

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): November 30, 2022

TONIX PHARMACEUTICALS HOLDING CORP.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-36019
(Commission
File Number)

26-1434750
(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.

On November 30, 2022, Tonix Pharmaceuticals Holding Corp. (the "Company") announced data from its fully human anti-SARS-CoV-2 monoclonal antibody platform in an oral presentation delivered by Seth Lederman, M.D., Chief Executive Officer of the Company, at the World Antiviral Congress 2022, held November 28 – 29, 2022 (the "Presentation"). A copy of the press release which discusses this matter is furnished hereto as Exhibit 99.01, and incorporated herein by reference. The Presentation, which may contain nonpublic information, is filed as Exhibit 99.02 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 and 99.02 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 8.01. Other Events.

On November 30, 2022, the Company announced data from its fully human anti-SARS-CoV-2 monoclonal antibody platform. The Presentation, entitled, "Platform for Generating Fully Human anti-SARS-CoV-2 Spike Therapeutic Monoclonal Antibodies" highlights the need for a broad array of monoclonal antibodies (mAbs) which can be scaled up quickly and potentially combined with other mAbs to treat or prevent COVID-19. The Company believes that the development of these fully human mAbs strengthens its pipeline of next-generation therapeutics to treat Covid-19.

Forward-Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's product development, clinical trials, clinical and regulatory timelines, market opportunity, competitive position, possible or assumed future results of operations, business strategies, potential growth opportunities and other statement that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe,"

“estimate,” “potential,” “predict,” “project,” “should,” “would” and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company’s filings with the SEC. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

Item 9.01 Financial Statements and Exhibits.

(d)	Exhibit No.	Description.
	99.01	Press release of the Company, dated November 30, 2022
	99.02	Platform for Generating Fully Human anti-SARS-CoV-2 Spike Therapeutic Monoclonal Antibodies
	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: November 30, 2022

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

Tonix Pharmaceuticals Announced Data from its Fully Human anti-SARS-CoV-2 Monoclonal Antibody Platform in an Oral Presentation at the World Antiviral Congress

Research Being Conducted in Collaboration with Scientists at Columbia University

SARS-CoV-2 Variants have Evaded Antibody Therapeutics Previously Granted FDA Emergency Use Authorization, but which are No Longer Recommended for Use by the NIH COVID-19 Guidelines Panel

Immunocompromised Individuals, Including Organ Transplant Recipients, are at Increased Risk of Severe COVID-19 and Poor Outcomes

Therapeutic Antibody Platform Leverages Tonix's Expanding Internal Development and Manufacturing Capabilities for Biologics

CHATHAM, N.J., November 30, 2022 – Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP), a clinical-stage biopharmaceutical company, today announced data from its fully human anti-SARS-CoV-2 monoclonal antibody platform in an oral presentation delivered by Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals, at the World Antiviral Congress 2022 in San Diego, Calif. The project is part of a broader research collaboration and option agreement with scientists at Columbia University designed to fill in important gaps in understanding the detailed immune responses to COVID-19, and to provide a foundation upon which to target vaccines and therapeutics to appropriate individuals by precision medicine. A copy of the presentation is available under the [Scientific Presentations](#) tab of the Tonix website at www.tonixpharma.com.

The presentation titled, “*Platform for Generating Fully Human anti-SARS-CoV-2 Spike Therapeutic Monoclonal Antibodies*” highlights the need for a broad array of monoclonal antibodies (mAbs) which can be scaled up quickly and potentially combined with other mAbs to treat or prevent COVID-19.

“We believe that the development of these fully human mAbs strengthens our pipeline of next-generation therapeutics to treat Covid-19,” said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. “Immunocompromised individuals, including organ transplant recipients, are at increased risk of severe COVID-19 and bad outcomes¹. Although five mAb products, containing 7 distinct mAbs, have received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) for either treatment or prophylaxis of COVID-19, only a single product, Evushield® is still recommended for use as a prophylaxis by the NIH COVID Guidelines panel or FDA^{2,3}. Moreover, concerns have been raised about the ongoing ability of Evushield to serve as a prophylaxis against COVID-19 in the face of new variants⁴. For these reasons, we believe there is a need for second generation mAb treatments and prophylactics for COVID-19⁵. 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.”

Ilya Trakht, Ph.D., Associate Research Scientist at Columbia and principal investigator of the sponsored research agreementsaid, “We are excited to work with Tonix because of their commitment to developing therapeutics to COVID-19. As new variants emerge, anti-spike mAbs that were highly effective against older variants of SARS-CoV-2, may quickly lose their place in the treatment landscape. To protect immunocompromised people, we are committed to assembling a diverse inventory of monoclonal antibodies to keep pace with circulating mix of SARS-CoV-2 variants. Our proprietary technology is based on CD40-ligand promoted B-cell expansion and the MFP-2S human hybridoma system”

Seth Lederman added, “This potential therapeutic antibody platform leverages our expanding internal development and manufacturing capabilities for biologics.”

¹Haidar 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

²<https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/> - accessed Nov 3, 2022

³“FDA Updates on Bebtelovimab” – “This information shows that bebtelovimab is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1.” – www.fda.gov/drugs/drug-safety-and-availability/fda-updates-bebtelovimab - Accessed Nov 4, 2022

⁴Wu, K.J. October 29, 2022. The Atlantic. “The End of Evushield: If you’re immunocompromised, this ... isn’t great.” www.theatlantic.com/health/archive/2022/10/covid-variants-antibody-treatments-immunocompromised/671929/

⁵Madison Muller, M. November 16, 2022 Bloomberg. “Doctors Are Running Out of Antibody Drugs to Treat Covid as Virus Mutates.” www.bloomberg.com/news/articles/2022-11-16/covid-s-mutations-leave-doctors-with-far-fewer-antibody-drugs-to-treat-virus?

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate suffering. Tonix’s portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix’s CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix’s lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expects interim data in the second quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the first quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the fourth quarter of 2022. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first quarter of 2023. Tonix’s rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix’s immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the first half of 2023. Tonix’s infectious disease pipeline consists of a vaccine in development to prevent smallpox and monkeypox, next-generation vaccines to prevent COVID-19, and a platform to make fully human monoclonal antibodies to treat COVID-19. TNX-801, Tonix’s vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the first half of 2023. Tonix’s lead vaccine candidate for COVID-19 is TNX-1850, a live virus vaccines based on Tonix’s recombinant pox live virus vector vaccine platform.

** All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of 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,” “expect,” 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, risks related to the 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. Tonix does not undertake an obligation to update or revise any forward-looking statement. 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 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. The information set forth herein speaks only as of the date thereof.

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TONIX
PHARMACEUTICALS

**Platform for Generating Fully Human
anti-SARS-CoV-2 Spike Therapeutic
Monoclonal Antibodies**

*Collaboration with Columbia
University*

Version 1121 November 30, 2022 (Doc 0391)

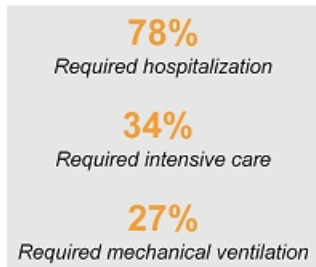
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Cautionary Note on Forward-Looking Statements

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.

Immuno-compromised People are at Increased Risk of Severe COVID-19 and Poor Outcomes¹

In a multicenter study of solid organ transplant recipients with COVID-19¹



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

¹Haider G, Mellors JW. Improving the Outcomes of Immunocompromised Patients With Coronavirus Disease 2019. *Clin Infect Dis*. 2021;73(8):e1397-e1401. doi:10.1093/cid/ciab397

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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-19¹



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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However, 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 varies as the dominant circulating variant changes^{1,2}

Monoclonal antibodies (mAbs)– two with active US Emergency Use Authorization (EUA) endorsed by NIH Guidelines Panel¹

- AbCellera/NIAID-VRC/Eli Lilly - bebtelovimab – EUA for treatment of mild or moderate COVID³
 - Nov 4 – FDA warns of reduced effect on omicron subvariants BQ.1 and BQ.1.1⁴
- AstraZeneca/Vanderbilt – Evusheld® (Tixagevimab/cilgavimab) – EUA for long term prophylaxis

Concerns about efficacy of mAbs against new variants

- Regeneron/Genentech - REGEN-COV® Casirivimab/imdevimab
 - *EUA revised Jan '22 to susceptible variants – unlikely to be effective against omicron¹*
- Eli Lilly/AbCellera/NIAID/Junshi-China Academy of Sciences – Bamlanivimab/etesevimab¹
 - *EUA revised Jan '22 to susceptible variants – unlikely to be effective against omicron¹*
- Vir/GSK – XEVURDY® (sotrovimab)¹ – active against omicron, but NIH COVID Guidelines panel recommends against use because less activity against omicron BA.2, BA.4 and BA.5 subvariants¹

Most therapeutic and prophylactic mAbs have originated from COVID-convalescent patient blood^{5,6}

¹<https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/>

²Ma, 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/671928/

³Indicated for individuals with mild-to-moderate COVID-19 who are at high risk for progression to severe disease

⁴FDA Updates on Bebtelovimab – "This information shows that bebtelovimab is not expected to neutralize Omicron subvariants BQ.1 and BQ.1.1."

⁵www.fda.gov/drugs/usage-safety-and-availability/fda-updates-betelovimab - Accessed Nov 4, 2022

⁶Vir isolated sotrovimab from the blood of a SARS-CoV-1 patient

⁷Regeneron 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.aba0827

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Need for a Strategy to Frequently Update Monoclonal Antibodies

Current and prior mAb therapeutics were developed in collaborations



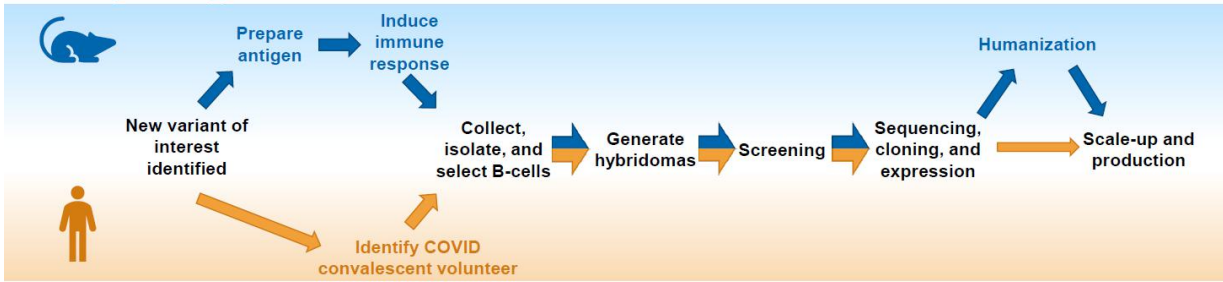
Dr. Luciana Borio is former National Security Council director for medical and biodefense preparedness and current senior fellow for global health at the think tank Council on Foreign Relations, a venture partner at ARCH.

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

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}

Mouse hybridoma approach³



TNX-3600⁴ Human COVID-19 convalescent patient approach

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

¹Vir isolated sotrovimab from the blood of a SARS-CoV-1 patient

²Regeneron 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

³Lu R-M, Huang Y-C, Liu J, 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

⁴TNX-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.

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Fully Human anti-SARS-CoV-2 Monoclonal Antibody Platform TNX-3600¹: COVID-19 Therapeutic and Preventive Agents

Given the unpredictable trajectory of the SARS-CoV-2 virus and new variants², 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 patients³

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 strains⁴

¹TNX-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

²Waltz, E. *Nature*. "Does the World Need an Omicron Vaccine?" 20 Jan 2022 <https://www.nature.com/articles/s41595-022-00198-z>

³Volunteers participated in an IRB-approved research protocol

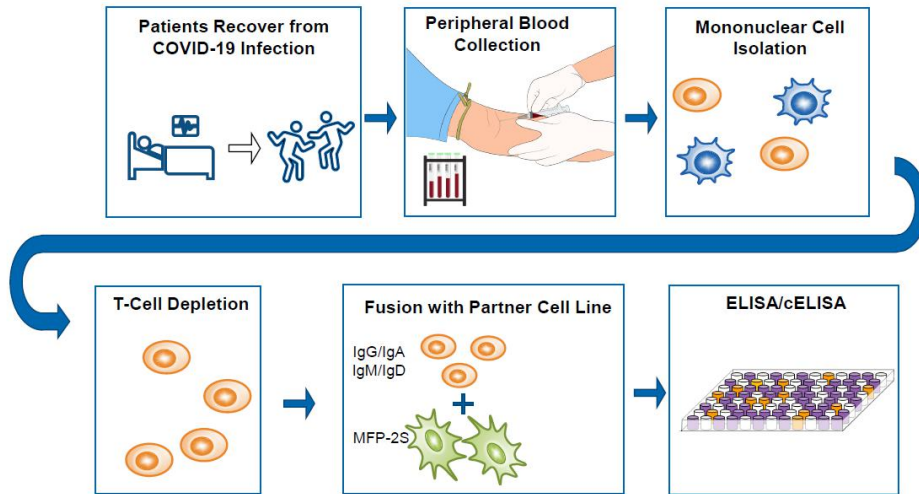
⁴Baum, A. et al. *Science*. 2020 Aug 21;369(6506):1014-1018. doi: 10.1126/science.abd0831. Epub 2020 Jun 15.

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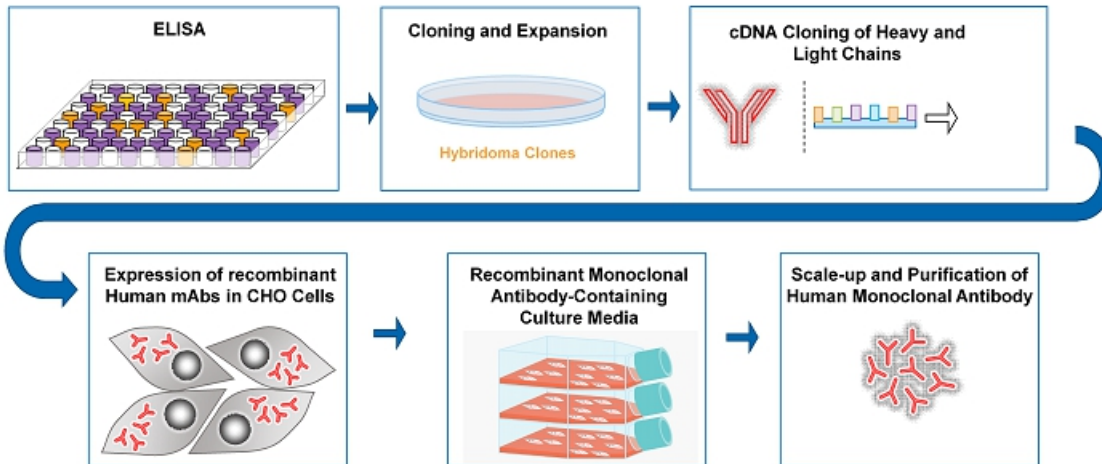
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Generation of Fully Human Monoclonal Antibodies (1 of 3)



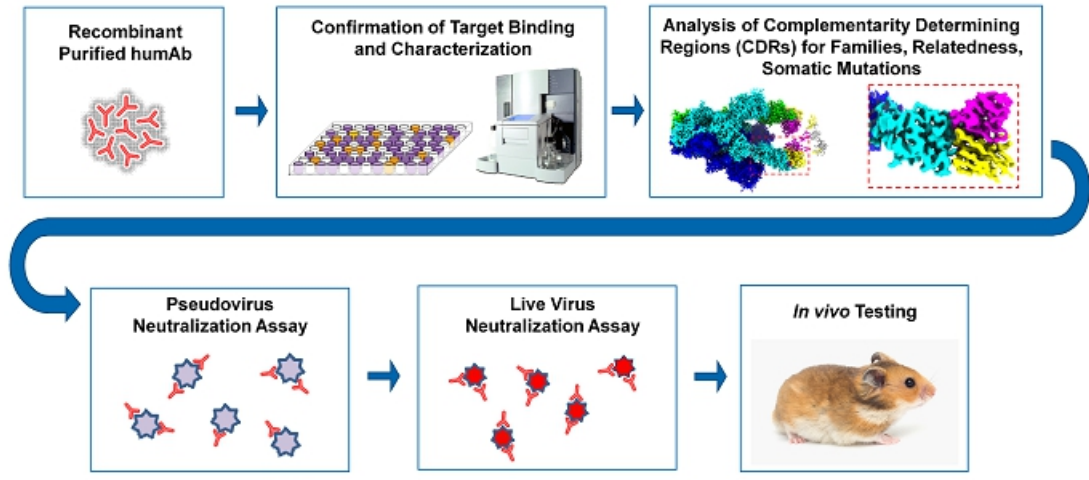
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Generation of Fully Human Monoclonal Antibodies (2 of 3)



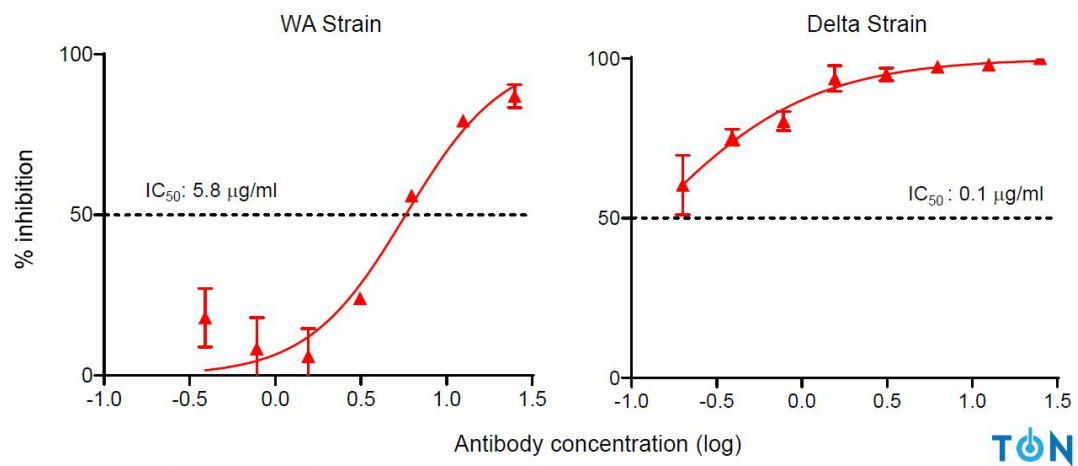
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Generation of Fully Human Monoclonal Antibodies (3 of 3)



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. © 2022 Tonix Pharmaceuticals Holding Corp.

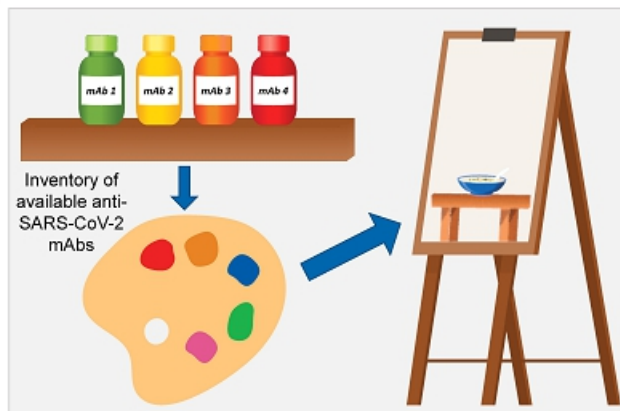
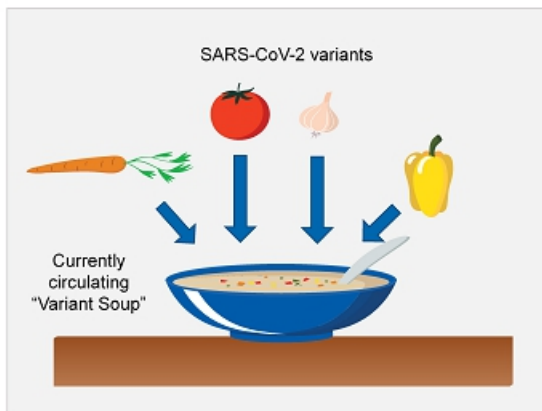
Therapeutic Monoclonal Antibody Development for COVID-19 has been Focused on a “Whack-a-Mole” 1x1 Monoclonal Antibody v. Variant Battle



- As new variants emerge, mAbs that were highly effective against older variants may quickly lose their place in the treatment landscape¹
 - 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 utility²

¹Waltz, 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/ncm-legal-regulatory-and-policy-framework/emergency-use-authorization/covid19drugs>.

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



¹Callaway, 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

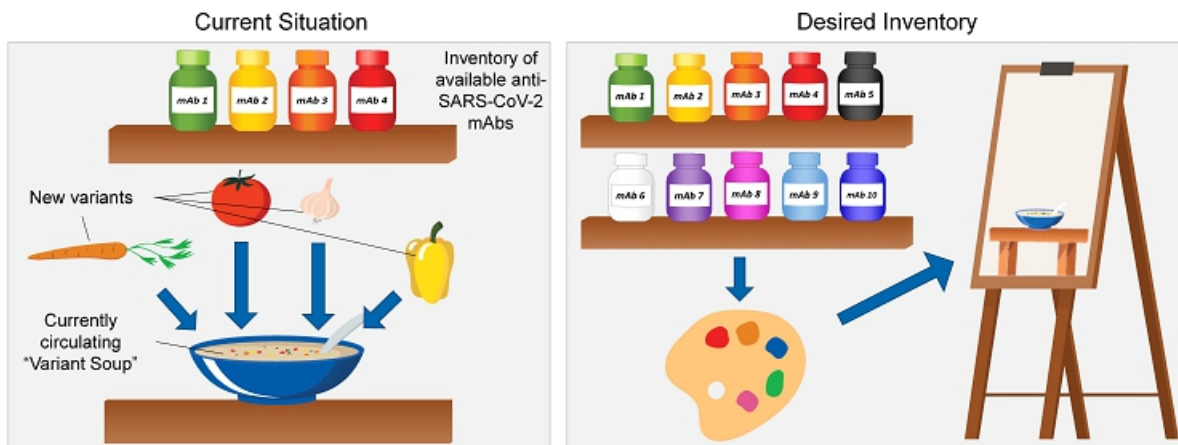
The Platform is Designed to Develop and Maintain a Diverse Inventory of Monoclonal Antibodies to Keep Up with SARS-CoV-2 “Variant Soup”¹



¹Callaway, 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/d41588-022-03445-6

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



¹Callaway, 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/d41588-022-03445-6

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Future of COVID-19 mAb Therapeutics and Prophylactics

- **Immune-evading SARS-CoV-2 variants are arising by divergent and convergent evolutionary processes¹**
 - 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**
 - With respect to EUA product Bectelovimab, the NIH Guidelines group wrote, “...there are no clinical efficacy data on the treatment of patients who are at high risk of progressing to severe COVID-19”²
 - For “updated” mRNA booster vaccines encoding omicron spike antigen, FDA approvals were granted without human efficacy data consistent with a “cartridge” approach

¹Callaway, 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

Investigators and Collaborators

- **Tonix**
 - Seth Lederman
 - Bruce Daugherty
 - Herb Harris
 - Candace Flint
- **Columbia**
 - Ilya Trakht
 - Gavreel Kalantarov
 - Sergei Rudchenko
 - Milan Stojanovic
- **Texas BioMed**
 - Viraj Kulkarni
 - Marco Argonza
- **Chicago BioSolutions**
 - Lijun Rong
- **Curia**
 - Brian Zabel

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 2022



Architectural Rendering

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THANK YOU

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