Waters J, *Biocentury*; October 26, (2018).
[8]Company data.

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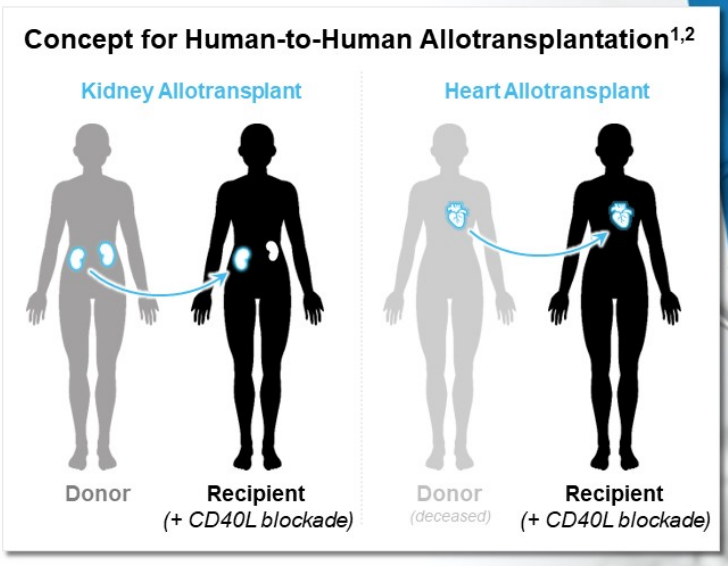
α-CD40L Treatment to Prevent Allograft Rejection

- Calcineurin inhibitors (CNIs), mainly tacrolimus, are the cornerstone of immunosuppressive therapy[1,2]
- However, CNIs cause irreversible and progressive deterioration of kidney function in all types of solid organ transplants[3,4]
- Costimulation blockade (anti-CD40L in particular) may be more effective at protecting allografts than CNIs[5]



[1]Enderby C, et al. *Am J Manag Care*. 2015;21(1 Suppl):s12-s23.
[2]Camilleri B, et al. *Exp Clin Transplant*. 2016;14(5):471-483.
[3]Naesens M, et al. *Clin J Am Soc Nephrol*. 2009;4(2):481-508.
[4]Nankivell BJ, et al. *N Engl J Med*. 2003;349(24):2326-2333.
[5]Cooper DKC, et al. *Blood Purif*. 2018;45(1-3):254-259.

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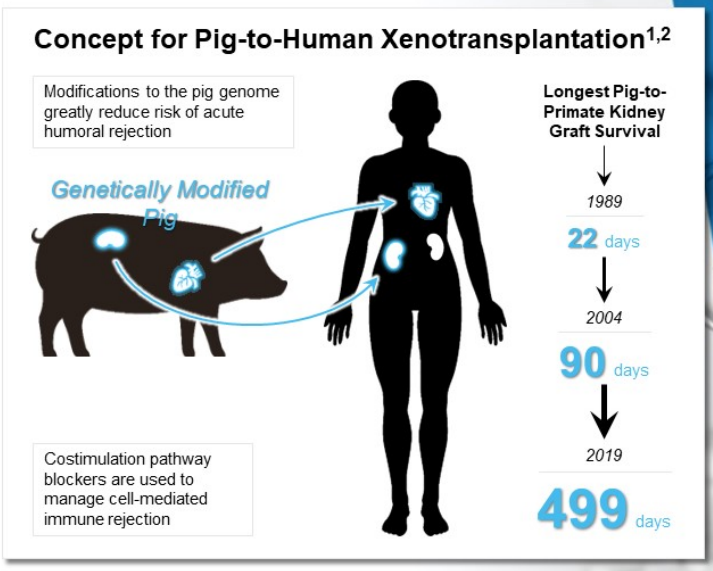
α-CD40L Beyond Allografts: Xenografts

- Allotransplantation is limited by a critical shortage of human organs; **pig-to-human xenotransplantation offers a promising alternative**[1,2]
- Costimulation blockade (anti-CD40L in particular) is more effective at protecting xenografts than CNIs[2]
- Blockade of CD40-CD40L has been associated with some of the longest pig-to-primate xenograft survivals[1,3]



[1]Samy KP, et al. *J Immunol Res*. 2017;2017:8415205.
[2]Cooper DKC, et al. *Blood Purif*. 2018;45(1-3):254-259.
[3]Längin, M. et al. Consistent success in life-supporting porcine cardiac xenotransplantation. *Nature* 564, 430–433 (2018)

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Tonix Collaboration with University of Maryland, Baltimore and United Therapeutics

- Tonix has entered into a sponsored research agreement (SRA) with University of Maryland, Baltimore to study TNX-1500 for the prevention of rejection of heart xenograft transplantation in NHPs
- UMB's preclinical studies will utilize genetically-modified porcine hearts supplied by Revivicor, Inc. (subsidiary of United Therapeutics)
- Primary objective is to study the activity TNX-1500 in preventing xenograft rejection in animals to support an IND application for human studies
- Previous preclinical studies in NHPs demonstrated that TNX-1500 showed activity in preventing allograft and xenograft organ rejection and was well tolerated

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Recent Xenotransplant Headlines

The New York Times **"In a First, Surgeons Attached a Pig Kidney to a Human, and It Worked"** Roni Caryn Rabin *October 19, 2021*	THE WALL STREET JOURNAL. **"Saved by a Pig's Heart"** The Editorial Board *January 12, 2022*	THE WALL STREET JOURNAL. **"Pig Kidneys Transplanted Into Brain-Dead Man as Patients Face Organ Shortages"** Amy Dockser Marcus *January 20, 2022*
THE WALL STREET JOURNAL. **"The Next Pig Thing in Medicine"** Sally Satel *February 9, 2022*	THE NEW YORKER **"The Medical Miracle of a Pig's Heart in a Human Body"** Rivka Galchen *February 21, 2022*	THE WALL STREET JOURNAL. **"The Patient Who Received a Pig Heart Dies Two Months After Transplant"** Allison Prang *March 9, 2022*

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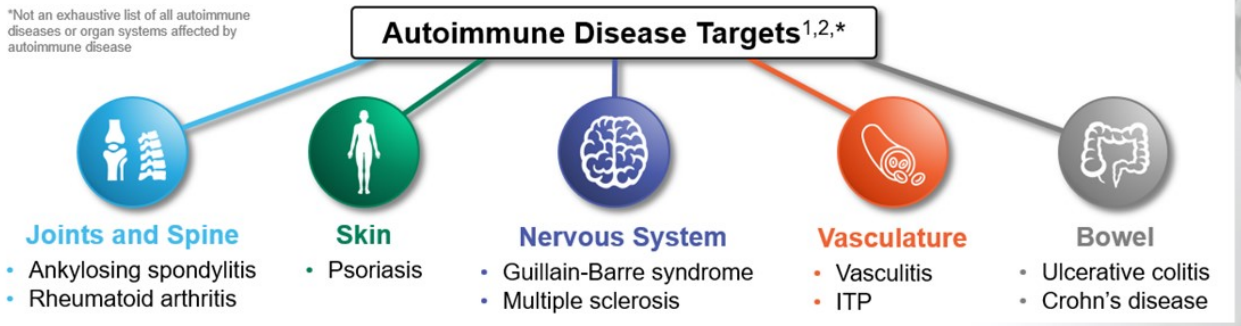
α-CD40L Beyond Allografts: Autoimmunity

- Autoimmune diseases are also characterized by immune system activity that attacks "self," which can damage various parts of the body[1,2]
- First-generation anti-CD40L Abs showed evidence of efficacy in autoimmunity before trials were halted due to thromboembolic events[3]

*Not an exhaustive list of all autoimmune diseases or organ systems affected by autoimmune disease



[1]Li P, et al. *Front Pharmacol*. 2017;8:460.
[2]WebMD. Accessed March 3, 2020. https://www.webmd.com/a-to-z-guides/autoimmune-diseases
[3]Tocoian A, et al. *Lupus*. 2015;24(10):1045-1056.

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Anti-CD40L for Sjögren's Syndrome

- Sjögren's is a **life-long autoimmune condition**, where tear and salivary glands are initially affected
- In 2019, there were an estimated **2.26 million prevalent cases** of primary Sjögren's syndrome worldwide. Forecasted to increase to 2.52 million prevalent cases by 2028

Horizon has announced two positive Phase 2 trials in Sjögren's Syndrome

September 12, 2022:

Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary endpoint[1]

January 18, 2023

Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary Endpoint in the Second Study Population; Only Phase 2 Trial to Meet Primary Endpoint in Both Patient Populations[2]

[1]Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary Endpoint | Horizon Therapeutics plc
[2]Horizon Therapeutics plc Announces Phase 2 Trial Evaluating Dazodalibep for the Treatment of Sjögren's Syndrome Meets Primary Endpoint in the Second Study Population; Only Phase 2 Trial to Meet Primary Endpoint in Both Patient Populations | Horizon Therapeutics plc

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TNX-1500: Key Considerations

- TNX-1500 may be used in large markets that are not currently well served
- There is a long history of use of monoclonal antibodies
- Tonix has engineered a potentially safer but similarly efficacious molecule relative to first generation anti-CD40L mAbs
- Intellectual property is in place (composition of matter)
- Manufacturing (CMC) is in progress

Key milestones:

- Pre-IND meeting (FDA) 3Q 2022; Phase 1 2Q 2023
- Autoimmune disorders – Planning INDs

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Development and Regulatory Strategy

- **1st Indication – Kidney allotransplantation (human to human)**
  - Replacement for nephrotoxic CNI's (calcineurin inhibitors, *e.g.* Prograf® (tacrolimus)[1], Neoral® (cyclosporin)[2]
  - Similar development path to the successful development of BMS's Nulojix® (belatacept)[3], CTLA-4/Ig biologic
  - Clinical development may combine with Nulojix or Rapamune® (rapamycin/sirolimus)[4]
- **2nd Indication – Heart or kidney xenotransplant (pig to human)**
  - CD40L:CD40 blockade considered essential
  - The engineered pig organ is also considered a biologic
- **3rd Indication –Lou Gehrig's Disease, or ALS[5]**
  - Animal models show strong activity; competitor Eledon (ELDN)
- **4th Indication (and beyond) – Autoimmune disease (e.g., Sjögen's Syndrome, Systemic Lupus Erythematosus)**
  - Autoimmune indications require large studies and represent large target markets

[1]http://www.accessdata.fda.gov/drugsatfda_docs/label/2009/050708s027,050709s021lbl.pdf
[2]http://www.novartis.us/sites/www.novartis.us/files/neoral.pdf
[3]https://packageinserts.bms.com/pi/pi_nulojix.pdf
[4]https://labeling.pfizer.com/showlabeling.aspx?id=139
[5]Amyotrophic Lateral Sclerosis

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TNFα Superfamily Members Are Targeted by mAbs

- CD40L is a member of the Tumor Necrosis Factor (TNFα) Superfamily[1]
- Other TNFα Superfamily members have proven to be effective targets for antagonist (blocking) mAbs[2]

anti-TNFα mAbs for the treatment of certain autoimmune conditions

- infliximab (Remicade®)
- adalimumab (Humira®)

TNFα antagonist receptor fusion protein

- etanercept (Enbrel®)

anti-RANKL (CD254) mAb for the treatment of osteoporosis, treatment-induced bone loss, metastases to bone, and giant cell tumor of bone

- denosumab (Prolia® or Xgeva®)

No mAb against CD40L has been licensed *anywhere* in the world

[1]Covey, L.R., et al. *Mol. Immunol.* 31:471-484. 1994. PMID: 7514269.
[2]Remicade® and Simponi® are trademarks of Janssen; Humira® is a trademark of AbbVie; Cimzia® is a trademark of UCB; Enbrel® is a trademark of Amgen; and Prolia® and Xgeva® are trademarks of Amgen.

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Recent mAb Transactions

2020 September

Immunomedics acquired by Gilead for $21B[1]

- TRODELVY™ (sacituzumab govitecan-hziy) is an anti-Trop-2 antibody-drug conjugate (ADC) approved for triple-negative breast cancer

2020 October

Momenta acquired by Johnson & Johnson for $6.5B[2]

- Nipocalimab (M281) is a clinically validated anti-FcRn antibody with a rare pediatric disease designation from the US FDA
- J&J called nipocalimab "a pipeline in a product"

2021 January

Kymab acquired by Sanofi for $1.1B[3]

- Is an anti-Ox40L for the treatment of autoimmune disease

Viela Bio acquired by Horizon for $3B[3]

- UPLIZNA® (inebilizumab-cdon) is an anti-CD19 (B-cell-depleting) antibody approved for the treatment of neuromyelitis optica spectrum disorder (NMOSD), which is a rare and severe autoimmune disease
- VIB4920 anti-CD40L is Viela's second program

2022 March

Sanofi and IGM Biosciences announce collaboration deal that could surpass $6B[4]

- The two companies will partner on immunoglobulin M (IgM) antibody agonists against three cancer targets and three immunology/inflammation targets

Horizon acquired by Amgen for $27.8B[5]

- Replenish Amgen's autoimmune and inflammatory disease portfolios
- Enbrel® (etanercept), faces the start of its loss of exclusivity on June 8, 2023, for patents related to its methods of treatment using aqueous formulations

[1]Gilead. September 13, 2020. Accessed June 3, 2021. https://www.gilead.com/news-and-press/press-room/press-releases/2020/9/gilead-sciences-to-acquire-immunomedics
[2]Johnson & Johnson. October 1, 2020. Accessed June 3, 2021. https://www.jnj.com/johnson-johnson-completes-acquisition-of-momenta-pharmaceuticals-inc
[3]Business Wire. February 1, 2021. Accessed June 3, 2021. https://www.businesswire.com/news/home/20210201005296/en/Horizon-Therapeutics-plc-to-Acquire-Viela-Bio-Inc.-to-Significantly-Expand-Development-Pipeline-and-Grow-Rare-Disease-Medicine-Portfolio
[4]BioSpace. March 29, 2022. Accessed March 29, 2022. https://www.biospace.com/article/sanofi-and-igm-partner-on-oncology-and-immunology-in-deal-worth-more-than-6-billion/
[5]Genetic Engineering & Biotechnology News. December 13, 2022. Accessed Jan 30, 2023. https://www.genengnews.com/rare-and-neglected-diseases/amgen-to-acquire-horizon-for-27-8b-expanding-rare-disease-pipeline/

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Other anti-CD40L Monoclonal Antibodies in Development

UCB (Co-developed with Biogen) – Systemic Lupus Erythematosus (SLE)
- Phase 3 Trial Currently Enrolling (NCT04294667)
  - Topline results expected 1H 2024[1]
- Dapirolizumab pegol (pegylated Fab)

Horizon (Agreed to be acquired by Amgen) – Sjögren's Syndrome (SjS)
- Two Positive Phase 2 studies reported[2,3]
- Dazodalibep (tn03 fusion protein)

Sanofi – Sjögren's Syndrome (SjS), Multiple Sclerosis (MS), Systemic Lupus Erythematosus (SLE)
- Phase 2 Trial Currently Enrolling in SjS (NCT04572841) and SLE (NCT05039840)
- Active Phase 2 Trial in Relapsing MS (NCT04879628)
- Frexalimab f.k.a. SAR441344 (Fc-modified)

Eledon – Amyotrophic Lateral Sclerosis (ALS) and Kidney Transplant
- Phase 2 Trial Completed in ALS (NCT04322149)
- Phase 1/2 Trial Currently Enrolling in Kidney Transplant (NCT05027906)
- Tegoprubart, f.k.a. AT-1501 (Fc-modified)

[1]https://www.ucb.com/our-science/pipeline
[2]https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating
[3]https://ir.horizontherapeutics.com/news-releases/news-release-details/horizon-therapeutics-plc-announces-phase-2-trial-evaluating-0

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mAbs Represent 5 of Top 10 Products by 2023 Projected Sales

- Over 100 mAbs have been approved by the US FDA, and significant growth potential remains[1]
- Global mAb market is projected to grow from $179B in 2021 to $452B in 2028 at a CAGR of 14.1%[2]

TOP 10 DRUGS WORLDWIDE BASED ON 2023 PROJECTED SALES[3]

[1]Mullard A. May 5, 2021. Accessed February 24, 2022. (https://www.nature.com/articles/d41573-021-00079-7)
[2]Forbes Business Insights. August 2021. Accessed February 24, 2022.
[3]Matej Mikulic. Statista. Jan 18, 2023. Accessed January 24, 2023. (https://www.statista.com/statistics/973523/top-drugs-by-year-on-year-sales-increase/)

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FUTURE OUTLOOK

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Management Team

Seth Lederman, MD
Co-Founder, CEO & Chairman

Gregory Sullivan, MD
Chief Medical Officer

Bradley Saenger, CPA
Chief Financial Officer

Jessica Morris
Chief Operating Officer

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Milestones: Recently Completed and Upcoming*

- ☑ 2nd Quarter 2022 Phase 3 RESILIENT study start of TNX-102 SL for the management of fibromyalgia
- ☑ 3rd Quarter 2022 Phase 2 PREVAIL study start of TNX-102 SL for the treatment of Long COVID

Expected Data

- ❑ 2nd Quarter 2023 Interim analysis results of Phase 3 RESILIENT study of TNX-102 SL in fibromyalgia

Expected Clinical Trial Initiations

- ❑ 1st Quarter 2023 Phase 2 study start of TNX-1900 for the treatment of migraine
- ❑ 1st Quarter 2023 Phase 2 study start of TNX-601 ER for the treatment of major depressive disorder
- ❑ 2nd Quarter 2023 Phase 2 study start of TNX-102 SL for the treatment of PTSD
- ❑ 2nd Quarter 2023 Phase 1 study start of TNX-1500 for prevention of allograft rejection
- ❑ 2nd Quarter 2023 Phase 2 study start of TNX-1300 for the treatment of cocaine intoxication
- ❑ 2nd Half 2023 Phase 1 study start of TNX-801 for prevention of monkeypox and smallpox

* We cannot predict whether the global COVID-19 pandemic will impact the timing of these milestones.

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THANK YOU

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