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): January 10, 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 its product candidates (the "Presentation") at the 2023 Biotech Showcase being held January 9, 2023 to January 11, 2023. 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	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: January 10, 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

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.**

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 **$140 M of cash** as of 9/30/22. Tonix has no debt.

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 Phase 2, Targeted 2Q 2023 Start Phase 2
TNX-1300[3]	Cocaine Intoxication - *FDA Breakthrough Designation*	Mid-Phase 2, Targeted 1Q 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 1H 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

TONIX PHARMACEUTICALS

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 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

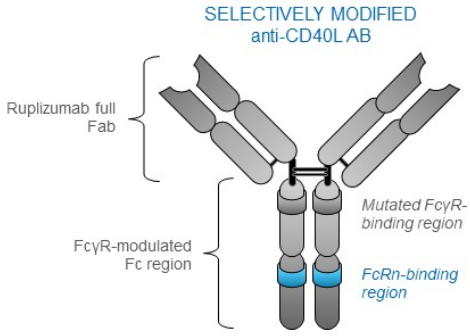
- Collaborations ongoing with Mass General Hospital on heart and kidney transplantation in non-human primates

Next Steps: Initiate Phase 1 study 1H 2023

Autoimmune Disease

Status: Potential future indication

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



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

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Internal Development & Manufacturing Capabilities

Infectious Disease R&D Center (RDC) – Frederick, MD

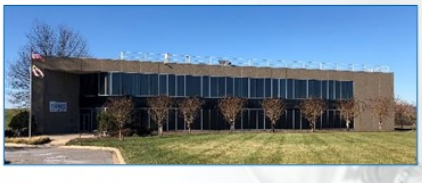
- **Function:** Accelerated development of vaccines and antiviral drugs against COVID-19, its variants and other infectious diseases
- **Description:** ~48,000 square feet, BSL-2 with some areas designated BSL-3
- **Status:** Operational

Advanced Development Center (ADC) – North Dartmouth, MA

- **Function:** Development and clinical scale manufacturing of biologics
- **Description:** ~45,000 square feet, BSL-2
- **Status:** Operational

Commercial Manufacturing Center (CMC) – Hamilton, MT

- **Function**: Phase 3 and Commercial scale manufacturing of biologics
- **Description:** ~44-acre green field site, planned BSL-2
- **Status:** Planning for site enabling work in 2023



Architectural Rendering

INFECTIOUS DISEASE PORTFOLIO

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Immuno-compromised People are at Increased Risk of Severe COVID-19 and Poor Outcomes[1]

In a multicenter study of solid organ transplant recipients with COVID-19[1]

78%
Required hospitalization

34%
Required intensive care

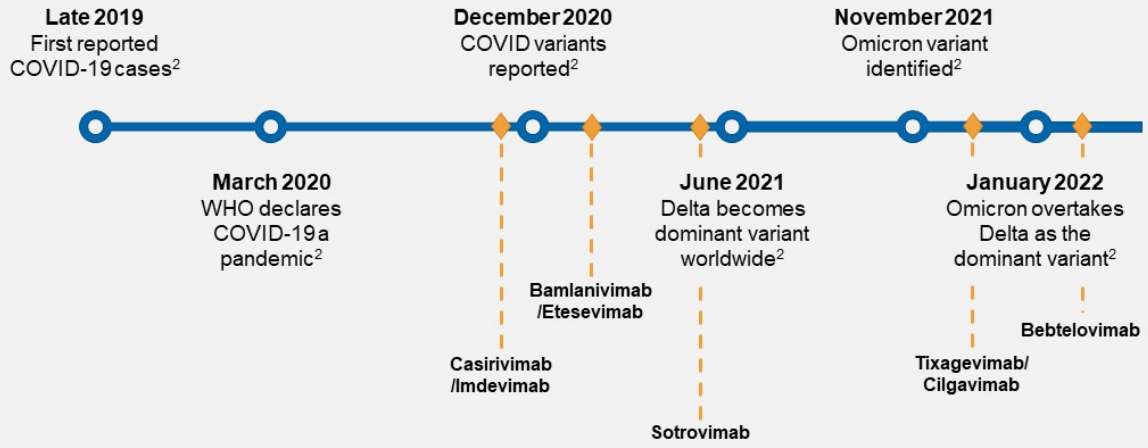
27%
Required mechanical ventilation

Therapeutic and prophylactic anti-SARS-CoV-2 neutralizing monoclonal antibodies (mAbs) have been useful in protecting the immunocompromised population

[1]Haidar G, Mellors JW. Improving the Outcomes of Immunocompromised Patients With Coronavirus Disease 2019. *Clin Infect Dis*. 2021;73(6):e1397-e1401. doi:10.1093/cid/ciab397

Timeline of COVID-19 and the Availability of Monoclonal Antibody (mAb) Therapeutics and Prophylactics

US regulators have relied on emergency use authorizations (EUAs) to accelerate the availability of mAbs for COVID-19[1]



[1]https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs. [2]https://asm.org/Resource-Pages/COVID-19-Resources.

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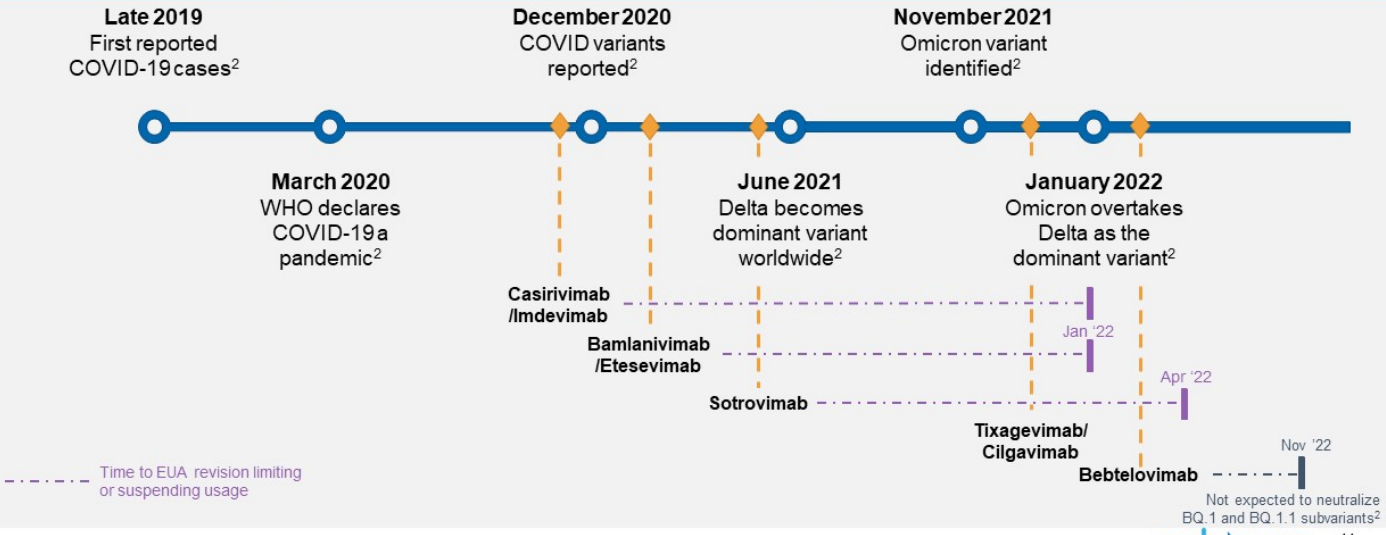


[1]https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs. [2]https://asm.org/Resource-Pages/COVID-19-Resources.
[2]https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-bebtelovimab

The Available anti-SARS-CoV-2 Monoclonal Antibodies are Losing Their Activity as SARS-CoV-2 Mutates and Evasive Variants Arise

The efficacy of any mAb treatment varied as the dominant circulating variant changed[1,2]

Therapeutic Monoclonal antibodies (mAbs) – none remaining with active US Emergency Use Authorization (EUA) endorsed by NIH Guidelines Panel[1,2]

- AbCellera/NIAID-VRC/Eli Lilly - bebtelovimab
- Regeneron/Genentech - REGEN-COV® Casirivimab/imdevimab
- Eli Lilly/AbCellera/NIAID/Junshi-China Academy of Sciences – Bamlanivimab/etesevimab
- Vir/GSK – XEVURDY® (sotrovimab)

Concerns about efficacy of the only preventative mAb product against new variants

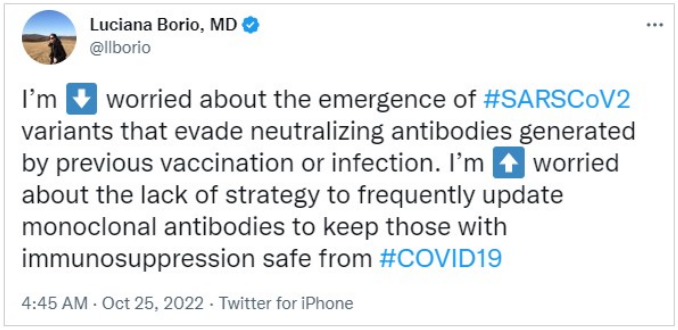
- AstraZeneca/Vanderbilt – Evusheld® (Tixagevimab/cilgavimab) – EUA for long term prophylaxis
  - CDC reports 82% prevalence of resistant strains[3,4]

Most therapeutic and prophylactic mAbs have originated from COVID-convalescent patient bloods[5,6]

[1]https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/ - download Jan 4, 2023
[2]Gardner, L. Jan 1, 2023. *Politico*. Once-favored Covid drugs ineffective on Omicron may be putting millions at risk - Once-favored Covid drugs ineffective on Omicron may be putting millions at risk (msn.com)
[3]Wu, K.J. October 29, 2022. The Atlantic. "The End of Evusheld: If you're immunocompromised, this … isn't great. www.theatlantic.com/health/archive/2022/10/covid-variants-antibody-treatments-immunocompromised/671929/
[4]CDC Dec 20, 2022 - HAN Archive - 00483 | Health Alert Network (HAN) (cdc.gov)
[5]Vir isolated sotrovimab from the blood of a SARS-CoV-1 patient
[6]Regeneron used both convalescent patient cells and a humanized mouse platform: Hansen J et al. *Science*. 2020 Aug 21;369(6506):1010-1014. doi: 10.1126/science.abd0827

Need for a Strategy to Frequently Update Monoclonal Antibodies

Current and prior mAb therapeutics were developed in collaborations



Dr. Luciana Borio is former National Security Council director for medical and biodefense preparedness and current senior fellow for global health at the think tank Council on Foreign Relations. She is a venture partner at ARCH.

A platform to quickly develop and test novel SARS-CoV-2 neutralizing mAbs may represent a significant advancement in the ability to update the pool of mAb treatments available to protect the immunocompromised population

Fully Human anti-SARS-CoV-2 Monoclonal Antibody Platform

TNX-3600[1]: COVID-19 Therapeutic and Preventive Agents

Given the unpredictable trajectory of the SARS-CoV-2 virus and new variants[2], we seek to contribute to a broad set of monoclonal antibodies from a variety of SARS-CoV-2+ volunteers and convalescent patients, that can be scaled up quickly and potentially combined with other monoclonal antibodies

Collaboration with Columbia University

Fully human mAbs generated from SARS-CoV-2+ asymptomatic individuals or COVID-19 convalescent patients[3]

Potential monotherapies or preventives

- Plan to seek indication similar to current EUA therapeutic mAbs for treating individuals with mild-to-moderate COVID-19 who are at high risk for progression to severe disease

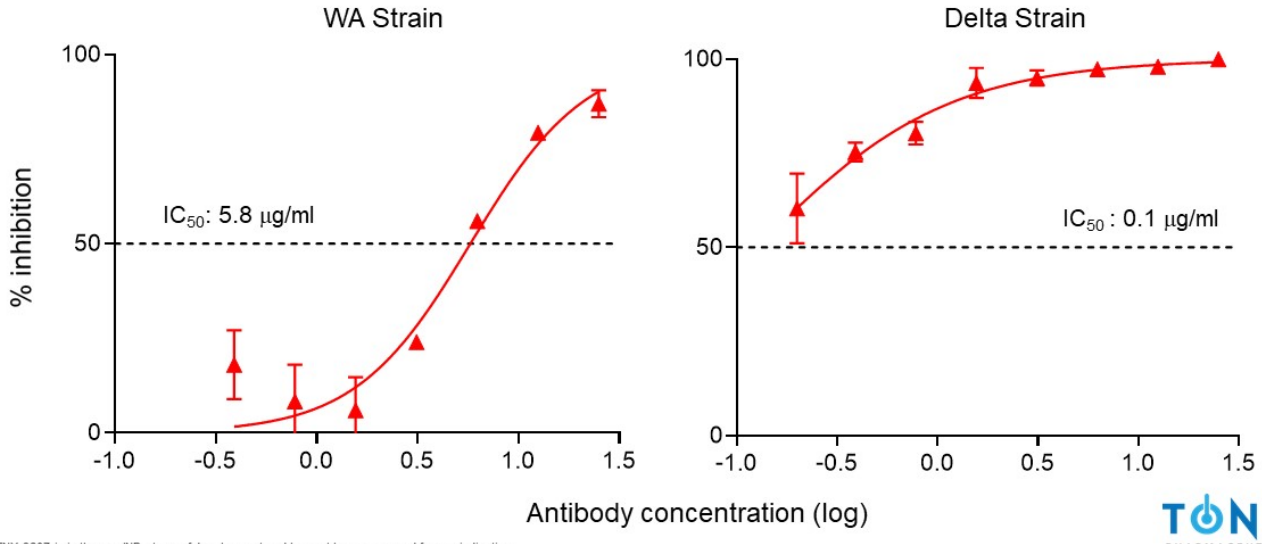
Potential combination therapy with other mAbs as therapeutics or prophylactics

- Combination therapies for other anti-SARS-CoV-2 monoclonal antibodies are believed to have reduced the emergence of drug resistant viral strains[4]

[1]TNX-3600 is the designation for a series of monoclonal antibodies; each is in the pre-IND stage of development and has not been approved for any indication
[2]Waltz, E. Nature. "Does the World Need an Omicron Vaccine?" 28 Jan 2022 https://www.nature.com/articles/d41586-022-00199-z
[3]Volunteers participated in an IRB-approved research protocol
[4]Baum, A. et al. *Science*. 2020 Aug 21;369(6506):1014-1018. doi: 10.1126/science.abd0831. Epub 2020 Jun 15.

Live virus *in vitro* Neutralization Assay: TNX-3607*

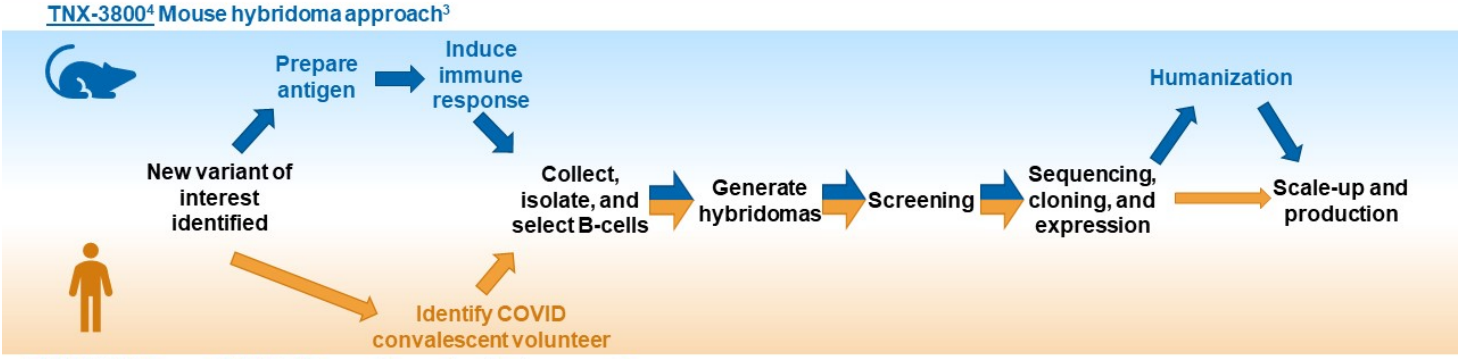
Example of a fully human mAb with potent neutralizing activity against parental Wuhan (WA) virus and Delta variant



*TNX-3607 is in the pre-IND stage of development and has not been approved for any indication.

Comparing Development Platforms for Novel anti-SARS-CoV-2 Monoclonal Antibodies

Most therapeutic and prophylactic mAbs have originated from COVID-convalescent patient blood[1,2]



Generating fully human mAbs starting from recovered patient blood samples has the potential to reduce the time required to create novel therapeutics in response to newly identified COVID-19 variants, relative to generating murine mAbs followed by humanization

[1]Vir isolated sotrovimab from the blood of a SARS-CoV-1 patent
[2]Regeneron used both convalescent patient cells and a humanized mouse platform: Hansen J et al. *Science*. 2020 Aug 21;369(6506):1010-1014. doi: 10.1126/science.abd0827
[3]Lu R-M, Hwang Y-C, Liu IJ, et al. Development of therapeutic antibodies for the treatment of diseases. *J Biomed Sci*. 2020;27(1):1. doi:10.1186/s12929-019-0592-z
[4]TNX-3600 and TNX-3800 are the designations for a series of monoclonal antibodies; each is in the pre-IND stage of development and has not been approved for any indication.

Humanized Murine anti-SARS-CoV-2 Monoclonal Antibodies

TNX-3800[1]: COVID-19 Therapeutic and Preventive Agents

Given the unpredictable trajectory of the SARS-CoV-2 virus and new variants[2], we seek to contribute to a broad set of monoclonal antibodies from a variety of SARS-CoV-2+ volunteers and convalescent patients, that can be scaled up quickly and potentially combined with other monoclonal antibodies

Licensed from Curia Global

Humanized mAbs generated from SARS-CoV-2+ mice immunized with SARS-CoV-2 spike protein[3]

Potential monotherapies or preventives

- Plan to seek indication similar to current EUA therapeutic mAbs for treating individuals with mild-to-moderate COVID-19 who are at high risk for progression to severe disease

Potential combination therapy with other mAbs as therapeutics or prophylactics

- Combination therapies for other anti-SARS-CoV-2 monoclonal antibodies are believed to have reduced the emergence of drug resistant viral strains[4]

[1]TNX-3800 is the designation for a series of monoclonal antibodies; each is in the pre-IND stage of development and has not been approved for any indication
[2]Waltz, E. Nature. "Does the World Need an Omicron Vaccine?" 28 Jan 2022 https://www.nature.com/articles/d41586-022-00199-z
[3]Volunteers participated in an IRB-approved research protocol
[4]Baum, A. et al. *Science*. 2020 Aug 21;369(6506):1014-1018. doi: 10.1126/science.abd0831. Epub 2020 Jun 15.

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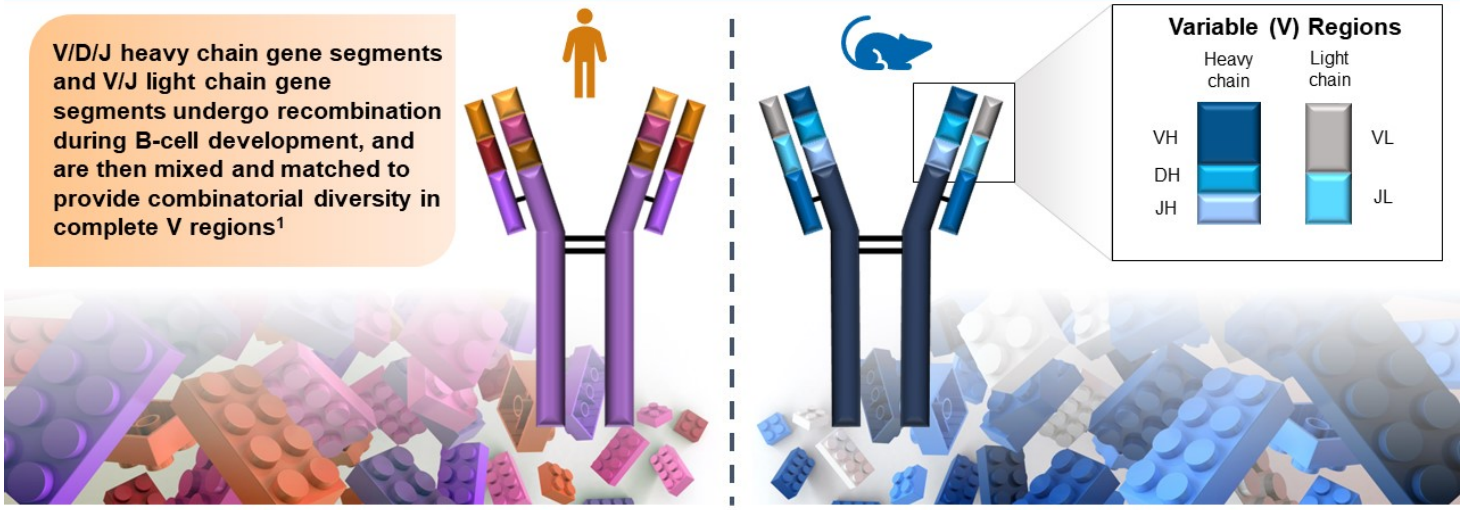
Human and Mouse Genomes Encode Different Repertoires of Component Regions for Antibody Production

The immune system generates a diverse set of antibodies from a limited pool of genes[1]

V/D/J heavy chain gene segments and V/J light chain gene segments undergo recombination during B-cell development, and are then mixed and matched to provide combinatorial diversity in complete V regions[1]



Human V, D, and J gene segments

Mouse V, D, and J gene segments

[1]Janeway CA Jr, et al. Immunobiology: The Immune System in Health and Disease. 5th edition. New York: Garland Science; 2001. The generation of diversity in immunoglobulins. Available from: https://www.ncbi.nlm.nih.gov/books/NBK27140/

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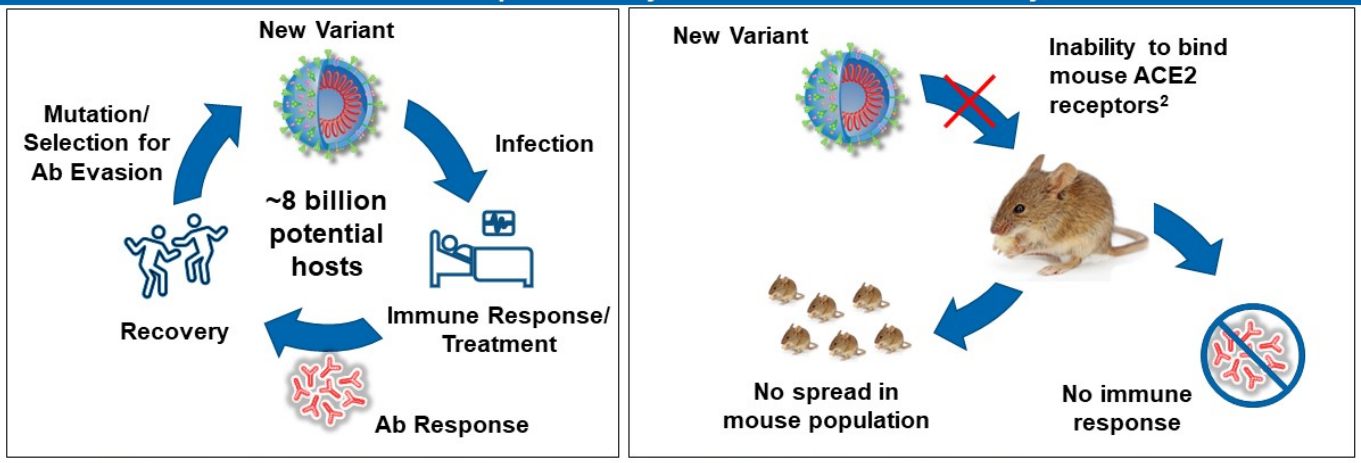
Mouse-derived Antibodies May Offer an Advantage in Retaining Broad Neutralizing Activity Against Novel Viral Variants

SARS-CoV-2 circulating in the human population is under constant selective pressure to evade antibodies produced by billions of human immune systems[1]



By circulating widely in the human population, variants may get a "head start" at evading human-derived monoclonal antibodies. Mice are not infected by SARS-CoV-2.

[1]Wang, Q, *et al.* Antibody evasion by SARS-CoV-2 Omicron subvariants BA.2.12.1, BA.4 and BA.5. *Nature* **608**, 603–608 (2022). https://doi.org/10.1038/s41586-022-05053-w
[2]Shou S, et al. Animal Models for COVID-19: Hamsters, Mouse, Ferret, Mink, Tree Shrew, and Non-human Primates. Mini Review. *Front Microbiol*. 2021;12doi:10.3389/fmicb.2021.626553

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Potential for Longer Period of Time for Mouse-Derived anti-SARS-CoV-2 Spike Protein Antibodies to be Useful

- **Mice have a different repertoire of antibodies[1]**
  - Bind to different epitopes than human-derived antibodies
- **Widespread, global COVID and SARS-CoV-2 infection are putting selective pressure on SARS-CoV-2 to evade human antibody repertoire**
  - Rapid evasion confounds the durability of individual mAb therapeutic products
  - Potentially speeded by recombination between variants
  - Both new products are needed and potentially new combinations of new with existing mAbs
- **Mice are not infected by SARS-CoV-2, so SARS-CoV-2 is not under selective pressure to evade murine antibody responses**
  - Mice are resistant to SARS-CoV-2 for a variety of reasons, including that their AC2 receptor homologue does not bind SARS-CoV-2 spike protein[2]
  - For "updated" mRNA booster vaccines encoding omicron spike antigen, FDA approvals were granted without human efficacy data consistent with a "cartridge" approach

[1]Callaway, E. Oct 28 2022. Nature (News). COVID 'variant soup' is making winter surges hard to predict: Descendants of Omicron are proliferating worldwide — and the same mutations are coming up again and again. www.nature.com/articles/d41586-022-03445-6
[2]https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/ - accessed Nov 3, 2022

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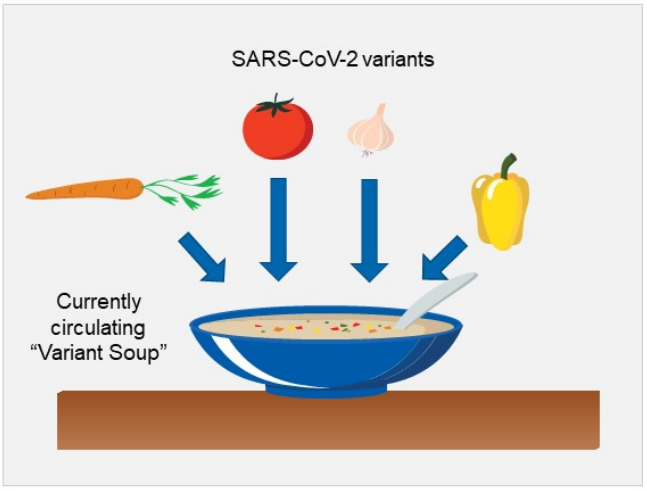
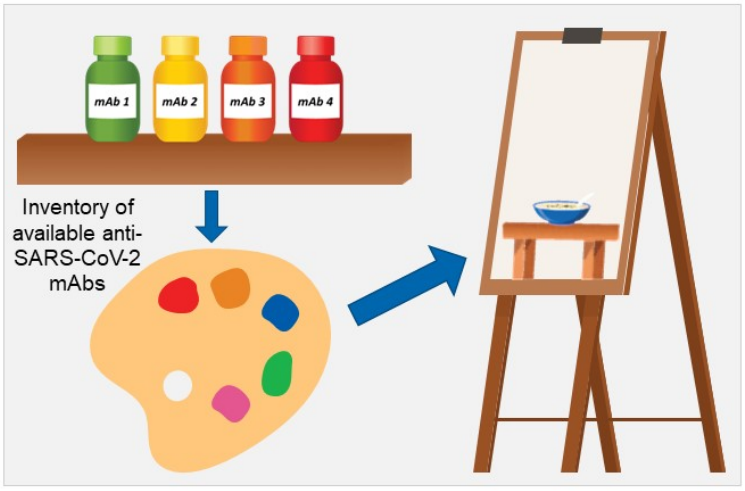
Therapeutic Monoclonal Antibody Development for COVID-19 has been Focused on a "Whack-a-Mole" 1x1 Monoclonal Antibody v. Variant Battle

- As new variants emerge, mAbs that were highly effective against older variants may quickly lose their place in the treatment landscape[1]
  - Antibodies receiving Emergency Use Authorizations (EUAs) may only have a lifespan of 1-2 years before shifts in the dominant circulating variant reduce their clinical utility[2]

[1]Waltz, E. Nature. "Does the World Need an Omicron Vaccine?" 28 Jan 2022 https://www.nature.com/articles/d41586-022-00199-z
[2]https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs.

As the Circulating Mix of SARS-CoV-2 Variants Changes, it Seems Prudent to Assemble a Diverse Inventory of Monoclonal Antibodies to Match It





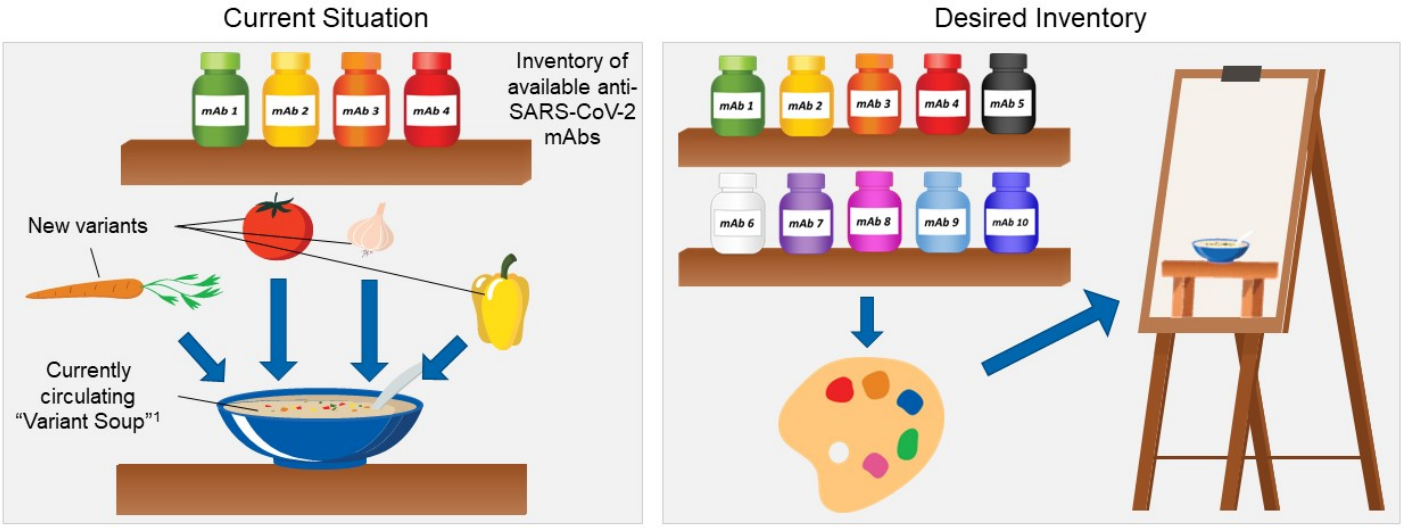
[1]Callaway, E. Oct 28 2022. *Nature* (News). COVID 'variant soup' is making winter surges hard to predict: Descendants of Omicron are proliferating worldwide — and the same mutations are coming up again and again. www.nature.com/articles/d41586-022-03445-6

The Platform is Designed to Develop and Maintain a Diverse Inventory of Monoclonal Antibodies to Keep Up with SARS-CoV-2 "Variant Soup"[1]

[1]Callaway, E. Oct 28 2022. *Nature* (News). COVID 'variant soup' is making winter surges hard to predict Descendants of Omicron are proliferating worldwide — and the same mutations are coming up again and again. www.nature.com/articles/d41586-022-03445-6

TONIX PHARMACEUTICALS

As the Circulating Mix of SARS-CoV-2 Variants Changes, it Seems Prudent to Assemble a Diverse Inventory of Monoclonal Antibodies to Match It



[1]Callaway, E. Oct 28 2022. Nature (News). COVID 'variant soup' is making winter surges hard to predict: Descendants of Omicron are proliferating worldwide — and the same mutations are coming up again and again. www.nature.com/articles/d41586-022-03445-6

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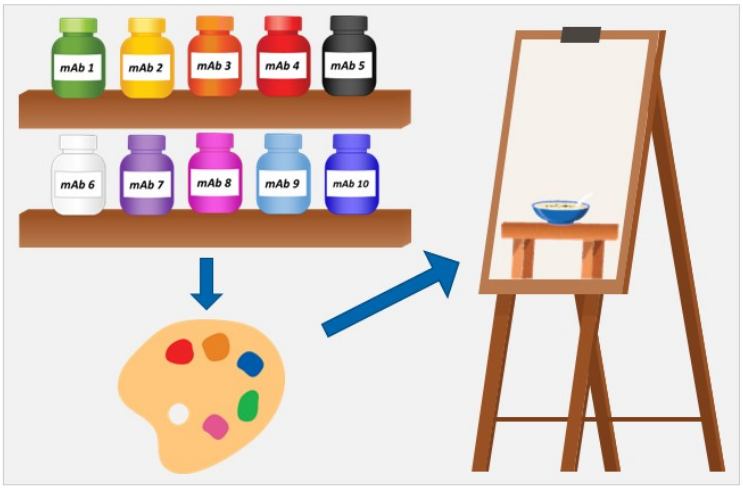
Murine-Derived Antibodies Provide Diversity in the Monoclonal Antibody Therapeutic Arsenal

Human Antibodies
- Faster to develop/deploy in response to new variants or pathogens
- May lose efficacy as new variants arise

Mouse Antibodies
- Slower development
- May retain ability to neutralize variants that evade human antibodies

Employing the tools to develop and maintain a diverse inventory of mAbs against novel pathogens is critical to protecting vulnerable populations in a rapid and sustainable fashion



Future of COVID-19 mAb Therapeutics and Prophylactics

- **Immune-evading SARS-CoV-2 variants are arising by divergent and convergent evolutionary processes[1]**
  - Potentially speeded by recombination between variants
- **To protect immuno-compromised individuals from a changing "soup" of SARS-CoV-2 variants, we need an extensive palate of mAbs**
  - Rapid evasion confounds the durability of individual mAb therapeutic products
  - Both new products are needed and potentially new combinations of new with existing mAbs
- **For life-saving, but short-lived products, we expect FDA to regulate with commensurate speed**
  - Joint EMA/FDA meeting held on Dec 15, 2022 to discuss criteria for approving new mAbs[2]
  - For "updated" mRNA booster vaccines encoding omicron spike antigen, FDA approvals were granted without human efficacy data consistent with a "cartridge" approach

[1]Callaway, E. Oct 28 2022. Nature (News). COVID 'variant soup' is making winter surges hard to predict: Descendants of Omicron are proliferating worldwide — and the same mutations are coming up again and again. www.nature.com/articles/d41586-022-03445-6
[2]Mast, J. Dec 15, 2022. STAT News. "Drugmakers ask regulators to change standards on new Covid antibody drugs for most vulnerable" www.statnews.com/2022/12/15/drugmakers-seek-standards-new-covid-antibody-drugs/

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
- ❑ 3rd Quarter 2023 Interim analysis results of Phase 2 PREVAIL study of TNX-102 SL in Long COVID

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-1300 for the treatment of cocaine intoxication
- ❑ 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 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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Bradley Saenger, CPA
Chief Financial Officer

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THANK YOU