



## **Forward Looking Statement**

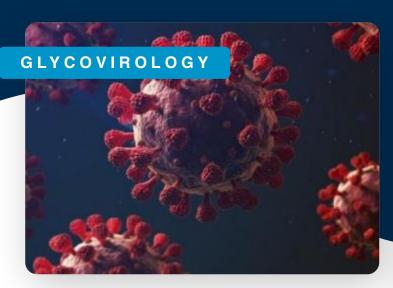
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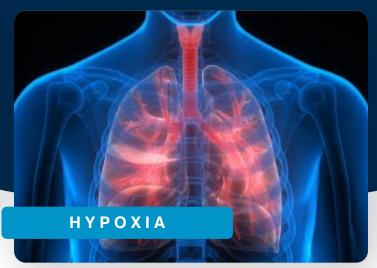
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## **Mission Statement**

**Bioxytran** is a clinical stage pharmaceutical company developing platform technologies in the fields of Glycovirology, Hypoxia and Degenerative Diseases to eliminate viruses and prolong lifespan using carbohydrate drug design.









## **Technology Overview**

### **ProLectin Rx – Glycovirology**

#### **Virology:**

- Covid-19
- Influenza
- Other virologic diseases

## Long term symptoms resulting from viral infections (long-hauler):

- ARDS
- Pulmonary Fibrosis

### **BXT-25 – Hypoxia & Degenerative Diseases**

#### Ischemia:

- Stroke
- Alzheimer
- Dementia
- Traumatic Brain Injury

## **Anemia Wound healing**

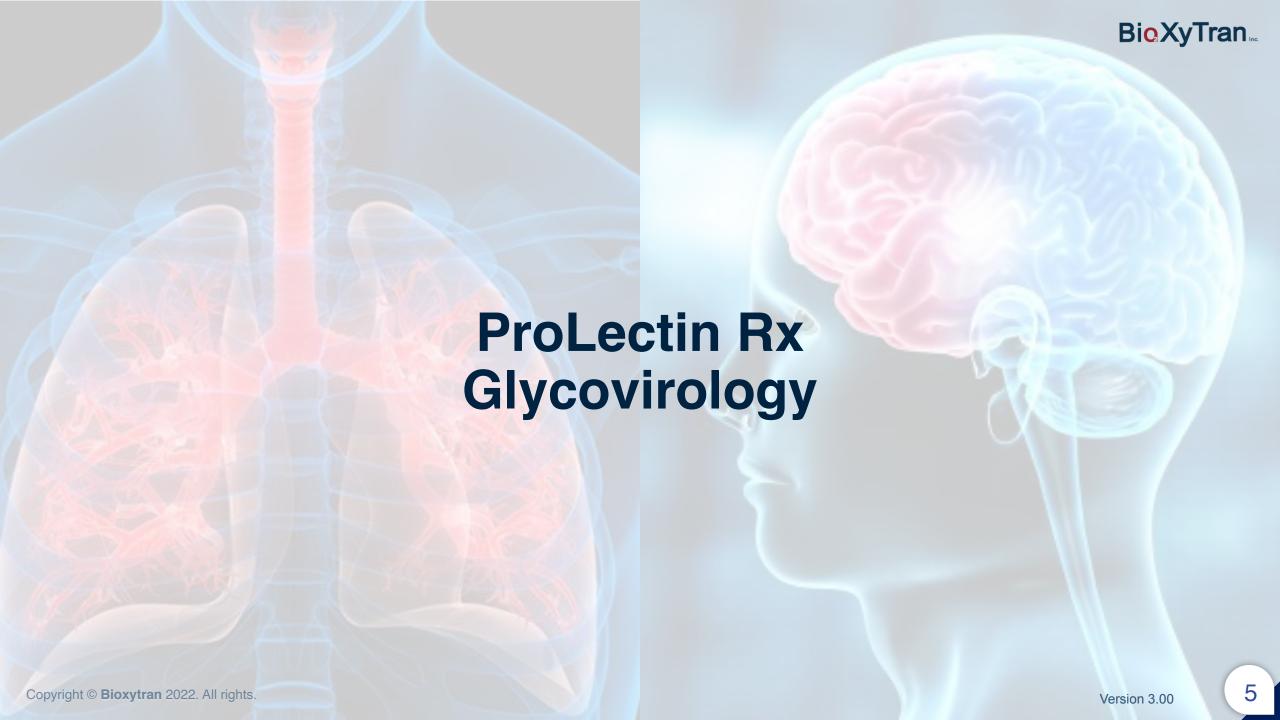
#### **Oncology and Fibrosis**

- Cancer Metastasis
- NASH
- Other Fibrotic condition

Platform Overlap

**ProLectin-M** is a licensed technology that targets COVID-19 mild to moderate cases

**OXYSENSE** is a licensed technology that uniquely allow the company to prove oxygen delivery to tissue. It will be used in clinical trials as a regulatory end-point



## **Lingering Effects of COVID-19**

#### Variants are complicating the vaccination strategy



#### **Herd Immunity**

80% level has not been reached



#### **Vaccination**

Not everyone wants to get vaccinated

Not everyone has access to vaccines



#### **New mutations**

Alpha, Delta, Omicron, ?



#### Higher risk of death

For at risk population



#### **Asymptomatic spread**

Spreads without showing symptoms

#### **Vaccinations Unknowns (risks)**

- Duration of protection
- Effectiveness against variants
- Frequency of boosters
- Long Term consequences of Immune system

If herd immunity is unattainable Therapeutic treatments are the ONLY fall back position



## **ProLectin-Rx Galectin Antagonist Platform**



Versatile

Mutation Agnostic Therapeutic

No Expected

Limitations



**Tested** (Academic Study\*)

No toxicity
Reduction of viral load to
undetectable levels



**Efficient** 

Quickly eliminates contagion

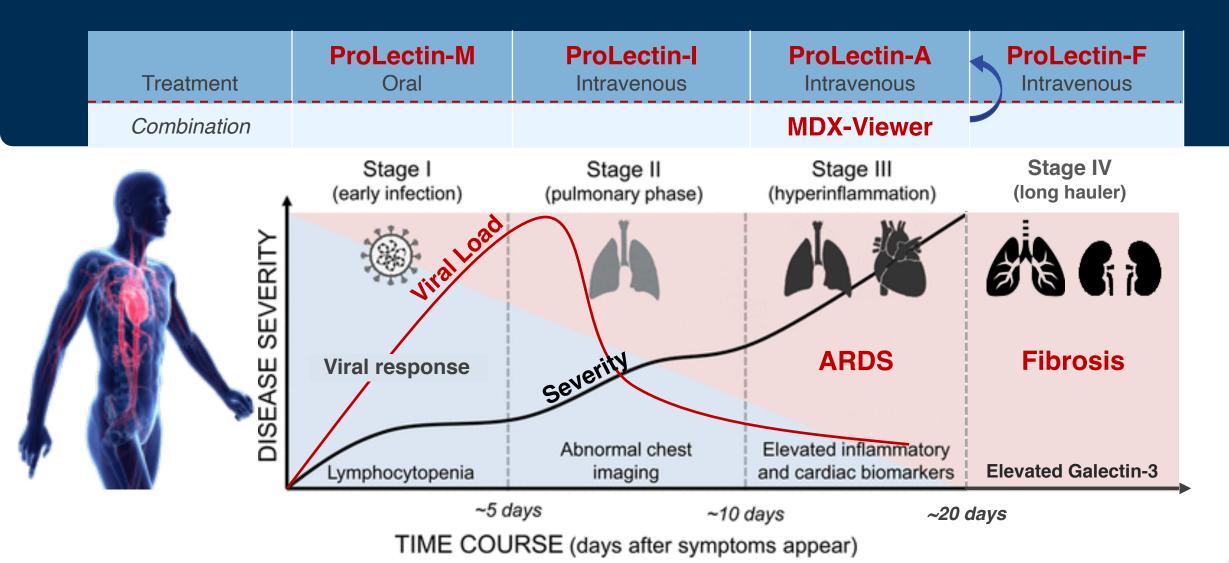
# First line of defense against <u>all</u> mutations of Coronaviruses

STATUS:

Clinical Trial Stage - IND Submitted

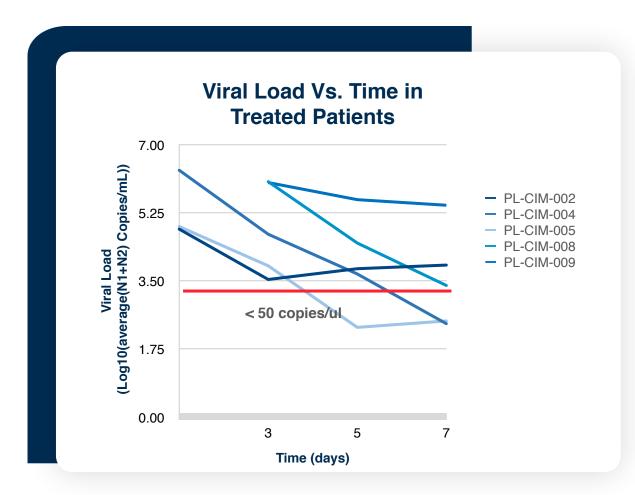
<sup>\*</sup>https://www.longdom.org/abstract/galectin-antagonist-use-in-mild-cases-of-sarscov2-pilot-feasibility-randomised-open-label-controlled-trial-61087.html

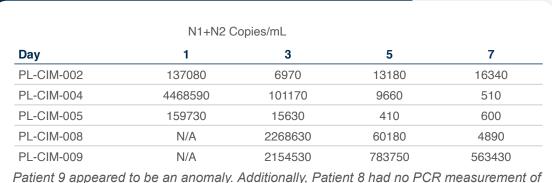
## **End-to-End Solution**



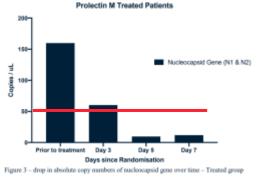


## **Patients Treated With Galectin Antagonist Experienced Reductions In Viral Load**



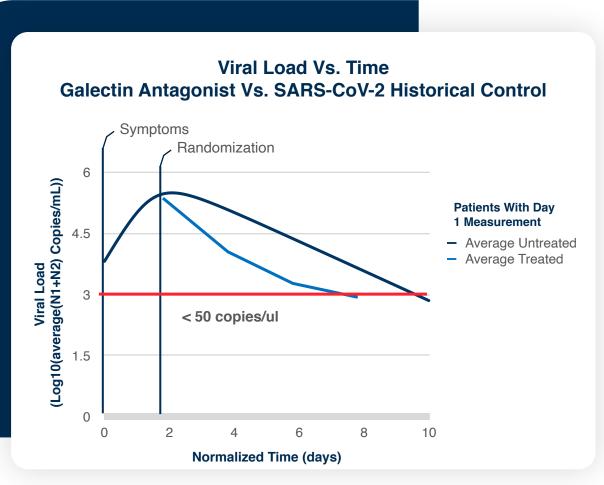


viral load on day 1, so day 1's PCR measurement was assumed to equal day 3's measurement.





## **Viral Curve Comparison**



Historical control is taken from a mathematical model using longitudinal data across four different studies of symptomatic, untreated cases<sup>1</sup>

Assumed symptom onset at a viral load of 6500 copies/mL (i.e. log10(3.81))<sup>1</sup>

Patients treated within 2 days of symptom onset (average 1.80 days)<sup>2</sup>

Upper and lower bounds of the model are 95% confidence interval<sup>1</sup>

<sup>1</sup> A quantitative model used to compare within-host SARS-CoV-2, MERS-CoV, and SARS-CoV dynamics provides insights into the pathogenesis and treatment of SARS-CoV-2 (plos.org)

<sup>&</sup>lt;sup>2</sup> Galectin Antagonist use in Mild Cases of SARS-CoV-2; Pilot Feasibility Randomised, Open Label, Controlled Trial (longdom.org)



## Galectin Antagonist Treatment Results in SARS-CoV-2 Spike Protein Specific Antibody Immunity



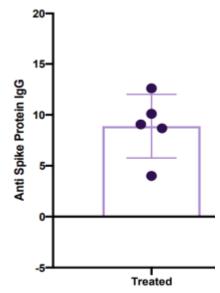


Figure 4 - difference in IgG on day 28



### **Introducing Post Infection Immunization**

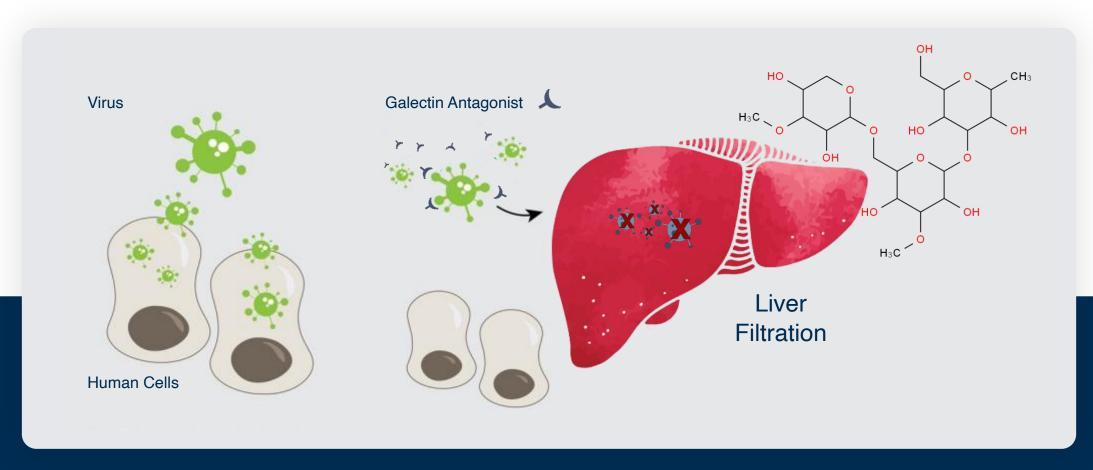
Galectin antagonists clear the blood of viral load thereby reducing the strain on the Innate immune system so the Adaptive immune system can build a robust response toward future infection.

https://www.longdom.org/abstract/galectin-antagonist-use-in-mild-cases-of-sarscov2-pilot-feasibility-randomised-open-label-controlled-trial-61087.html



## **Galectin Antagonists Tags Virus For Elimination**

#### Theoretical Mechanism of Action



## **Clinical Research**

## Galectin Antagonist use in Mild Cases of SARS-CoV-2: Pilot Feasibility Randomised, Open Label, Controlled Trial

Alben Sigamani\*, Mathu Ruthra, Sudhishma, Samarth Shetty, Madhavi, Anup Chugani, Hana Chen-Walden, David Platt and Thomas Kutty

Importance: Novel SARS-CoV-2 virus has infected nearly 100 million people across the world and is highly contagious. There is a need for a novel mechanism to block viral entry and stop its replication.

**Background:** Spike protein N Terminal Domain (NTD) of the novel SARS-CoV-2 is essential for viral entry and replication in human cell. Thus the S1 NTD of human coronavirus family, which is similar to a galectin binding site-human galactose binding lectins, is a potential novel target for early treatment in COVID-19.

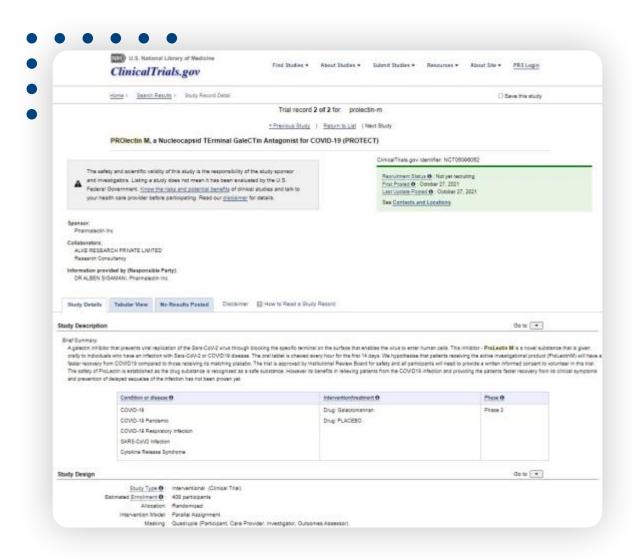
**Objectives:** To study the feasibility of performing a definitive trial of using galectin antagonist–Prolectin-M as treatment for mild, symptomatic, rRT-PCR positive, COVID-19.

Main outcomes and measures: Cycle threshold (Ct) value is number of cycles needed to express fluorescence, on real time reverse transcriptase polymerase chain reaction. Ct values expressed for RNA polymerase (Rd/RP) gene+Nucleocapsid gene and the small envelope (E) genes determine infectivity of the individual. A digital droplet PCR based estimation of the Nucleocapid genes (N1+N2) in absolute copies/µL determines active viral replication.

https://www.longdom.org/abstract/galectin-antagonist-use-in-mild-cases-of-sarscov2-pilot-feasibility-randomised-open-label-controlled-trial-61087.html



## **Proposed Clinical Trial Design**





#### **Clinical Trial**

- 408 participants
- Double Blind Randomized Controlled Trial (DBRCT)
- Change in seropositivity at day 14
- Broad inclusion criteria (Vaccination status irrelevant)

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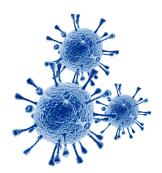


## **Glycovirology Development Pipeline**

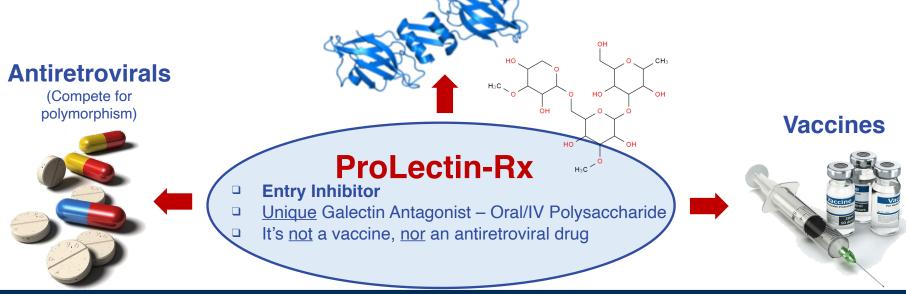




## **Therapeutic Approaches for COVID-19**



## Immunomodulatory





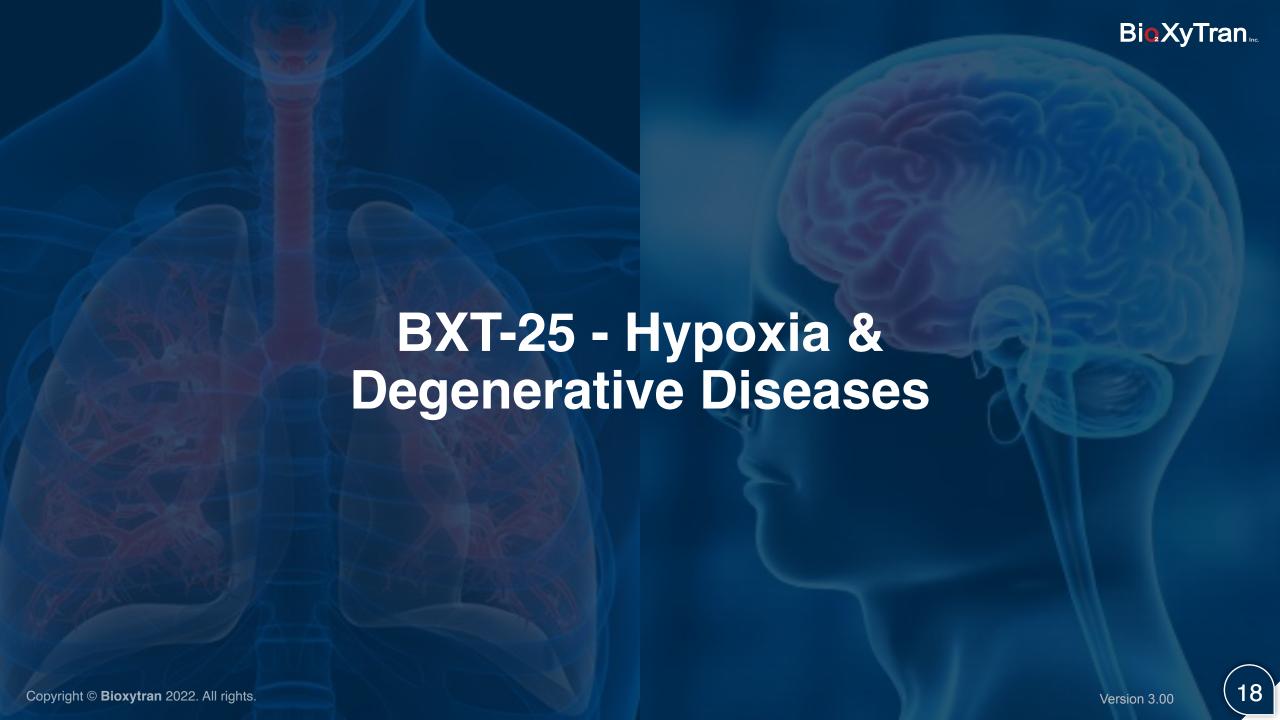
Regenerative Medicine
(Stemcells)



## **Competitive Landscape**Oral COVID-19 Therapeutics

Drug	Company	Description	Gov. Award	Clinical stage
Molnupiravir	Merck	Mutagenesis via RdRp – forced mutations induced apoptosis	\$2.2 billion	EUA
Paxlovid	Pfizer	3CL protease inhibitor – Antiviral & Immune sensitization; Ritonovir – inhibitor enhancer	\$5.3 billion	EUA
Tollovir	Todos Medical	3CL protease inhibitor – Antiviral & Anti-Cytokine activity	n/a	Phase 2/3
Tempol	Adamis	RNA-dependent RNA Polymerase (RdRp) via antioxidant & Anti-Cytokine activity	n/a	Phase 2/3

Governments are End Users of Therapeutics (Big Pharma Involvement - Unnecessary)





## **The Brain Stroke Epidemic**

A Challenge to Worldwide Healthcare, a \$500 Billion Medical Indication Costs





33.0 million

Global, regional, and national burden of stroke and its risk factors, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019 The Lancet Neurology, Vol 20, Issue 10, October 01, 2021 Copyright © **Bioxytran** 2022. All rights.

7,700 million

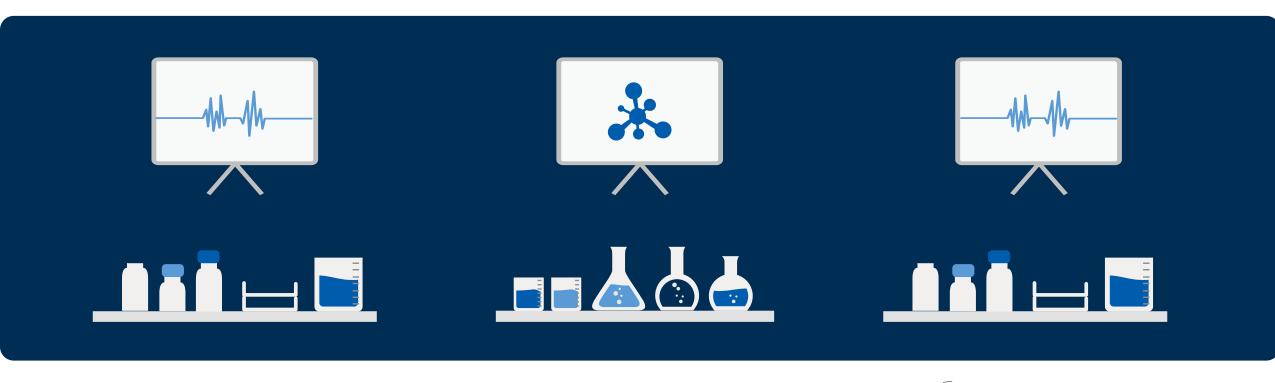
12.2 million

World (total)

estimated \$500 billion



## The Golden Hour Dilemma









Ambulance arrives at home



Arrival and initial assessment and treatment in ER



Thombolysis or PTCA/CABG



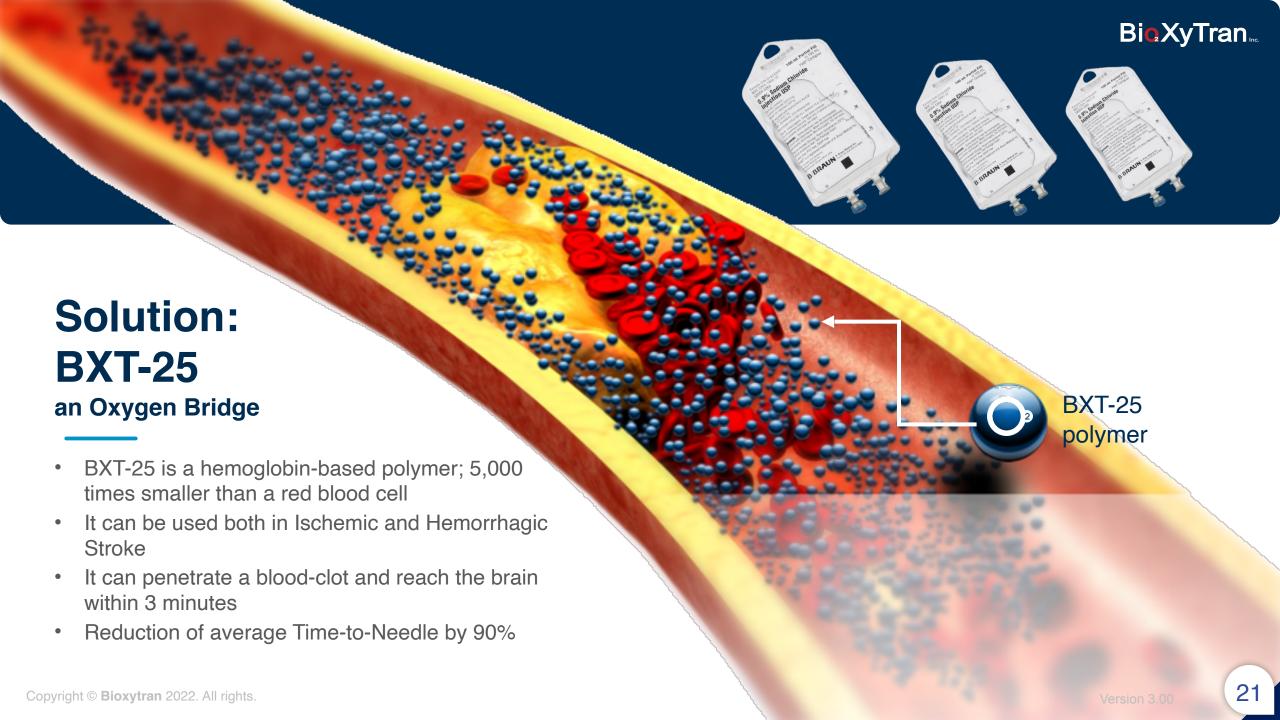
Blockage Removed

Time to Needle

## 2.5 hours

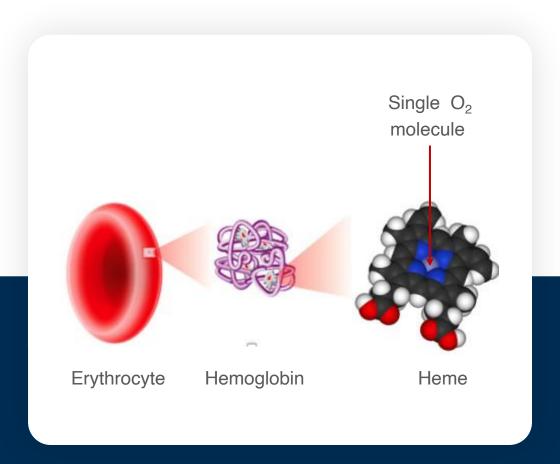
Equivalent to 9 Years of Aging\*

<sup>\*</sup> Time Is Brain—Quantified, Jeffrey L. Saver, Stroke. 2006;37:263–266 Copyright © **Bioxytran** 2022. All rights.





# How It Works? BXT-25 – Stabilized Oxygen-carrying Protein



- Delivered as an IV solution
- Universally compatible with all blood types
- Non-immunogenic
- Low viscosity
- Stable at room temperature
- 3-year shelf-life in liquid formulation
- Extended shelf-life in dry formulation



infused by an ER team

## **Proprietary Manufacturing Process of BXT-25**



crosslink

reattach to a polymer

source Red blood cells

Protein

Key Assays for BXT-25 chemical and structural specifications are: Electron spray Ionization, Amino Acid Analysis, Gel Electrophoresis, Circular Dichroism, Reverse phase HPLC and Immunoblotting

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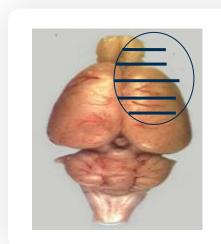
## **Proof of Concept of BXT-25 in Animals**

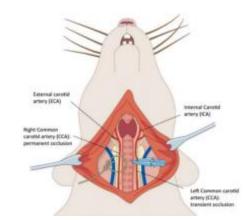
Absence of nitric oxide scavenging, no increased blood pressure in diabetic mice (Harvard Medical School, 2013)

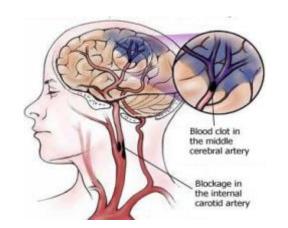
Oxygen delivery and brain recovery in stroke induced rats with similar chemistry to BXT-25 (Harvard Medical School, 2013)

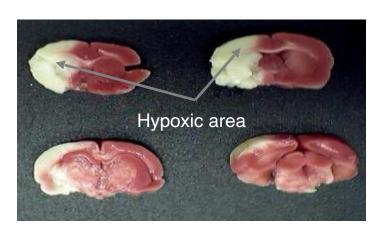
No toxicity from replacing 90% of the blood in dogs with similar chemistry to BXT-25: (QTest Labs, Columbus OH, 2014)

#### Middle Cerebral Artery Blockage Model in Rats









https://www.hindawi.com/journals/ccrp/2014/864237/



# **Limited Effective Treatment Options**



Our competition is tPA and similar drugs, aiming to dissolve, or remove, a clot. These are time-consuming and require an MRI since blood-thinners are fatal in hemorrhagic strokes.

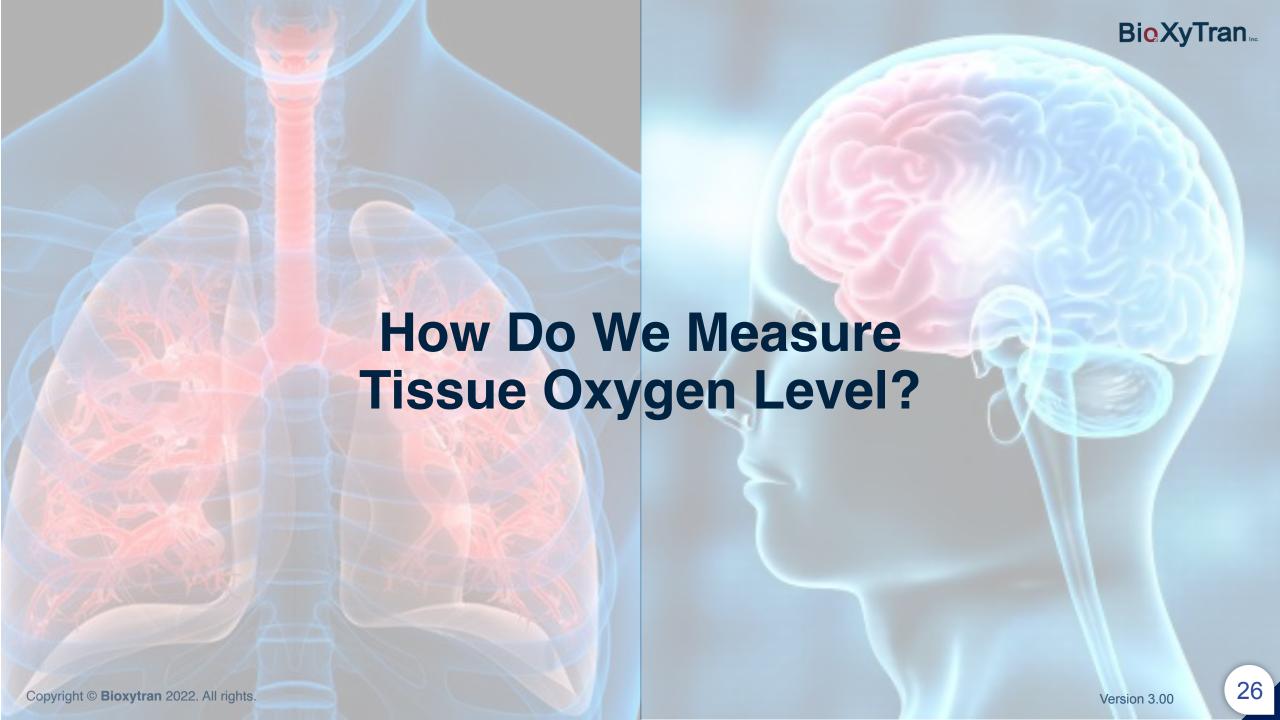
# THERE ARE NO DRUGS AVAILABLE TO DELIVER OXYGEN TO THE BRAIN

Drug	Company	Description
rtPA	Genentech, Johnson & Johnson	Thrombolytic agent used to break apart blood clot that causes ischemic stroke
Abciximab	Eli Lilly /Centrocor	Platelet aggregation inhibitor
Cerovive	AstraZeneca	Nitrone based neuro protectant
Candesartan	AstraZeneca	Angiotensin receptor blocker (ARB)
Ancrod	Knoll Pharmaceuticals	Anticoagulant that acts by breaking down fibrinogen

BXT-25 is designed to support the oxygenation of the brain until the clot is dissolved by medication or removed by surgery

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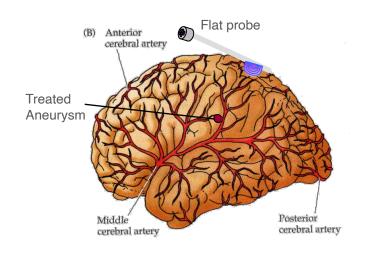
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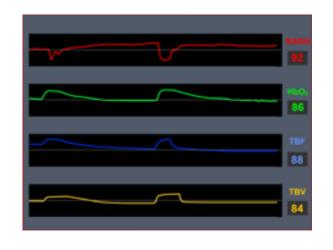


## **FDA Approved Companion Diagnostics**

OXYSENSE - A clinical end-point for measuring oxygen delivery to the brain in real-time



#### Tissue/brain monitored parameters



Mitochondrial NADH (ATP)

Hb Saturation (O<sub>2</sub>)

Cerebral Blood Flow

Tissue Reflectance

Brain metabolic score



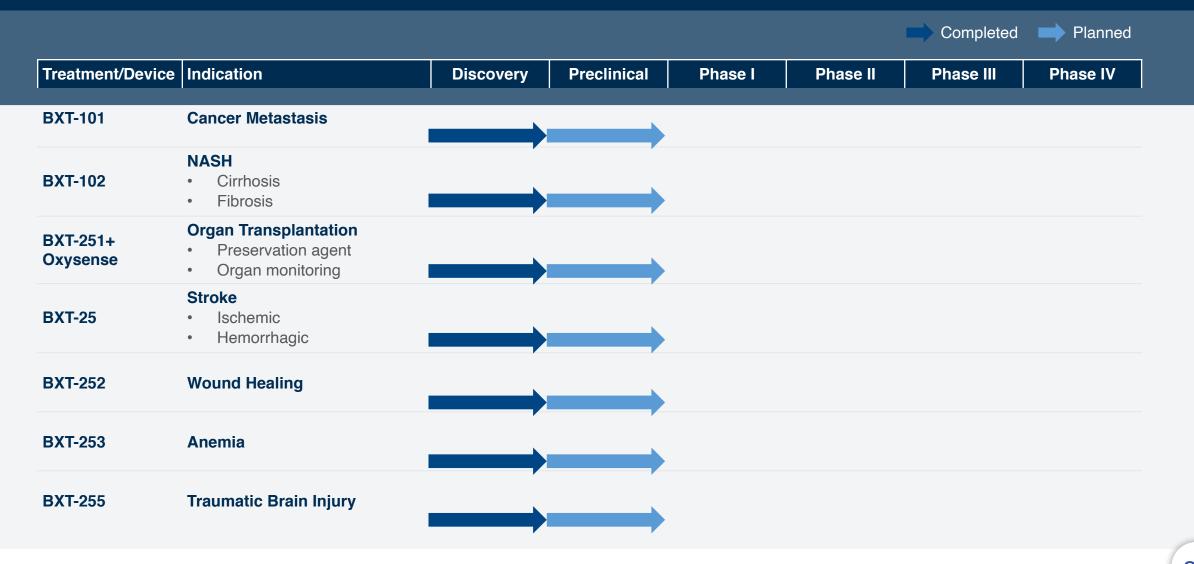
Measures real time tissue oxygenation levels



Assists in determining organ viability



## Degenerative Disease/Hypoxia Development Pipeline



# Business Development & Strategy



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## Clinical Trial Strategy

	_	2021			2022			
Product	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
ProLectin-M			Р	re-clinical Deve	lopment	Phase I/II	Phase III	
ProLectin-I				Pre-clinica	al Developme	ent	Phase I/II	Phase III
ProLectin-F				Pre-clinica	al Developme	ent	Phase I/II	Phase III
ProLectin-A / BXT-25	·				Pre	-clinical Develor	oment	Phase I/II



## **Business Strategy**





- One issued US patent (US6245316B1)
- Two international patents pending approval
- Additional applications to strengthen our IP position are ongoing



### **Business Development Strategy**

- Collaboration agreement with qualified partner's
- Out-license agreements with Big Pharma



## **Big Pharma Licensing Targets**

THERAPEUTIC AREAS

Virology Neuroscience Oncology Cardiovascular Immunology Hematology Respiratory Stroke Inflammation

#### IDEAL PLATFORM DRUG FOR MANY BIG PHARMAS

- Johnson & Johnson Oncology, Neuroscience, Immunology, Cardiovascular, Vaccines, HIV
- Roche Holdings Oncology, Neuroscience, Immunology, Hematology, Ophthalmology
- Pfizer Oncology, Neuroscience, Cardiovascular, Diabetes
- Novartis Oncology, Neuroscience, Immunology, Cardiovascular, Respiratory, Ophthalmology
- Merck Oncology, Neuroscience, Immunology, Cardiovascular, Respiratory, Diabetes, Vaccines
- Sanofi Aventis Oncology, Neuroscience, Immunology, Inflammation, Diabetes, Vaccines
- AbbVie Oncology, Neuroscience, Immunology, Virology
- GlaxoSmithKline Oncology, Immunology, Respiratory, HIV, Vaccines
- Eli Lilly Oncology, Neuroscience, Immunology, Diabetes, Pain
- Gilead Oncology, Respiratory, Hematology, Inflammation, HIV
- Bristol Meyers Squibb Oncology, Immunology, Cardiovascular, Hematology, Inflammation
- Allergan Neuroscience, Ophthalmology, Gastroenterology
- AstraZeneca Oncology, Cardiovascular, Respiratory
- Biogen Oncology, Neuroscience, Inflammation, Stroke, Pain
- Amgen Oncology, Cardiovascular, Hematology, Inflammation

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## **Use of Proceeds**

Current Round – S-1	ProLectin-M	ProLectin-I	ProLectin-F	ProLectin-Rx*
Estimated Project Cost in thousands USD*	\$ 2,700	\$ 1,650	\$ 1,000	\$ 5,350
Development & GLP	-	-	-	-
Pre-Clinical	100	150	150	400
IND Submission	150	200	200	550
Clinical Trials	2,000	1,000	500	3,500
G&A	450	300	150	900
End Point	Phase III	Phase II/a	Phase II/a	Total

<sup>\* \$2.6</sup> million have previously been spent on proof-of-concept and GMP manufacturing of ProLectin-M, -I, and -F

Future Round	ProLectin-A	BXT-25	Total Upcoming*
Estimated Project Cost in thousands USD*	\$ 10,000	\$ 10,000	\$ 20,000
Development & GLP	3,150	3,150	6,300
Pre-Clinical	1,200	1,200	2,400
IND Submission	300	300	600
Clinical Trials	4,000	4,000	8,000
G&A	1,350	1,350	2,700
End Point	Phase II/a	Phase II/a	Total



## The Team

#### Management

#### David Platt PhD, CEO, CSO, Chairman

Carbohydrate chemistry expert, founded four publicly traded companies/3 NASDAQ listings, raised \$150m in public markets, created \$1B in shareholder value, and led development of four drugs candidates.

#### Ola Soderquist CPA, MSA, MBA, CFO

>30 years multi-industry financial experience.

#### Mike Sheikh, EVP BD

>10 years of business development in life sciences. Broker and Research Analyst.

#### Veronika Tyukova MBA, PM Dir

>15 years of PM in Hi-Tech, Manufacturing and Commercialization.

#### **Board of Directors**

#### Anders Utter MBA, Director

Audit Committee Chair, >25 years of managerial finance and accounting in medical devices and manufacturing.

#### Dale Conaway DVM, Director

Veterinary Medical Officer, Federal Research.

#### Alan Hoberman PhD, Director

Executive Director of Site Operations and Toxicology at Charles River Laboratories.

#### Hana Chen-Walden MD, Director

>30 years experience in pharmaceutical regulatory affairs in US and Europe.

#### **Advisory Board**

#### **Avraham Mayevsky PhD, Professor Emeritus**

Worldwide authority in the field of minimal invasive monitoring of tissue and organ physiology; and professor at the Faculty of Life Sciences, Bar-Ilan University, Israel.

#### Alben Sigamani, MD

Professor and Head of Clinical Research Narayan Health, Bangalore. >17 years of experience in clinical research

#### Thomaskutty Alumparambil, C.C.P

> 30 years of clinical experience that includes heart, lung, and liver transplants.

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