BioXyTran® Inc.
Tissue Regeneration For Life

Bioxytran, Inc.
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Ticker (Exchange)	(BIXT-OTCBB)
Recent Price (08/26/2022)	$1.01
52-week Range	$0.0005 - $1.15
Shares Outstanding	110.8 million
Market Capitalization	$112 million
Average volume	88,500
Insider Ownership +>5%	78%
Institutional Ownership	--
EPS (Qtr. ended 06/30/2022)	($0.01)
Employees	4

BIXT (OTCBB One-year Stock Chart)

BIOXYTRAN TECHNOLOGY OVERVIEW

ProLectin - Glycovirology	BXT-25-Hypoxia & Degenerative Diseases
VIROLOGY	**ISCHEMIA**
▪ COVID-19	▪ Stroke
▪ Influenza	▪ Alzheimer's
▪ Other virologic diseases	▪ Dementia
	▪ Traumatic Brain Injury
LONG TERM SYMPTOMS RESULTING FROM VIRAL INFECTION	
▪ ARDS	**ANEMIA**
▪ Pulmonary Fibrosis	**WOUND HEALING**

Source: Bioxytran, Inc.

COMPANY DESCRIPTION

Bioxytran, Inc. ("Bioxytran" or "the Company") is a clinical stage pharmaceutical company developing therapeutics in two areas: (1) **glycovirology†** and anti-viral therapeutics; and (2) **hypoxic** conditions, **necrosis**, and degenerative diseases. Bioxytran's glycovirology efforts, conducted through its subsidiary, Pharmalectin Inc., are focused on developing a novel technology platform—ProLectin—designed to reduce the viral load and modulate the immune system through **galectin-3** inhibition. Galectin-3 inhibitors have the capability to bind with proteins on the surface of a virus, preventing the virus from attaching to and entering the cell. Using its ProLectin technology platform, Bioxytran is developing a group of therapeutic candidates that provide an end-to-end solution for **COVID-19**, including treatment for severe conditions derived from the disease. The Company's lead candidate, ProLectin-M, is a chewable tablet for treating mild-to-moderate COVID-19 that binds with the spike proteins on the virus' surface and acts as a cell-entry inhibitor. With an initial focus on COVID-19, Bioxytran believes that its technology can be used to create therapeutics targeting a considerable number of viruses, as well as the potential creation of a single molecule designed to target multiple receptors responsible for various aspects of a disease. Bioxytran's second technology platform—its hypoxia program—relies on the application of its proprietary **co-polymer** chemistry manufacturing process to enhance the **hemoglobin** molecule, creating an injectable intravenous drug that prevents necrosis by carrying oxygen to brain cells that have limited or blocked blood flow. Bioxytran's lead candidate in this research area is BXT-25, an oxygen-carrying small molecule intended to treat hypoxic conditions in the brain resulting from **stroke**. BXT-25 development is on hold pending the raise of additional capital.

KEY POINTS

- ProLectin-M complements the Company's intravenous drug candidates: ProLectin-I, for the treatment of more severe cases of COVID-19; ProLectin-F, for the treatment for COVID-related lung-**fibrosis**; and ProLectin-A, for the treatment of COVID-related **ARDS**.
- To its knowledge, Bioxytran is the only company planning to develop a viable end-to-end solution for COVID-19 using a **galectin** inhibitor to combat the virus.
- During proof-of-concept studies, ProLectin-M was found to bind strongly to the COVID-19 virus, preventing entry of the virus into its target cells. Treatment with ProLectin-M resulted in symptom-free patients within 24 to 72 hours, with a significant **PCR** reduction of viral load to undetectable levels within three days, while displaying no serious adverse events.
- The Company is currently working on a Phase 3 clinical trial with the CDCSO in India and is preparing its IND application for a Phase 2 clinical trial with the FDA for ProLectin-M. Bioxytran expects both trials to be completed by fourth quarter 2022.
- Bioxytran's management and scientific advisory board hold extensive expertise in **complex carbohydrate chemistry (CCC)** and regulatory and clinical development, with multiple submissions and approvals to the FDA.
- The Company's cash position as of June 30, 2022 was $500,677. On August 15, 2022, Bioxytran entered into a subscription agreement netting the Company cash of $576,000.

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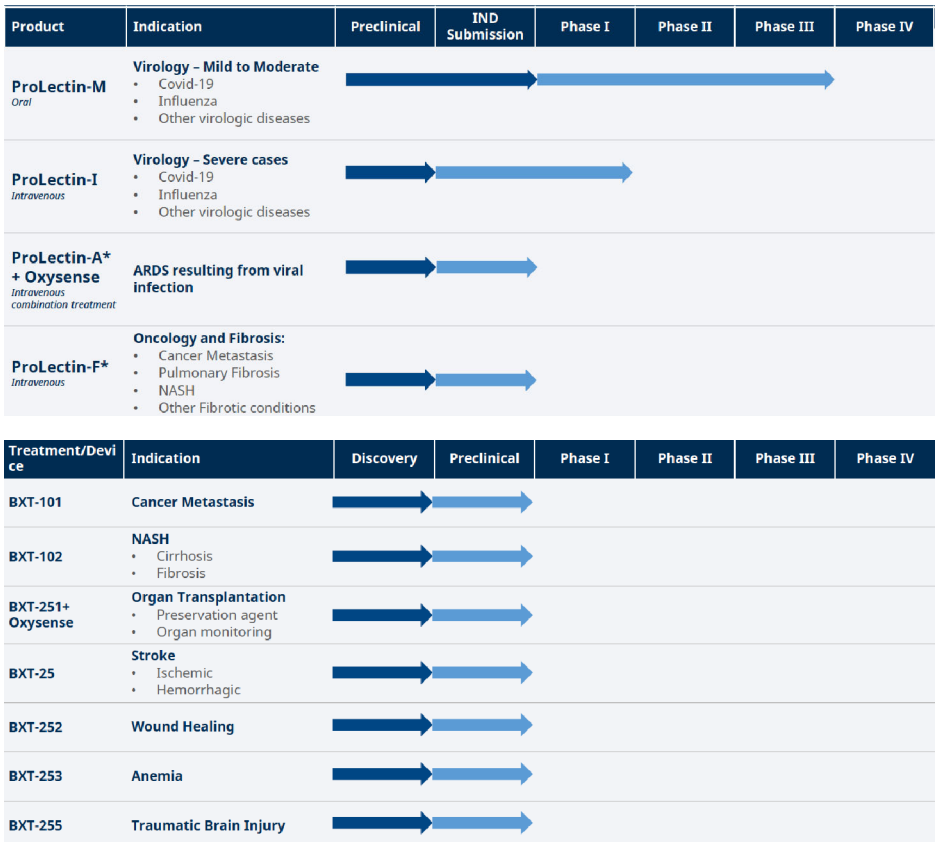
Executive Overview

Bioxytran, Inc. ("Bioxytran" or "the Company") is a clinical stage pharmaceutical company developing platform technologies in the fields of glycovirology, hypoxia, and degenerative diseases. The Company is focused on the development and commercialization of therapeutic drugs designed to target conditions in two different medical areas: (1) glycovirology and anti-viral therapeutics, with an initial focus on COVID-19; and (2) hypoxic conditions, necrosis, and degenerative diseases, with an initial focus on conditions in the brain resulting from stroke. The Company's pipeline for both of its technology platforms is summarized in Figure 1.

Figure 1

BIOXYTRAN PIPELINE



Source: Bioxytran, Inc.

PROLECTIN TECHNOLOGY PLATFORM

Bioxytran's glycovirology efforts are conducted through its subsidiary, Pharmalectin Inc., of which the Company maintains 85% ownership. Pharmalectin is developing a novel technology platform—ProLectin—designed to reduce the viral load and modulate the immune system using glycovirology principles. The novel anti-viral approach is based on the use of the galectin inhibitor for the development of therapeutics for viral diseases, with a special emphasis on **Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)**—the virus that causes COVID-19. The technology is built on the lifetime work of the Company's founder, Dr. David Platt (biography on page 10). Although the Company's initial focus is the SARS-CoV-2 virus, Bioxytran believes that its technology can be used to create antiviral therapeutics targeting a significant number of viral pathogens, as well as the potential creation of a multiple-antagonist molecule that can target the various biological pathways responsible for different aspects of a disease.

Using its ProLectin technology platform, Bioxytran is developing an end-to-end solution for COVID-19, including treatment for severe conditions derived from the disease. The Company's lead candidate, ProLectin-M, is a chewable tablet for the treatment of mild-to-moderate COVID-19. ProLectin-M complements the Company's intravenous drug candidates: ProLectin-I, for the treatment of more severe cases of COVID-19; ProLectin-F, for the treatment of COVID-related lung-fibrosis; and ProLectin-A, for the treatment of COVID-related Acute Respiratory Distress Symptom (ARDS).

Glycovirology Overview

Glycovirology is a new field of molecular biology research that aims to characterize the interactions between viruses and **glycans**—complex carbohydrates molecules found on the surface of cells. Glycans are involved in many biological processes, including intercellular communication, cell-cell recognition, cell growth and differentiation, cell death, and the transmission of signals in immune responses. This is done through the binding of proteins called **lectins** to specific glycans.

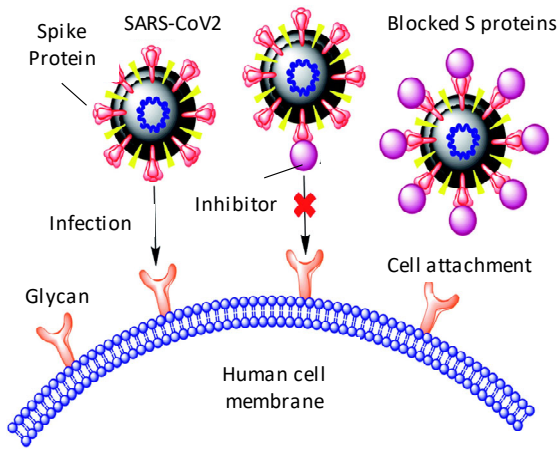
Within the lectin protein family, one type of lectins, specifically galectins**,** have been found to play multiple roles in regulating virus infections. For a virus to gain access to a cell, proteins on the virus' surface must bind to certain glycans on a cell surface, allowing them to enter the cell, and marking the initial steps of a viral infection. This mechanism of viral infection—controlled by the binding of a virus' surface proteins to specific glycans—could allow researchers to create therapeutic agents that attach directly to these viral proteins, preventing the binding of these viruses to the cell surface, and acting as cell-entry inhibitors (Source: *Viruses*, Vol. 10(11); 636, 2018). This is the strategy that the Company employs, using its technology platform to develop galectin inhibitors that target the virus (instead of the cells), binding with the virus surface proteins, and blocking the binding of the virus to cells.

Glycovirology and COVID-19 (SARS-CoV-2)

The outbreak of SARS-CoV-2, the causative agent of COVID-19, was declared a global pandemic by the World Health Organization. As of August 2022, more than 600 million cases have been reported worldwide, resulting in over 6.4 million deaths. The U.S. is still considered one of the epicenters of the disease, with roughly 94 million cases and over a million deaths.

Galectin-3 (one of the 15 galectin subtypes) inhibition has been shown to be beneficial in treating COVID-19. Galectin-3 expression in healthy tissues is highest in the lungs, followed by the gastrointestinal tract. This is noteworthy since, in addition to respiratory issues, an increasing number of patients infected with COVID-19 have reported gastrointestinal symptoms, such as diarrhea, nausea, and vomiting, indicating a possible correlation between the presence of Galectin-3 and the areas affected by the disease (Source: *PeerJ,* Vol. 8: e9392, 2020).

Figure 2
GALECTIN INHIBITORS' MECHANISM OF ACTION



Source: RSC Advances, Vol. 10:29873-29884, 2020.

A primary factor in the use of galectin-3 inhibitors to prevent COVID-19 infection has to do with the SARS-CoV-2 virus morphology. A key structural protein of the virus, the spike (S) protein, which protrudes out from the viral surface and gives coronaviruses their distinctive crownlike appearance, is the sole protein responsible for mediating viral entry into the host cell. This spike protein has the ability to bind to specific glycans on human cell surfaces, facilitating the entry of the virus into the cell. However, a conserved region of the spike protein, called the galectin fold, is nearly identical in morphology to human galectin-3. Given this structural similarity, the Company believes that inhibitors against human galectin-3 also have the capability to bind to the spike protein, preventing the binding of the virus to human cells and the subsequent infection of the cells. This proposed mechanism is shown in Figure 2 (Source: *PeerJ*. Vol. 8: e9392, 2020).

Galectin-3 also displays additional properties that may be beneficial in treating COVID-19. The development of **cytokine release syndrome (CRS)**—a severe immune reaction in which the body overproduces too many pro-inflammatory **cytokines**—has been identified as a major cause of fatality in COVID-19 patients. CRS may be life threatening and lead to acute respiratory distress syndrome (ARDS) and multiple organ failure. Galectin-3 Inhibitors have been shown to reduce the levels of these inflammatory cytokines *in vitro* and have shown anti-inflammatory effects *in vivo*, resulting in possible prevention of CRS (Source: *PeerJ.* Vol. 8: e9392, 2020).

ProLectin Pipeline

Pharmalectin is using its ProLectin platform to develop multiple product candidates that provide an end-to-end solution for mild-to-severe COVID-19 cases, including treatment of organ damage and long-term conditions derived from the disease. To the Company's knowledge, it is the only company planning to develop a viable end-to-end solution for COVID-19 using a galectin inhibitor to combat the virus. If given early enough in the disease progression, the Company's pipeline candidates may be able to block viral entry and act as an antiviral by eliminating the virus from the blood stream. At a later stage in the disease, it can restore adaptive immune function to help eradicate the virus from the body and inhibit patients' progress to severe disease. Finally, in severe cases of COVID-19, it can interrupt the process leading to CRS and treat COVID-related lung fibrosis.

In addition to COVID-19, Bioxytran is assessing the application of its technology to target influenza and other virologic diseases. The Company is further assessing its technology platform to treat fibrosis and cancer.

Because galectins are involved in the regulation of viral infection for a significant number of viruses, Bioxytran believes that its technology mechanism of action can be applied to target many viral conditions—such as influenza or herpes—including the potential creation of a multiple-antagonist molecule that can bind with different galectins implicated in a variety of viral infections, resulting in a single customized antiviral that can treat different viral conditions.

ProLectin-M

Bioxytran's lead glycovirology pharmaceutical drug candidate is ProLectin-M, a chewable tablet for which the Company has an exclusive license (developed by NDPD Pharma, Inc.), to treat mild-to-moderate COVID-19. The Company is currently working on a Phase 3 clinical trial with The Central Drugs Standard Control Organisation (CDCSO), India's national regulatory body for cosmetics, pharmaceuticals and medical devices, and is preparing its investigational new drug (IND) application for a Phase 2 clinical trial with the United States Food and Drug Administration (FDA), to be followed by a Phase 2/3 submission with the EMEA in first quarter 2023. Bioxytran expects the Phase 3 trial in India and the Phase 2 trial in the U.S. to be completed by fourth quarter 2022.

ProLectin-M's mechanism of action is to bind with the virus' spike proteins inhibiting viral entry. If given early enough in the disease progression, the Company believes that ProLectin-M can block viral entry of SARS-CoV-2 into the cells and tag it for elimination through the liver. The Company conducted a proof-of-concept Phase 1/2 clinical trial in India, finalized in October 2020, with results published in the *Journal of Vaccines & Vaccinations,* as well as a follow-up *in vitro*-study. To Bioxytran's knowledge, this was the first clinical trial using a galectin antagonist on SARS-CoV-2 and represents a novel way to block viral entry and replication of the virus.

Results of the proof-of-concept study and the *in-vitro* follow-up study indicated that ProLectin-M binds relatively strongly to SARS-CoV-2, preventing entry of the virus into its target cells, resulting in a dose-dependent reduction in viral load and cell infectivity. No serious adverse events were recorded during the trial, with ProLectin-M showing non-toxicity while displaying efficacy for the treatment of mild-to-moderate COVID-19. Key results are as follows:

- The treated group displayed a significantly faster reduction of viral load versus the control group. Treatment with ProLectin-M lowered viral protein levels to undetectable levels within 3 days, also resulting in a positive effect in controlling infection.

- All participants in the active arm of the trial were clinically asymptomatic before day 28, with ProLectin-M showing an ability to block viral replication.

- ProLectin-M cleared the blood of the viral load, thereby reducing the strain on the innate immune system, allowing the adaptive immune system to build a robust response toward future infection.

Phase 3 Trial (ClinicalTrials.gov Identifier: NCT05096052)

The Company is currently working on a Phase 3 clinical trial with the CDCSO in India and is preparing its IND for a Phase 2 clinical trial with the FDA, expected to be followed by a Phase 3 submission with the EMEA. The trials are designed to test the Company's hypothesis that patients receiving ProLectin-M, irrespective of their vaccination status or underlying medical conditions, will have a faster recovery from COVID-19 compared to those receiving its matching placebo and prevent hospitalization. The Phase 3 trial in India and the Phase 2 trial in the U.S. are expected to be completed by fourth quarter 2022.

ProLectin Intravenous (IV) Candidates

The Company is also utilizing its ProLectin technology platform to develop three IV drug candidates for more severe cases of the disease as well as to treat organ damage and long-term conditions derived from the viral infection: (1) ProLectin-I, with similar galectin-3 blocking capabilities as the oral drug, ProLectin-M, but IV-injectable for severe cases of COVID-19; (2) ProLectin-F, for the treatment of patients developing lung fibrosis as a result of the use of ventilator in COVID-19 treatment; and (3) ProLectin-A, for the treatment of COVID-related ARDS. The Company is preparing a Phase 1/2 trial of 60 people on fibrosis of the lung in India using ProLectin-F, expected to be completed by November 2022.

Future ProLectin Applications

Current drug design protocols normally start by determining a target (often times a protein receptor) responsible or involved in the biological process that results in a disease, and then creating an inhibitor to block that interaction of the protein and the receptor in order to stop the resulting negative consequences. Whether it is a monoclonal antibody or a small molecule, the intended target normally remains a single receptor or protein. While current advances in drug design and discovery have been focused on improving or optimizing the interaction between the target and the therapeutic compound (e.g., strengthening or fine tuning the binding between both), the next step in the evolution of drug design would be the creation of a single molecule that targets multiple receptors responsible for different aspects of the disease. This approach can result in eliminating the need to use combinations of therapeutic compounds to treat all aspects of a disease that leads to increased side effects and drug-drug interaction (DDI) issues.

A recent study, sponsored by Bioxytran and co-authored by the Company's CEO David Platt, describes a methodology using **Nuclear Magnetic Resonance (NMR)** imaging that can optimize carbohydrate drug design to target multiple receptors (Source: *International Journal of Molecular Sciences*, Vol. 23 (14): 7739, 2022). This is of significance for glycovirological conditions where multiple galectins may be involved in the pathology of the disease.

Bioxytran believes that this methodology provides a blueprint that could allow for the creation of carbohydrate drugs that can treat the entire disease instead of singular targets. For example, in a disease that is caused by the upregulation of different biological pathways involving galectins, NMR could be used to screen different agents that create the desire effect, resulting in a single molecule that would inhibit all galectins involved, treating different aspects of the disease and eliminating the need for multiple drugs to achieve the same result. Furthermore, the same process could be used for the regulation of different galectins implicated in different viral infections, resulting in a single customized antiviral that can treat different viral conditions.

DEGENERATIVE DISEASE/HYPOXIC CONDITION

Bioxytran is additionally developing an innovative technology platform of oxygen therapeutic treatments for hypoxic conditions, necrosis, and degenerative diseases, with an initial focus on therapeutic molecules for stroke. Bioxytran hypoxic condition's pipeline uses technology developed by the Biopure Corporation, which separates the hemoglobin molecule from **red blood cells (RBCs)**. Biopure filed for bankruptcy in 2009 and its technology is in the public domain. Once the hemoglobin molecule is extracted, the Company applies its proprietary co-polymer chemistry manufacturing process to enhance the hemoglobin molecule, creating an injectable intravenous drug that prevents necrosis (or cell death) by carrying oxygen to human tissue or brain cells that have limited or blocked blood flow.

Bioxytran's lead candidate in this research area is BXT-25, an oxygen-carrying small molecule intended to treat hypoxic conditions in the brain resulting from stroke. At this point, BXT-25 development is on hold until the Company raises additional capital. Once funding is obtained, the Company plans to begin pre-clinical studies on this indication, with future plans to explore additional drug candidates using chemical structures that are a sub-class of BXT-25 to treat wound healing and brain damage due to hypoxia, as well as other related conditions, such as cardiovascular **ischemia**, dementia, Alzheimer's disease, anemia, cancer, and brain trauma.

Additionally, Bioxytran has an exclusive license for an FDA-cleared companion diagnostic, MDXViewer, which allows the Company to detect oxygen delivery to brain tissue. To the Company's knowledge, the diagnostic device is the only technology approved by the FDA that allows for measurement of oxygenation of a specific tissue, as opposed to measurements of arterial oxygen levels

Stroke

Stroke, also known as cerebrovascular accident (CVA) or brain attack, occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked by a clot (ischemic stroke [consisting of 87% of all strokes]) or ruptures (hemorrhagic stroke). A stroke results in poor blood-flow to the brain, which leads to brain cells necrosis (cell death). A stroke can cause lasting brain damage and neurological deficits, long-term disability, or even death.

There are approximately 795,000 cases of stroke in the U.S. and over 12.2 million cases of stroke worldwide each year, resulting in 130,000 deaths and 6.55 million deaths, respectively (Sources: Centers for Control Disease and Prevention [CDC] and *The Lancet*, Vol. 20 (10): 795-820, 2021). The global stroke management market was valued at $31.7 billion in 2020 and is projected to reach $67.8 billion by 2030. The stroke market represents a tremendous opportunity since existing treatments are limited. In contrast to breakthroughs in many disease categories over the past two decades, stroke treatment, specifically development of therapeutic drugs, has had minimal improvement for the past 25 years (Source: Allied Market Research's *Stroke Management Market by and Application: Global Opportunity Analysis and Industry Forecast, 2021–2030*, 2022).

The time it takes from the onset of a stroke to the time treatment starts (also known as "**Time to Needle**") is key to the effective recovery from the condition. In patients experiencing a typical large vessel ischemic stroke, 120 million neurons are lost each hour. Compared with the normal rate of neuron loss in brain aging, the ischemic brain ages 3.6 years each hour without treatment (Source: *Stroke,* Vol.37(1):263-266, 2006).

BXT-25 Overview

The Company's lead pharmaceutical therapeutic candidate is BXT-25, an oxygen-carrying small molecule consisting of bovine hemoglobin stabilized with a co-polymer. BXT-25 is a combination of **heme** (the oxygen carriers of human RBCs) derived from hemoglobin, and a co-polymer designed to stabilize it in the blood system. The production of BTX-25 starts with the isolation of hemoglobin from RBCs of bovine sources, and the extraction of heme from the hemoglobulin. The Company then applies its proprietary co-polymer chemistry manufacturing process to stabilize and modify the heme. This modified molecule is designed to be an injectable intravenous drug to prevent necrosis, or cell death, by carrying oxygen when blood flow to the brain is blocked during the initial stages of stroke. This product is being developed as an early intervention for use as both in- an out-of-hospital settings for the treatment of patients with ischemia of the brain resulting from a stroke.

BXT-25 molecules are 5,000 times smaller than RBCs. BXT-25 circulates in the blood collecting oxygen from the lungs and releasing the oxygen molecules where the tissue has developed ischemia, or lack of oxygen. The oxygen is delivered to the brain immediately upon infusion (less than 3 minutes). BXT-25 has oxygen affinity that mimics human RBCs and is not expected to cause adverse effects. The Company believes that BXT-25 is non-immunogenic and universally compatible with all blood types. It is recognized by the **blood-brain barrier (BBB)** and has low viscosity, allowing it to safely deliver oxygen to the brain.

BXT-25 displays the following key attributes that contributes to its effectiveness and helps the pre-clinical drug candidate to potentially improve the outcome of stroke victims:

(1) *Molecule size.* The BXT-25 molecule is designed to be 5,000 times smaller than an RBC, which the Company believes will enable it to reach hypoxic tissue more effectively than RBCs, as its size enables the therapeutic molecule to transport oxygen through blocked arteries and into oxygen-deprived tissue.

(2) *Blood type compatibility.* BTX-25 does not include any of the antigens present in the surface of RBC (which determine the blood type), and therefore may be compatible with all blood types.

(3) *Flexibility.* The ability of BXT-25 to be stored at room temperature for long periods could allow the Company to create a triage kit for ambulances and first responders, which may be used as an "Oxygen Bridge" to ensure survival in the critical hours immediately after a stroke. In addition, since BXT-25 can be used both in ischemic and hemorrhagic stroke, the Company believes that it can be safely administered to any stroke patient quickly, even before any diagnostic or imaging test is conducted, working as a bridge until more robust therapeutic options can be implemented.

(4) *Safety profile.* BXT-25 is made up of two FDA-approved components—heme and the co-polymer—which the FDA generally regards as safe.

MDXViewer

In order to support its BTX-25 development, Bioxytran obtained an exclusive license for MDXViewer, an FDA cleared technology that allows for real-time measurements of tissue oxygenation and oxygen supply to the brain, developed by MDX Lifesciences, Inc. Bioxytran obtained the license for the use of the technology for clinical monitoring of oxygen delivery through oxygen carriers. MDXViewer allows the Company to prove oxygen delivery to tissue, providing a clinical endpoint for measuring oxygen supply to the brain in real-time in order to support BTX-25 clinical trials. To the Company's knowledge, the diagnostic device is the only technology cleared by the FDA that allows for measurement of oxygenation of a specific tissue, as opposed to the measurement of arterial oxygen levels.

Company Background

Bioxytran is a clinical stage pharmaceutical company founded on June 9, 2008. On September 21, 2018, the Company was reorganized through a reverse merger with U.S. Rare Earth Minerals, Inc. (USREM) agreeing to acquire the assets after reaching a settlement with respect to a secured promissory note, which had been in default. On November 7, 2018, U.S. Rare Earth Minerals, Inc. changed its name to Bioxytran, Inc. Pharmalectin BVI, Bioxytran's foreign subsidiary was organized on March 17, 2021 as a British Virgin Islands (BVI) Business Corporation and is the owner and custodian of the Company's copyrights, trademarks, patents, and licenses. The Company currently has 4 employees and is headquartered in Needham, Massachusetts.

On August 15, 2022, Bioxytran entered into a subscription agreement with an accredited investor for the issuance of 1,400,000 shares of the Company's Common Stock, for a total investment of $600,000 ($0.43/share, at market valuation), resulting in in the Company receiving net cash in the amount of $576,000 after commissions.

Milestones

Over the past 12 months, Bioxytran has achieved significant milestones as it continues to advance the development of its technology platforms. An overview of achieved and potential milestones with regard to the Company's development efforts is provided below, with potential upcoming milestones outlined thereafter.

Recent Milestones

- Completed a $1.467 million convertible note financing in January 2022 and a $600,000 subscription agreement with a private party in August 2022
- Listed on OTCPK in June 2022
- Received trademark for the ProLectin therapeutic; approved June 2022
- Filing of three patents/applications:
    - WO 2022/099061 - Polysaccharides for Use in Treating SARS-CoV-2 infections
      The invention provides a method for treating SARS-CoV-2 by administering an effective amount of galactomannans – approved May 2022;
    - WO2022/099061 - Polysaccharides for IV Administration that Treat SARS-CoV-2 infections
      The invention provides a method for treating SARS-CoV-2 by administering an effective amount of pectin polysaccharides to a subject in need thereof – approved May 2022;
    - US 63/320544 (provisional) - Lectin-Binding Carbohydrates for Treating Viral Infections
      The invention provides a method of treating a viral infection in a subject in need by administrating to the subject an effective amount of lectin-binding carbohydrates – submitted March 2022.
- Applied for an IND for ProLectin-M with the CDCSO, India (August 2022)
- Published two peer-reviewed articles regarding Glycovirology—*International Journal of Health Sciences*, Vol. 6 (S4): 6671–6683, 2022; and *International Journal of Molecular Sciences*, Vol. 23 (14): 7739, 2022).

Potential Milestones

- Prepare an IND for ProLectin-M with the FDA (September 2022)
- Prepare an IND for ProLectin-F with the CDCSO (September 2022)
- Complete ProLectin-M's Phase 2 trial in U.S. (Acute COVID) by December 2022
- Complete ProLectin-M's Phase 3 trial in India (Acute COVID) by September 2022
- Complete ProLectin-F's Phase 1/2 trial in India (Fibrosis) by November 2022
- Complete GLP manufacturing of BXT-25 by December 2022

Company Leadership

MANAGEMENT

The Company's management and scientific advisory team hold extensive expertise in complex carbohydrate chemistry (CCC) and regulatory and clinical development, with multiple submissions and approvals to the FDA. Biographies of these individuals are provided below.

David Platt, Ph.D., Chief Executive Officer (CEO) and Chairman

David Platt, Ph.D. is the chief executive officer (CEO) and Chairman of the Board of Directors for Bioxytran. Dr. Platt is a world-renowned expert in carbohydrate chemistry and has founded three publicly traded companies, creating nearly $1 billion for investors. He has raised $150 million directly in public markets in the U.S. and has led the development of two drug candidates from concept through Phase II clinical trials. Prior to Bioxytran, Dr. Platt founded Boston Therapeutics Inc. in 2010 (BTHE-OTC), where he served as CEO from 2010 to April 1, 2015 and as a director from March 2015 to June 8, 2016. From 2001 to 2009, Dr. Platt was a founder, CEO, and Chairman of the Board at Pro-Pharmaceuticals, Inc. (PRWP-OTC and PRW-AMEX, now GALT-NASDAQ). From 1995 to 2000, Dr. Platt was the founder of International Gene Group (IGGI-NASDAQ, GLGS now LPJC). Dr. Platt received a Ph.D. in Chemistry in 1988 from Hebrew University in Jerusalem. In 1989, he was a research fellow at the Weizmann Institute of Science, Rehovot, Israel, and from 1989 to 1991, was a research fellow at the Michigan Foundation (re-named Barbara Ann Karmanos Institute). From 1991 to 1992, Dr. Platt was a research scientist with the Department of Internal Medicine at the University of Michigan. He has published peer-reviewed articles and holds many patents, primarily in the field of carbohydrate chemistry.

Ola Soderquist CPA, CMA, CM&AA CFO

Ola Soderquist, MBA, CPA, CMA, CM&AA has more than 30 years of senior international entrepreneurial management experience within technology companies. Mr. Soderquist's managerial experience portfolio includes start-ups, private, public, venture capital, and private equity ownership. He has served in CFO and other managerial capacities in multiple industry sectors and companies. His public company tenures include companies in the Wallenberg Sphere (1986-1996): Industrivarden (INDU-OMX), Electrolux (ELUX-OMX), Ericsson (ERIC-NASDAQ), Swedish Match (SWMA-OMX) and SKF AB (SKF-OMX), and most recently in Traction (TRAC-OMX) (1996-2001) and Belden (BDC-NYSE) (2006-2011). His private company experience includes CFO and CAO positions in Proditec, Inc. (2001-2006), LFA Corp. (2012-2014) and Faria Beede Instruments, Inc. (2014-2016). Mr. Soderquist is a multi-lingual senior finance professional poised to work globally and cross-functionally, particularly with complex projects involving change management, business integration, systems implementation, continuous improvement, and process excellence. He obtained a BS and an MSA from Stockholm School of Economics and an MBA from Babson College.

Mike Sheikh, EVP Business Development

Mike Sheikh, BS, is a U.S. Air Force Academy graduate and pilot. He has a Bachelor of Science in economics and flew KC-135 tankers as well as worked as a budget officer in the comptroller's squadron. He has prior experience as a broker and research analyst. After the brokerage industry, he was a business development officer for a variety of specialty finance companies. He is a long-time biotech consultant for public or private biotech companies with disruptive technologies. Mr. Sheikh is the founder of Falcon Strategic Research, which focuses on companies that are not covered by traditional Wall Street analysts. He is also the founder of an investor relations firm.

INDEPENDENT BOARD OF DIRECTORS

Hana Chen-Walden MD, Director

Dr. Hana Chen-Walden, M.D. is an endocrinologist and has specialized in regulatory affairs in the pharmaceutical industry in the U.S. and Europe. Dr. Chen-Walden has more than 35 years of regulatory experience with the EMEA and in individual European countries. Since 2004 to present, Dr. Chen-Walden consulted for European Clinical and Regulatory Consultancy in medical monitoring, quality assurance, and regulatory input for clinical studies in the fields of oncology, cardiology, diabetes, neurology, respiratory diseases, and medical devices. Dr. Chen-Walden received a Doctorate of Medicine from University of Tel Aviv, Israel. Dr. Chen-Walden has practiced medicine in Germany and France.

Anders N. Utter, Director

Anders N. Utter has more than 25 years of finance, accounting, and management experience in medical devices, consulting, and manufacturing industries in capacities such as CFO, controller, and managing director. He had progressively increased management experience in the European Nolato Group and later on in the Amplex Group. Mr. Utter has had a broad business exposure with IFRS and GAAP reporting as well as with SOX compliance. He has also worked with M&A evaluations, financing, and integration as well as more hands-on manufacturing cost accounting and reporting. He is currently in charge of the finance control at one of General Cable's entities. Mr. Utter is and has been serving as a director on boards in both profit as well as non-profit organizations. He holds an MBA from Babson College and a BA from Uppsala University in Sweden.

Alan M. Hoberman Ph.D., Director

Alan M. Hoberman, Ph.D. is president and CEO of Argus International, Inc., overseeing a staff of scientists and other professionals who provide consulting services for industry, government agencies, law firms, and other organizations, both in the U.S. and internationally. From 2014 to September 15, 2016, Dr. Hoberman served as a member of the board of directors of Boston Therapeutics, Inc. Between 1991 and 2013, he held a series of positions of increasing responsibility at Charles River Laboratories Preclinical Services (formerly, Argus Research Laboratories, Inc.), most recently as Executive Director of Site Operations and Toxicology. He currently works with that organization to design, supervise, and evaluate reproductive and developmental toxicity, neurotoxicity, inhalation, and photobiology studies. Dr. Hoberman holds a Ph.D. in toxicology from Pacific Western University, an MS in interdisciplinary toxicology from the University of Arkansas, and a BS in biology from Drexel University.

Dale H. Conaway, Director DVM

Dale H. Conaway, DVM, is a Director of the Company. Dr Conaway is a Veterinary Medical Officer in Federal Research. From 2001 to 2006, he was the Deputy Regional Director (Southern Region). From 2010 to September 15, 2016, Dr. Conaway served as a member of the Board of Directors of Boston Therapeutics, Inc. From 1998 to 2001, Dr. Conaway served as Manager of the Equine Drug Testing and Animal Disease Surveillance Laboratories for the Michigan Department of Agriculture. From 1994 to 1998, he was Regulatory Affairs Manager for the Michigan Department of Public Health Vaccine Production Division. Dr. Conaway received a DVM degree from Tuskegee Institute and an MS degree in pathology from the College of Veterinary Medicine at Michigan State University.

SCIENTIFIC ADVISORY BOARD

Prof. Avraham Mayevsky Ph.D.

Prof. Avraham Mayevsky, Ph.D. is a worldwide authority in the field of minimal invasive monitoring of tissue and organ physiology. Prof. Mayevsky is a professor at the Faculty of Life Sciences, Bar-Ilan University, Israel. He founded Vital Medical Ltd. He served as Head of the Department of Life Sciences and Dean of the Faculty of Natural Sciences at Bar-Ilan University, where he established a center of tissue physiology. He served as Visiting professor at University of Pennsylvania and Johns Hopkins Medical School World (a recognized expert in tissue physiology, especially in brain metabolism). He has published over 150 papers and patents, has published over 170 papers in scientific journals, and is the author of five patents. Prof. Mayevsky completed Ph.D. from Weizmann Institute of Science, Rehovot, Israel.

Prof. Kevin H Mayo, Ph.D.

Prof. Kevin H Mayo, Ph.D. is a well-known authority in the field of structural biology and structure-based drug design and discovery. He received degrees from Boston University (BA) and the University of Massachusetts (PhD), and was postdoctoral associate at the Max-Planck Institute for Biochemistry (Alexander von Humboldt Fellow with Nobel Laureate Rudolf Moessbauer) and Yale University (Chemistry). Dr. Mayo is presently Professor of Biochemistry, Molecular Biology & Biophysics, as well as Lab Medicine & Pathology, at the University of Minnesota (UMN), Minneapolis. He is also Director of the High Field Nuclear Magnetic Resonance Center at the UMN. Over the years, Prof. Mayo has consulted with numerous pharmaceutical companies and is co-founder of PepTx, Inc., a start-up pharmaceutical company based in Minnesota. He also currently holds Visiting Professorships at Maastricht University (The Netherlands), Ludwigs-Maximillian-University (Munich, Germany), and Northeast Normal University (Changchun, China). Prof. Mayo has published over 250 papers in peer-reviewed scientific journals and is the author of 28 patents.

Dr. Madhumohan, Ph.D.

Dr. Madhumohan, Ph.D. is currently working as Head R&D in ESIC Medical College and Hospital, expert in Cancer genomics, Stem cell biology, infectious diseases, and drug discovery. His 15 years of experience in cancer biology, stem cells, gene therapy, and genomics in academics and industries (JNJ Oncology USA and Boehringer Ingelheim Germany) which contributes significantly to the patient community. His interdisciplinary translational research collaborations with bioengineers and clinicians to develop new approaches to identify cancer cells, liquid biopsies and single cell 3D organoids, stem cell therapy for diabetic ulcers and DMD. He established the first mobile BSL3 lab in India for vaccine and drug development, He was Technical Advisor to BBIL COVAXIN. Dr. Madhumohan has received several international and national grants (Indo-USA, Indo-German, Indo-Swiss, and Indo-Australia) and National (ICMR, DST and DBT). Dr. Madhumohan has been integrating genomics and gene editing technologies in stem cells and cancer cells as a way to define innovative strategies to improve the autologous transplantation functionality of stem cells.

MEDICAL ADIVISORY BOARD

Dr. Hana Chen-Walden, M.D.

Dr. Hana Chen-Walden, M.D. is an endocrinologist and has specialized in regulatory affairs in the pharmaceutical industry in the U.S. and Europe. Dr. Chen-Walden has more than 35 years of regulatory experience with the EMEA and in individual European countries. Since 2004 to present, Dr. Chen-Walden consulted for European Clinical and Regulatory Consultancy in medical monitoring, quality assurance, and regulatory input for clinical studies in the fields of oncology, cardiology, diabetes, neurology, respiratory diseases, and medical devices. Dr. Chen Walden received a Doctorate of Medicine from University of Tel Aviv, Israel. Dr. Chen-Walden has practiced medicine in Germany and France.

Dr. Alben Sigamani, M.D.

Dr. Alben Sigamani, M.D. is currently Professor and Head of Clinical Research, Narayan Health, Bangalore. He has over 17 years of experience in clinical research and in managing multi-center academic and regulatory Randomized Controlled Trials in India. He has several publications to his credit with a citation index (h-index) of 24. Dr. Sigamani is a Medical Professional (MD) in Clinical Pharmacology & Therapeutics with a Master's Degree in Clinical Trials from the University of London. In 2020, Dr. Sigamani obtained "COVID-19: Tracking the Novel Coronavirus Certificate" from the London School of Hygiene and Tropical Medicine.

Thomaskutty Alumparambil. B.S., C.C.P

Thomaskutty Alumparambil. B.S., C.C.P has over 30 years of clinical experience, including heart, lung, and liver transplants. He is an expert on quality control and quality assurance programs, surgical protocols, blood gas analysis, and anticoagulation management.

Intellectual Property

Bioxytran believes that its competitive position depends on the expansion and protection of its intellectual property (IP). The Company plans to use its issued patents and proprietary technology to develop its technology platforms to the point where the company would be in a position to license its product candidates to large pharmaceutical companies capable of finishing the regulatory process and managing the distribution of the product. Bioxytran relies on both owned IP positions as well as IP obtain through licensing partnerships, with plans to enhance its IP position by executing additional patent applications and licensing deals. Pharmalectin BVI, Bioxytran's foreign subsidiary, is the owner and custodian of the Company's copyrights, trademarks, patents, and licenses.

ProLectin Platform IP Position

The Company's lead glycovirology pharmaceutical drug candidate, ProLectin-M, is a complex polysaccharide that binds to and blocks the activity of human galectin-3. Bioxytran's patent position consists of two parts: (1) owned IP assets; and (2) licensed assets.

Issued and Pending Patents

A patent a method for treating SARS-CoV-2 by administering an effective amount of pectin polysaccharides to a subject issued in 2022 by the International Bureau of the Patent Cooperation Treaty (PCT) expiring in February 2041 ("Polysaccharides for IV Administration that Treat SARS-CoV-2 Infections" - WO2022/099061) and assigned to Bioxytran outright by David Platt, as well as a provisional patent ("Lectin-Binding Carbohydrates for Treating Viral Infections" - US 63/320544). The patents were assigned to the Company outright by Bioxytran's founder Dr. David Platt. Dr. Platt did not receive any compensation from the Company in consideration of his assignment for the patent.

Licensed Technology

Pharmalectin has an exclusive license to the molecule (developed by NDPD Pharma, Inc.) for treating mild-to-moderate COVID-19 ("Polysaccharides for Use in Treating SARS-CoV-2 Infections" - WO2022/099052). Furthermore, Pharmalectin has received an international trademark for ProLectin (WO0000001646681).

BTX-25 IP Position

Bioxytran's patent position, with respect to its hypoxia and degenerative disease program, consists of: (1) owned IP assets; (2) licensed assets; and (3) technology in the public domain.

Issued and Pending Patents

An issued patent related to the Company's co-polymer technology issued in 2009 by the U.S. Patent and Trademark Office expiring in February 2029 ("Method patent for producing modified pectins consisting of neutral sugar sequences"). This patent was assigned to the Company outright by Bioxytran's founder Dr. David Platt. Dr. Platt did not receive any compensation from the Company in consideration of his assignment for the patent.

Licensed Technology

Bioxytran has an exclusive license for an FDA-cleared technology—MDXViewer— developed by MDX LifeSciences, Inc. MDX LifeSciences has licensed a patent ("Tissue Metabolic Score for Patient Monitoring" - US20210153816A1) to Bioxytran for clinical monitoring of oxygen delivery through oxygen carriers. The technology provides a clinical end-point for measuring oxygen supply to the brain in real-time.

Public Domain Information

The Company's degenerative disease/hypoxic technology platform uses a technology developed by the Biopure Corporation, which separates the hemoglobin molecule from RBCs. Biopure filed for bankruptcy in 2009 and the technology the Company uses from Biopure is in the public domain.

Core Story

Bioxytran, Inc. ("Bioxytran" or "the Company") is a clinical stage pharmaceutical company developing platform technologies in the fields of glycovirology, hypoxia, and degenerative diseases. The Company is focused on the development and commercialization of therapeutic drugs designed to target conditions in two different medical areas: (1) glycovirology and anti-viral therapeutics, with an initial focus on SARS-CoV-2; and (2) hypoxic conditions, necrosis, and degenerative diseases, specifically focused on brain conditions resulting from stroke.

Bioxytran's glycovirology approach is conducted through the operations of its subsidiary, Pharmalectin Inc., of which the Company has an 85% ownership. The effort is focused on developing, manufacturing, and commercializing therapeutic drugs designed to address viral diseases in humans using galectin inhibitors, with an initial focus on COVID-19. The technology is built on the lifetime work of Bioxytran's founder, Dr. David Platt (biography on page 10). In addition to COVID-19, Bioxytran is targeting influenza and other virologic diseases, and plans to assess the use of the technology to address long term symptoms resulting from viral infection, as well as its application in oncology and fibrotic diseases.

Bioxytran is also developing treatments for hypoxic conditions, necrosis, and degenerative diseases, with an initial focus on therapeutic molecules for stroke. The Company's technology platform aims to deliver oxygen to affected areas for stroke, wound, and brain damage treatment, as well as other related conditions, such as dementia, Alzheimer's Disease, anemia, and traumatic brain injury. Figure 3 provides a summary of the Company's technology platforms and areas of interest.

Figure 3
BIOXYTRAN TECHNOLOGY OVERVIEW

ProLectin - Glycovirology	BXT-25-Hypoxia & Degenerative Diseases
VIROLOGY	**ISCHEMIA**
▪ COVID-19	▪ Stroke
▪ Influenza	▪ Alzheimer's
▪ Other virologic diseases	▪ Dementia
	▪ Traumatic Brain Injury
LONG TERM SYMPTOMS RESULTING FROM VIRAL INFECTION	
▪ ARDS	**ANEMIA**
▪ Pulmonary Fibrosis	**WOUND HEALING**
TECHNOLOGY	
ProLectin-M is a licensed technology that targets mild-to-moderate COVID-19 cases.	MDXViewer is a licensed technology that uniquely allows the Company to prove oxygen delivery to tissue. It is expected to be used in clinical trials as a regulatory endpoint.

Source: Bioxytran, Inc.

The Company's glycovirology pipeline is based on the ProLectin technology platform, a novel method designed to reduce the viral load and modulate the immune system using a galectin inhibitor. Galectins are human proteins that are structurally similar to proteins present in the surface of viruses that facilitate the entry of the virus into the target cell, resulting in infection (this process further explained on page 20). Galectin antagonists can bind to viral surface proteins, blocking the entry of the virus into the body's cells. Although the initial focus of the Company is the SARS-CoV-2 virus, Bioxytran believes that its technology can capitalize on the regulation capabilities of galectins to create antiviral therapeutics targeting a significant number of viral pathogens.

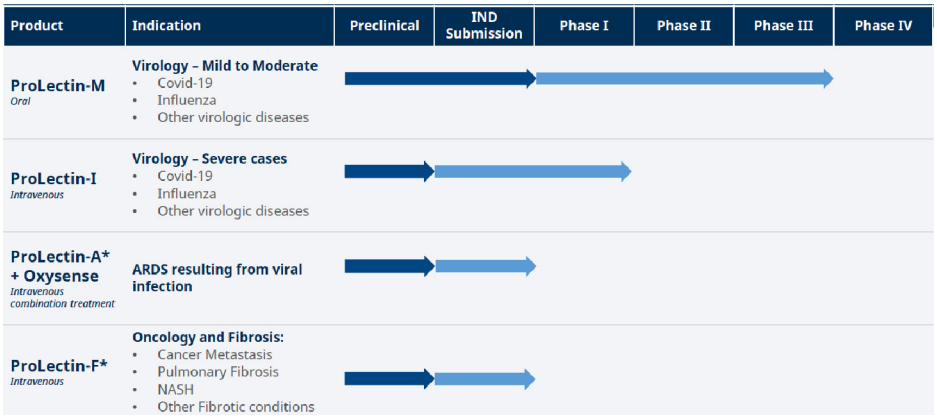
Through the use of its ProLectin technology platform, Bioxytran is initially developing an end-to-end solution for mild-to-severe COVID-19 cases. The pipeline includes ProLectin-M, for treating mild-to-moderate COVID-19, as well as the Company's intravenous drug candidates: ProLectin-I, an IV treatment for more severe cases of COVID-19; ProLectin-F, an IV treatment for COVID-related lung-fibrosis; and ProLectin-A, an IV treatment of COVID-related Acute Respiratory Distress Symptom (ARDS).

Bioxytran's degenerative disease/hypoxic condition pipeline uses a technology developed by the Biopure Corporation, which separates the hemoglobin molecule from red blood cells (RBCs). Biopure filed for bankruptcy in 2009 and the technology the Company uses from Biopure is in the public domain. Once the hemoglobin molecule is extracted, the Company applies its proprietary manufacturing process to enhance the hemoglobin molecule, creating an injectable intravenous drug that prevents necrosis, or cell death, by carrying oxygen to human tissue or brain cells that have limited or blocked blood flow. Bioxytran's lead candidate in this research area is BXT-25, an oxygen-carrying small molecule intended to treat hypoxic conditions in the brain resulting from stroke. BXT-25 is an injectable anti-necrosis drug specifically designed to diffuse oxygen into the brain tissues in order to treat a person immediately after an ischemic stroke.

BXT-25 development is currently on hold until the Company raises additional capital. Once funding is obtained, Bioxytran plans to begin pre-clinical studies on this indication, with future plans to explore additional drug candidates using chemical structures that are a sub-class of BXT-25 to treat wound healing due to hypoxia, cardiovascular ischemia, anemia, cancer conditions, and trauma. Figure 4 provides a summary of the Company's pipeline for both areas of interest.

Figure 4

BIOXYTRAN PIPELINE



Source: Bioxytran, Inc.

The Company's strategy for both technology platforms relies on the combination of three different development options: (1) internal development; (2) collaboration agreement with qualified partners; and (3) out-license agreements with large pharmaceutical companies. Bioxytran aims to develop its technology platforms and product candidates to the point where the Company would be in a position to license the drug to large pharmaceutical companies capable of conducting clinical trials and finishing the regulatory process. In this scenario, the marketing and distribution of the product would be the responsibility of the Company's license collaborators, allowing Bioxytran to benefit from its technologies without the need to create a sales and marketing staff to commercialize its pharmaceutical products.

PROLECTIN TECHNOLOGY PLATFORM—GLYCOVIROLOGY

Bioxytran's subsidiary, Pharmalectin Inc., is focused on developing, manufacturing, and commercializing therapeutic drugs designed to address viral diseases in humans. The Company is developing a novel technology platform—ProLectin—designed to reduce the viral load and modulate the immune system using glycovirology principles. The novel anti-viral approach is based on the use of galectin inhibitors for the development of therapeutics for viral diseases, with an initial focus on SARS-CoV-2.

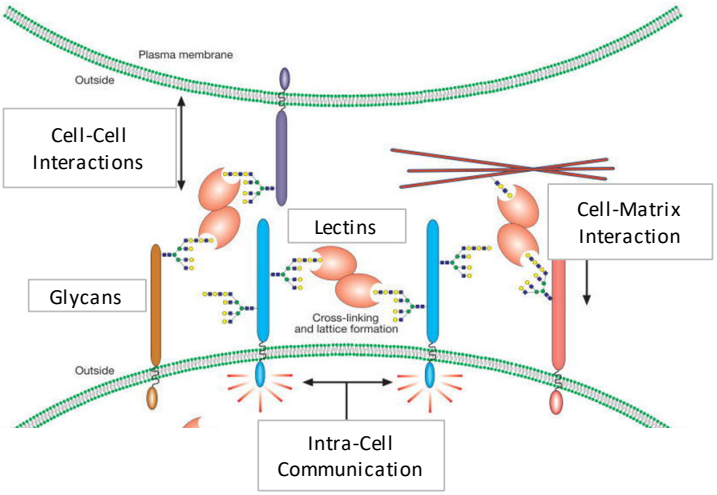
Viruses exhibit specific proteins on their surface that play a key role in facilitating the entry of the virus into the target cell, resulting in infection. Many of these proteins are structurally similar to human proteins called galectins. By creating galectin antagonists that bind to these viral proteins, the Company aims to prevent infection by creating antiviral compounds that block the entry of the virus into the body's cells. Bioxytran believes that its technology can be used to target many viral conditions, as well as the potential to create a multiple-antagonist molecule that can target the various biological pathways responsible for different aspects of the disease, or different viruses at the same time.

Bioxytran's glycovirology therapy is a novel approach in virology science. Vaccines aim to pre-empt an infection by stimulating the production of antibodies to be used when a virus attack takes place. Bioxytran's approach is based on the prevention of a virus' ability to enter a cell, rendering the virus harmless. The Company believes that this approach could accomplish the same goal as a vaccine and other traditional anti-viral therapies, but with patients obtaining the immunity effects from an actual infection, which is known to provide better protection.

GLYCOVIROLOGY

Glycovirology is a new field of molecular biology research that aims to characterize the interactions between viruses and glycans (complex carbohydrates [sugar] molecules found on the surface of cells from most organisms). Specific recognition and binding of glycans by proteins, called lectins, facilitates many biological processes, including a key role in intercellular communication, cell-cell recognition, cell growth and differentiation, cell death, and the transmission of signals in immune responses. Lectins play crucial roles in the function of cells, organs, and the immune system of humans and other mammals through their interaction with glycans. The interaction and binding between lectins and cell surface or extracellular glycans can affect cell behavior, including cell movement, signaling, and other cellular functions (both cell-to-cell interaction as well as cell-to-matrix interactions). Interactions of lectins with intracellular ligands may also contribute to the regulation of intracellular pathways (as depicted in Figure 5).

Figure 5
GLYCAN-LECTIN INTERACTIONS



Source: NIH's Essentials of Glycobiology, Chapter 33.

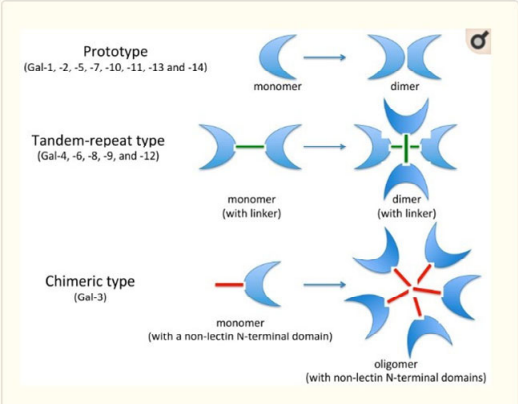
Galectin-3

Within the lectin protein family, galectins are the most widely expressed class of lectins in all organisms. The interactions between lectins and their target glycans occur via a **carbohydrate recognition domain (CRD)** within the lectin. Galectins are a subfamily of lectins that have a CRD that binds specifically to **ß-galactoside**.

Galectins are involved in a wide variety of both intra- and extra-cellular functions as well as physiological processes, many of which are directly linked with immunity and disease, including regulation of cell survival and adhesion, promotion of cell-to-cell interactions, growth of blood vessels, cancer formation and metastasis, and regulation of the immune response and inflammation. In addition, galectins have been found to play major roles in human viral infections (Source*: Journal of Microbiology, Immunology and Infection*, Vol. 53 (6): 925-935, 2020). Understanding the unique structural features and roles of the different galectins, including their different physicochemical attributes, cellular location, and binding affinity, is a key step needed for the creation of specific glycan ligands for therapeutic purposes (Source: *Frontiers in Chemistry*, Vol. 03, 2019).

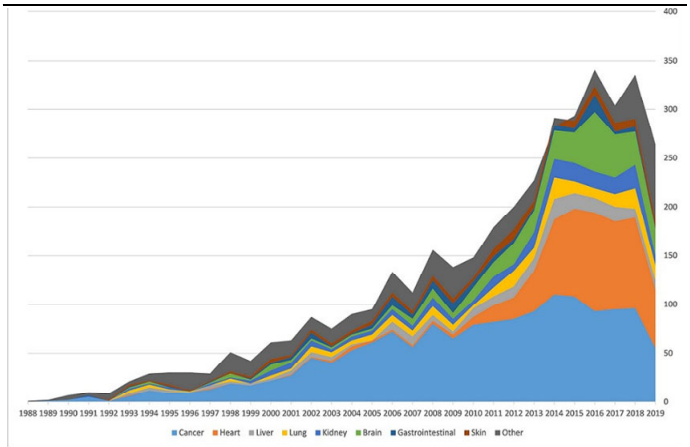
There are 15 galectin protein subtypes (shown in Figure 6), with galectin-1 and galectin-3 the two most studied galectins to date and the most prominently involved in pathological processes. Galectin-3, in particular, expresses in many different immune cells and modulates broad biological functions, including cell adhesion, cell activation, cell growth, apoptosis, and inflammation. Galectin-3 has also been shown to directly bind to pathogens and to have various effects on the functions of the cells of the innate immune system (Source: *Mediators of Inflammation*, Vol. 2017, Article ID 9247574, 2017).

Figure 6
GALECTINS



Source: Pharma IQ.

Figure 7
GALECTIN-3 RESEARCH



Source: Pharma IQ.

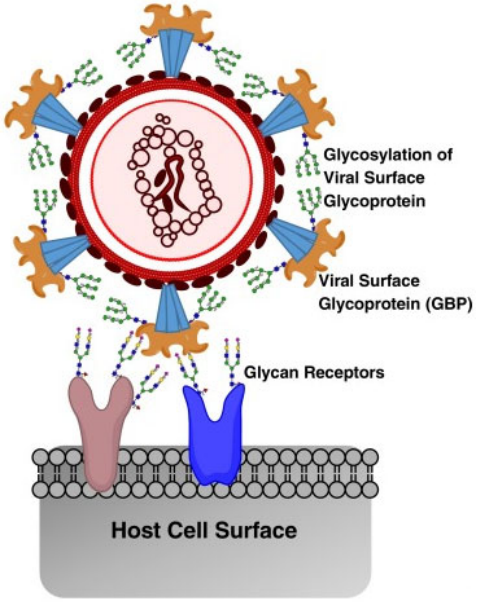
Galectin-3, first expressed and named by the Company's CEO Dr. Platt (Source: *Biochemistry*, Vol. 32(16):4455-60, 1993), is structurally unique among all galectins, displaying the only **chimeric** structure. The galectin-3 protein has emerged over the last decade as a major focus of research and pharmaceutical development for a wide range of different diseases. Galectin-3 is involved in the development of cancer as well as brain, kidney, lung, and liver disease. Drug development has progressed the furthest with fibrosis in both the liver and the lungs, though cancer immunotherapy and heart disease are also being targeted. Recent advances in glycobiological research also indicate that glycans and galectins mediate key interactions at the virus-host interface, playing a key role in controlling viral spread and/or activation of the immune system.

As of 2019, according to the PubMed database, over 3,800 research papers have been published on the galectin-3 protein over the past 30 years. This research has exploded over the past decade, with 2,700 papers published since 2008 (Figure 7). Galectin-3 is likely to remain an important area of focus for medical research, as researchers expand their understanding of its role in disease processes and how its presence can be used as a biomarker or a target for effective therapies (Source: PharmaIQ's, *Why Galectin-3 Has Emerged as a Focus For Drug Research And Development*, 2019).

Galectins in Viral Infections

Research indicates that galectins play multiple roles in regulating virus infections. Several galectins express positive, negative, or even dual regulatory roles on virus propagation. Glycans-virus interaction can also be used by viruses to gain entry to a cell, marking the initial steps of a viral infection (Source*: Journal of Microbiology, Immunology and Infection*, Vol. 53 (6): 925-935, 2020).

Figure 8
VIRUS GLYCAN BINDING



Source: Current Opinion in Structural Biology.

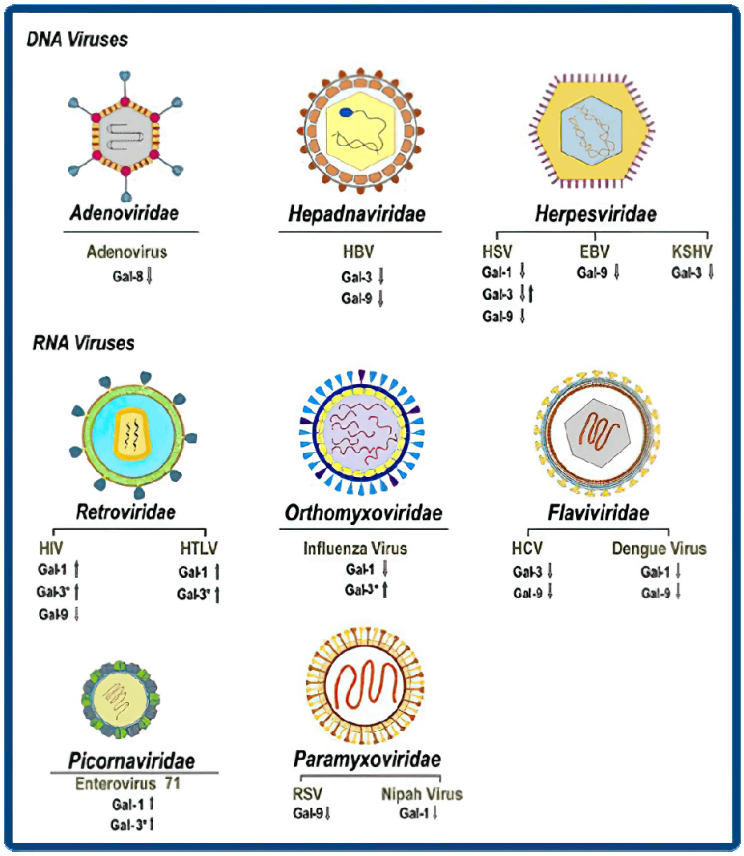
A virus cannot make people sick unless it gets inside a living cell. Glycans sit on the surface of cells and control the gates through which different molecules enter. Many viruses enter cells by displaying surface proteins with structures similar to naturally occurring lectins that bind to the glycan molecules during the initial stages of infection. In other cases, the reverse occurs, with host cells displaying proteins that specifically bind to glycans on viral surfaces. In both instances, the binding allows the virus to attach to the cell surface and migrate through the cell membrane. Figure 8 provides an illustration of this process.

For a virus to gain access to a cell, glycoproteins on the virus' surface must bind to certain glycans, recognizing them as their primary receptors for attachment and entry. For example, the spike proteins found in SARS-CoV-2 (the virus that causes COVID-19) share unique structural similarities with a specific lectin (galectin-3), a protein that binds to some glycans prominent on lung cell surfaces. This allows SARS-CoV-2 to bind and enter the cells (Source: *Peer Journal*, Vol. 8, 2020). Although this viral infection process has been known for some time, only recent advances in glycan microarray screening technology and other related technologies have allowed researchers to identify specific glycan receptors and the epitopes linked to specific viruses.

This could allow researchers to create therapeutic agents that attach directly to the binding domain of different viruses, preventing the binding of these viruses to glycans and acting as cell-entry inhibitors (Source: *Viruses*, Vol. 10(11); 636, 2018). Galectins with well-characterized glycan specificities can be leveraged in biomedical applications, such as antiviral therapeutics (Source: PLoS Computational Biology, Vol. 17(10): e1009470, 2021). This is the strategy that Bioxytran employs, using its technology platform to develop galectin inhibitors that achieve this objective by targeting the virus (instead of the cells), binding with the virus and blocking the binding of the virus to cells.

Although the initial focus of the Company is the SARS-CoV-2 virus, Bioxytran believes that its technology can be used to effectively capitalize on the regulation capabilities of galectins to address multiple viruses. For perspective, Figure 9 (page 21) illustrates the different galectins involved in the regulation of different types of viruses, with the down and up arrows indicating negative and positive regulations of galectins to virus infection, respectively (Source: *Journal of Microbiology, Immunology, and Infection*, Vol. 53 (6): 925-935, 2020).

Figure 9
VIRUSES AND GLYCAN INTERACTION



Source: Journal of Microbiology, Immunology and Infection.

GLYCOVIROLOGY IN COVID-19– SCIENCE BEHIND BIOXYTRAN'S PROLECTIN PLATFORM

The outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19), has been declared a global pandemic by the World Health Organization as of March 2020. As of August 2022, more than 600 million cases have been reported worldwide, resulting in over 6.4 million deaths. The U.S. is still considered one of the epicenters of the disease, with roughly 94 million cases and over a million deaths.

Despite the emergence of vaccines against the viral infection, there is an urgent need to identify and develop the next generation of vaccines and therapies. The next generation of COVID-19 vaccines could have broader epitope coverage to provide cross-immunity against SARS-CoV-2 variants, confer a longer duration of protection, and be easily updated in a timely manner for protection against any new variants. New vaccine platforms could allow researchers to select those platforms that may be more suitable for certain age groups, certain subpopulations, and certain variants. The same applies to existing therapeutic regiments and new ones currently in development (Source: *New England Journal of Medicine*, Vol. 386:2140-2142, 2022).

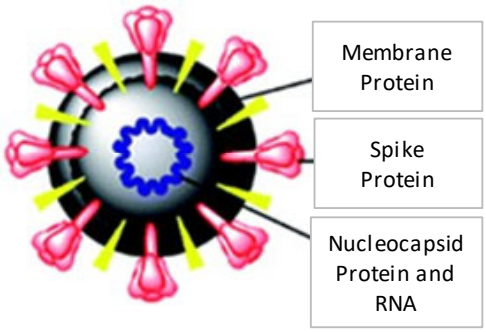
Galectin-3 inhibition has shown numerous effects that may be beneficial to treating COVID-19. In general, galectins are theorized to participate in the antiviral defense, which starts at the initial recognition of the virus before it binds to the cell, all the way through the activation and amplification of the innate and adaptive responses of the immune system. Galectin-3 protein expression in healthy tissues is highest in the lungs, followed by the gastrointestinal tract. This is noteworthy since, in addition to respiratory issues, an increasing number of patients infected with COVID-19 have reported gastrointestinal symptoms, such as diarrhea, nausea, and vomiting, indicating a possible correlation between the presence of Galectin-3 and the areas affected by the disease (Source: *PeerJ,* Vol. 8: e9392, 2020).

Use of Galectin-3 Inhibition to Prevent COVID-19 Infection

Therapies against COVID-19 can be divided into two categories. One acting on the human immune system and the other acting on the coronavirus itself. A novel approach belonging to the latter group is the use of galectin inhibitors to block the binding of the virus to human cell receptors and prevent its entry into the host cell. To accomplish this, researchers rely on their understanding of the virus protein structure. As shown in Figure 10, two groups of proteins characterize coronaviruses: structural proteins, such as spike (S), membrane (M), or nucleocapsid (N), in addition to the non-structural proteins, such as RNA polymerase (Source: *RSC Advances*, Vol. 10: 29873-29884, 2020).

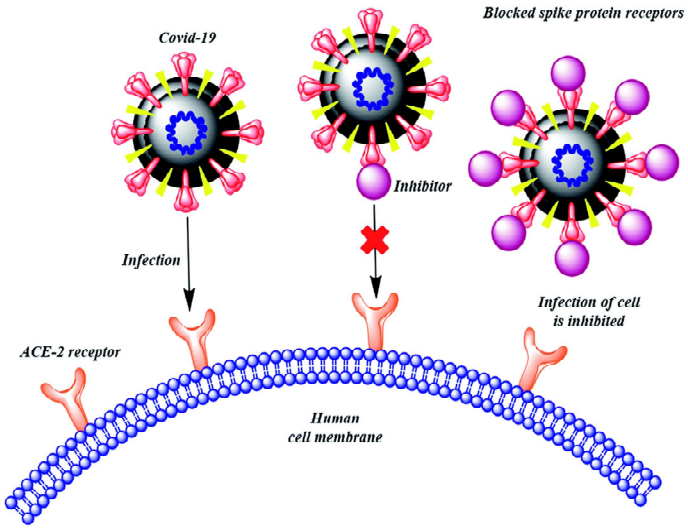
The S protein is of particular importance to the Company's therapeutic approach as it is the sole protein responsible for mediating viral entry into the host cell. The S protein protrudes out from the viral surface and gives coronaviruses a crownlike appearance by forming spikes on their surface. These proteins bind to specific glycans on human cell surfaces, facilitating the entry of the virus into the cells. However, the spike proteins found in SARS-CoV-2 is nearly identical in morphology to human galectin-3. Given this structural similarity, the Company believes that inhibitors against human galectin-3 also have the capability to bind to the spike protein domain responsible for the binding of the virus to human cells, preventing the coupling and subsequent infection of the cells. The proposed mechanism by which galectin-3 inhibitors may disrupt SARS-CoV-2 attachment is shown in Figure 11 (Source: *PeerJ*. Vol. 8: e9392, 2020).

Figure 10
SARS-CoV-2 VIRUS



Source: RSC Advances, Vol. 10:29873-29884, 2020.

Figure 11
GALECTIN INHIBITORS' MECHANISM OF ACTION



Source: RSC Advances, Vol. 10:29873-29884, 2020.

Furthermore, galectin-3 also displays properties that are beneficial in treating COVID-19. The development of cytokine release syndrome (CRS) has been identified as the major cause of fatality in COVID-19 patients. CRS is a severe immune reaction in which the body overproduces too many pro-inflammatory cytokines into the blood, leading to a surge of more immune cells to the site of infection. This translates into an inflammatory cycle that is not easily brought back to homeostasis. CRS may be severe or life threatening and lead to acute respiratory distress syndrome (ARDS), and multiple organ failure. COVID-related CRS is a direct result of aberrant immune activation following SARS-CoV-2 infection and results in excess release of inflammatory cytokines, such as interleukin (IL)-1, tumor necrosis factor α (TNF-α), and IL-6. Galectin-3 inhibitors have been shown to reduce the levels of both IL-6 and TNF-a *in vitro* and have shown anti-inflammatory effects *in vivo*, resulting in possible prevention of CRS (Source: *PeerJ.* Vol. 8: e9392, 2020).

Key Clinical Studies Supporting the Use of Galectin-3 Inhibitors

Multiple studies have assessed the ability of galectin inhibitors to impede SARS-CoV-2 by binding to the spike protein and preventing the virus from infiltrating the host cell. One comprehensive study evaluated the effect of 330 galectin inhibitors on the virus' ability to bind with the host cells. This study provided an insight into the probable repurposing of galectin inhibitors against SARS-CoV-2 and related coronaviruses. Results of the study suggest that many of the galectin inhibitors screened in the study displayed high binding score against the S protein. More importantly, they exhibited great potential to disrupt the SARS-CoV-2 binding interaction and thus prevent the virus from infecting the host cell (Source: *RSC Advances*, Vol. 10: 29873-29884, 2020).

Another study provided a review of the available literature on the use of galectin-3 inhibitors in treating COVID-19. Researchers found that galectin-3 inhibitors can produce a dual mechanism of action beneficial in treating COVID-19, both impeding viral attachment to host cells and suppressing the host inflammatory response. Researchers assessed that the spike proteins of the COVID-19 virus show strikingly similar morphology to galectin-3 and exhibit similar binding capabilities, highlighting the ability of galectin inhibitors to impair viral attachment and infection. Furthermore, galectin-3 exhibits potent pro-inflammatory effects, and has been shown to play a critical role in the development of CRS. Thus, inhibiting galectin-3 can result in a reduction of the host inflammatory response and prevent CRS. The study indicated that the combination of the strong correlation of organs showing both high galectin-3 expression and symptoms of SARS-CoV-2, anti-inflammatory effects of galectin-3 inhibition, and theorized ability of galectin inhibitors to impair viral attachment, making galectin-3 an attractive potential target in treating COVID-19 (Source: *PeerJ*. Vol. 8: e9392, 2020).

Further studies expanded the potential benefits of galectin-3 inhibitors in preventing and treating COVID-19, mediating the acute and chronic consequences of infection and inflammation. One study provided an updated review of the literature linking galectin-3 to COVID-19 pathogenesis, confirming galectin inhibitors' ability to prevent viral entry and modulated the host immune and inflammatory response, as well as described their ability to reduce the post-infectious incidence of pulmonary fibrosis. Pulmonary fibrosis has been observed following SARS-CoV-2 infection and is likely to be a major complication in survivors of COVID-19. Among other mediators, elevated levels of TGF-ß have been observed following SARS-CoV-2 infection. Galectin-3 promotes the upregulation of TGF-ß receptors, leading to fibroblast activation and collagen deposition. Thus, galectin-3 inhibition has been shown to reduce virus-induced lung fibrosis. Researchers concluded that the indications for targeting galectin-3 in treating COVID-19 are widespread. Harmful processes directly mediated or affected by galectin-3 have been shown in several stages of the disease process. As such, researchers determined that galectin-3 represents a highly promising target for COVID-19 treatment that should be investigated (Source: *F1000Research*, Vol. 9:1078, 2020).

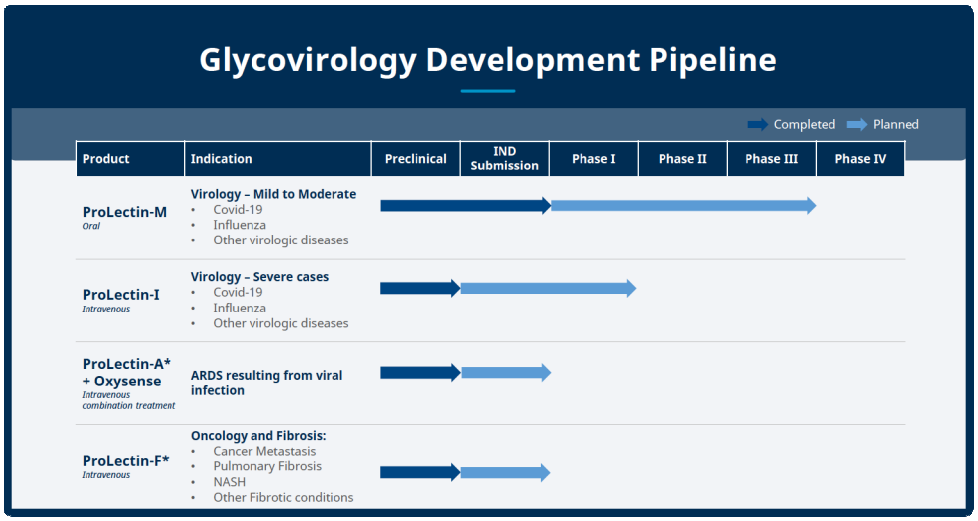
PROLECTIN PIPELINE

The Company's glycovirology pipeline is based on the ProLectin technology platform, designed to reduce the viral load and modulate the immune system using a galectin inhibitor. Bioxytran is using the novel platform to develop an end-to-end solution for mild-to-severe COVID-19 cases, including treatment for organ damage and long-term conditions derived from serious viral infections. The pipeline, illustrated in Figure 12 (page 24), includes ProLectin-M, for treatment of mild-to-moderate COVID-19, designed to block viral entry into the host cell and tag the virus for elimination through the liver; ProLectin-I, an IV treatment for more severe cases of COVID-19; ProLectin-F, an IV treatment for COVID-related lung-fibrosis; and ProLectin-A, an IV treatment of COVID-related Acute Respiratory Distress Symptom (ARDS).

In addition to COVID-19, Bioxytran's future development plans include the assessment of its technology for the treatment of the large number of virus families. Because galectins are involved in the regulation of viral infection for a significant number of viruses, Bioxytran believes that its technology mechanism of action can be applied to target many viral conditions—such as influenza or herpes—including the potential creation of a multiple-antagonist molecules that can bind with different galectins implicated in different viral infections, resulting in a single customized antiviral that can treat different viral conditions at the same time. The Company is further capitalizing on the previous use of pectin as a fibrosis drug and a cancer drug to assess its technology platform for treating these conditions.

Figure 12

BIOXYTRAN'S GLYCOVIROLOGY PIPELINE

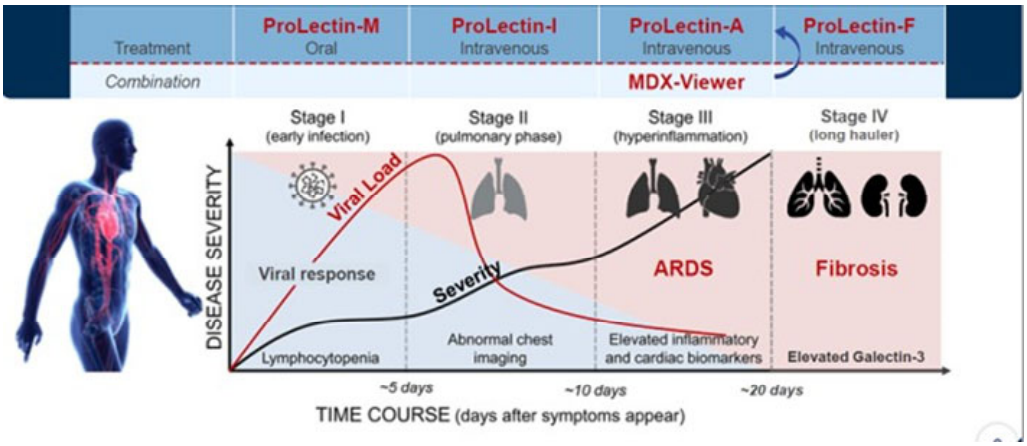


Source: Bioxytran, Inc.

To Bioxytran's knowledge, Pharmalectin is the only company planning to develop a viable end-to-end solution for COVID-19 using galectin inhibitors, as shown in Figure 13. If given early enough in the disease progression, the Company's pipeline candidates can block viral entry and act as an antiviral by eliminating the virus from the blood stream after several treatments. At a later stage in the disease pathology, they can restore adaptive immune function to help eradicate the virus from the body and inhibit patients' progress to severe disease. Finally, in severe cases of COVID-19, they can interrupt the process leading to the cytokine storm believed to be responsible for many of the fatal cases of the disease and treat COVID-related lung fibrosis.

Figure 13

BIOXYTRAN COVID-19 THERAPEUTIC APPROACH



Source: Bioxytran, Inc.

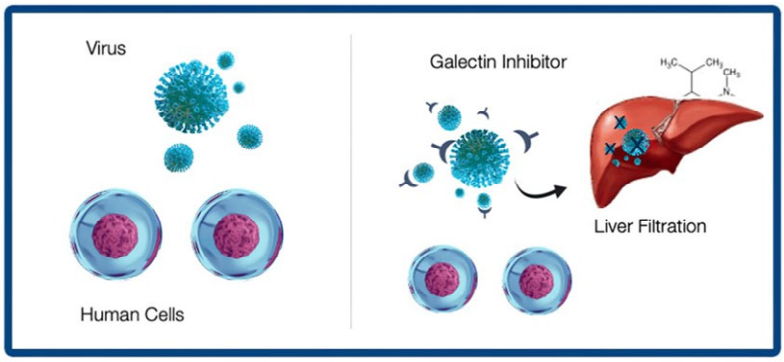
The Company believes that its galectin antagonist may be able to not only reduce the viral load of COVID-19, but also modulate the immune response by reducing the cytokine storm and returning the immune system to homeostasis. Bioxytran believes that its ProLectin technology platform, and its resulting pipeline, provide a first line and end-to-end defense against COVID-19, displaying the following competitive advantages: (1) effectiveness: reduction of viral load to undetected levels during Phase 1/2 trials as well as the possibility to treat its most common severe resulting conditions; (2) versatility: ProLectin product candidates are mutation agnostic; (3) no limitations: no exclusion for age or underlying medical conditions; and (4) safety: no toxicity reported in Phase 1/2 trials.

ProLectin-M

The Company's lead glycovirology pharmaceutical drug candidate is ProLectin-M, a complex polysaccharide that binds to and blocks the activity of human galectin-3. Pharmalectin has an exclusive license for the molecule (developed by NDPD Pharma, Inc.), to treat mild-to-moderate COVID-19. The Company is currently working on a Phase 3 clinical trial with the CDCSO in India and is preparing its IND application for a Phase 2 clinical trial with the FDA, to be followed by a Phase 2/3 submission with the EMEA in first quarter 2023. Bioxytran expects the Phase 3 trial in India and the Phase 2 trial in the U.S. to be completed by fourth quarter 2022.

ProLectin-M is a chewable tablet to treat mild-and-moderate COVID-19 cases. If given early enough in the disease, the Company believes that ProLectin-M can block viral entry of SARS-CoV-2 into the cells and tag it for elimination through the liver, as depicted in Figure 14. ProLectin-M's mechanism of action is to bind with the virus' spike proteins, inhibiting viral entry. The spike protein contains the conservative lectin receptor, making it more resistant to viral mutations.

Figure 14
PROLECTIN-M ANTIVIRAL APPROACH



Source: Bioxytran, Inc.

The Company has conducted a proof-of-concept Phase 1/2 clinical trial, published in the *Journal of Vaccines & Vaccinations,* as well as a follow-up *in vitro*-study, as highlighted below.

Phase 1/2 Trial—The Journal of Vaccines & Vaccinations, Vol. S10: 003, 2020.

A Proof-of-Concept Phase 1/2 clinical trial approved by the Institutional Review Board (IRB) and conducted at Mazumdar Shaw Medical Center, Narayana Health, in Bangalore, India was finalized in October 2020. The objective of the trial was to demonstrate the feasibility of a large randomized controlled clinical trial using galectin antagonist ProLectin-M as a treatment for mild, symptomatic, **real time reverse transcriptase polymerase chain reaction (rRT-PCR)** positive COVID-19, and assess the possible mechanism of action for galectin antagonists as a treatment in COVID-19. To the Company's knowledge, this was the first clinical trial using a galectin antagonist on SARS-CoV-2 and represents a novel way to block viral entry and replication of the virus.

The test included 10 participants, randomly assigned in a 1:1 ratio to receive a 4-gram tablet of ProLectin-M; and standards of care (SoC) (Treatment group) or only SoC (Control group). ProLectin-M was administered orally once every hour up to a maximum dose through the day of 40 grams or 10 tablets a day. During the trial, there were no serious adverse events, with ProLectin-M showing non-toxicity while displaying efficacy for the treatment of mild-to-moderate COVID-19.

- Symptoms and Positivity/Negativity Rate

Clinical trial data show the patients in the treatment group to be symptom free within the first 24-72 hours with a significant reduction of viral load, completely eliminated in 5 to 7 days. rRT-PCR testing done on patients in the treatment group had three participants (60%) turn negative by day 7 and all turned negative by day 14, staying negative until day 28. In the SoC group, two participants had zero detectable viral loads at baseline, 2 participants tested negative on day 14, and the last participant remained positive on day 28.

- Effect on Infectiousness

Cycle threshold (Ct) value is number of cycles needed to detect a specific pathogen using rRT-PCR, with lower values reflecting higher virus loads. Ct values expressed for RNA polymerase gene + Nucleocapsid gene (Rd/RP+N), and the small envelope genes (E) determine infectivity of the individual, with a cycle threshold of <25 considered to be infectious.

There was a significantly higher increase in Ct values for Rd/Rp+N and E genes in the treated group when compared to the control group. This shows the positive effect of the treatment in controlling infection, as a higher Ct value correlates with lower risk of infectiousness. By day 7, following treatment with ProLectin-M, Ct value of Rd/Rp+N gene increased by 25.85 versus an increase of only 9.45 in the control group, a significant difference of 16.41 points. Similarly, small envelope (E) gene increased by 28.27 versus an increase of 10.5 points, a difference of 17.75 points. Of note, participants in control group, remained potentially infective even on day 7 and day 14. Results are listed on Figure 15.

Figure 15
TRIAL RESULTS - INFECTIVITY

	Treated	Control	
SARS CoV-2 status at 7 days	3/5 negative	No Change	
	Treated	**Control**	**Diference**
Ct Change from baseline - Rd/Rp+N Gene (Day 7)	25.85	9.45	16.41
Ct Change from baseline - E Gene (Day 7)	28.27	10.52	17.75

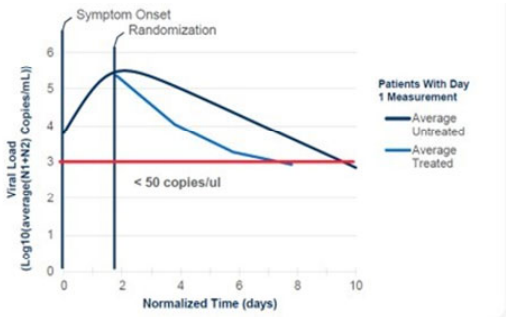
Source: Journal of Vaccines & Vaccination.

- Effect on Viral Load and Viral Replication

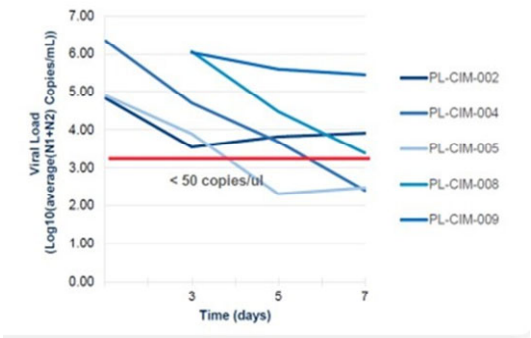
Treatment with ProLectin-M lowered viral protein levels to undetectable levels in 3 days. As shown in Figure 16, initiating treatment 2 days following symptoms onset, the treated group displayed a significantly faster reduction of viral load versus the control group. Figure 16 also shows the viral load decrease for all five treated patients.

Figure 16
VIRAL LOAD VS. TIME

PROLECTIN-M Vs. CONTROL



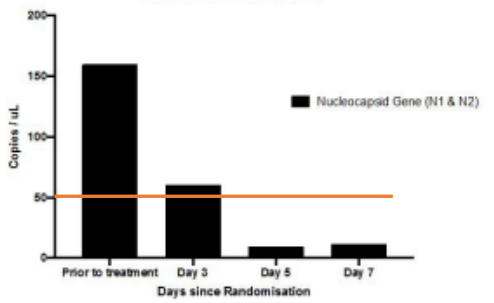
PROLECTIN-M TREATED PATIENTS



Source: Bioxytran, Inc.

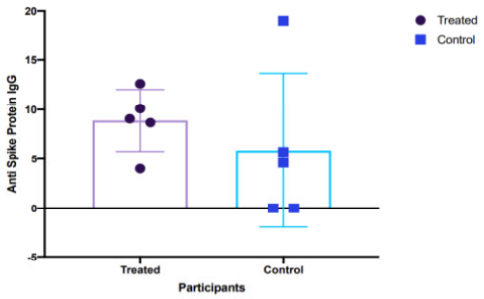
Furthermore, a PCR-based estimation of the Nucleocapsid genes (N1+N2) in absolute copies/µL determines active viral replication. The expression of N1 and N2 genes went below detectable thresholds by day 3, demonstrating that treatment with ProLectin-M resulted in undetectable levels of viral protein levels in 3 days (Figure 17).

Figure 17
NUCLEOCAPID GENES (N1+N2) IN TREATED PATIENTS



Source: Bioxytran, Inc.

Figure 18
IgG AGAINST SPIKE PROTEIN - DAY 28



Source: Bioxytran, Inc.

Researchers also analyzed the immune response of the treated patients against the control group by detection of anti-spike protein IgG on day 28, an expression of humoral response against the virus. All participants in the active arm of the trial were clinically asymptomatic before day 28 and had a reactive IgG, demonstrating an ability to block viral replication (Figure 18). ProLectin-M clears the blood of viral load thereby reducing the strain on the innate immune system, allowing the adaptive immune system to build a robust response toward future infection.

The Company plans to file an Emergency IND with the FDA, which has already been filed with The Central Drugs Standard Control Organisation (CDSCO), India's national regulatory body for cosmetics, pharmaceuticals, and medical devices. An initial pre-IND was submitted to the FDA in December 2020. In parallel, Pharmalectin has filed an additional IND with the CDSCO for an IV treatment of SARS-CoV-2 in moderate COVID-19 infections (ProLectin-I) and for treatment of lung-fibrosis as a result of use of a ventilator in treating COVID-19 (ProLectin-F), respectively.

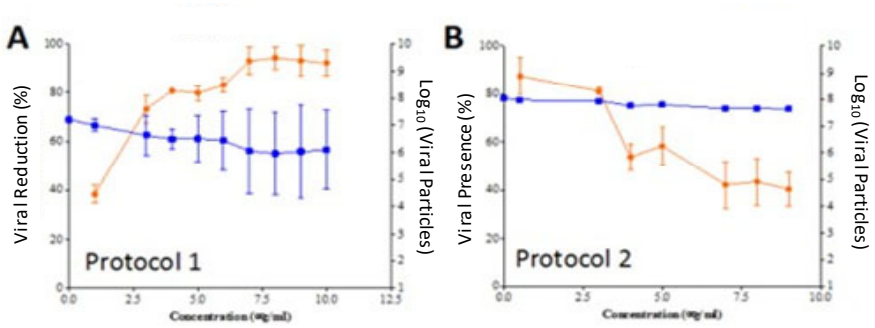
In Vitro Study—International Journal of Health Sciences, Vol. 6 (S4): 6671–6683, 2022.

The Company also conducted *in vitro* studies on the use of ProLectin-M as a treatment for mild, symptomatic COVID-19. The study investigated the effect of ProLectin-M on **Vero cells** infected with SARS-CoV-2 virus. The study was conducted using two protocols: Protocol 1-Vero cells were initially treated with ProLectin-M prior to being infected with SARS-CoV-2 (with dosage ranging from 1.0 µg/mL to 10.0 µg/mL); and Protocol 2-Vero cells were initially cultured with the SARS-CoV-2 virus prior to being treated with ProLectin-M.

Results indicated that ProLectin-M binds relatively strongly to galectin-3, preventing entry of the virus into its target cells, resulting in a dose-dependent reduction in viral load and cell infectivity. Researchers hypothesized that ProLectin-M functions *in situ* by binding to and antagonizing galectin-3, which normally interacts with SARS-CoV-2 to promote viral entry into cells. Utilizing NMR spectroscopy to assess interactions between ProLectin-M and lectin, the study was able to demonstrate that galectin-3 binds to ProLectin-M and indicated that the overall structure of galectin-3 is not significantly perturbed upon binding.

The study suggests that ProLectin-M-galectin-3 binding significantly blocks SARS-CoV-2 entry into cells, thus reducing viral RNA replication. In both protocols, the drug efficiently decreased viral load by rendering nearly 99% (i.e., 2 log) reduction in viral RNA copy number compared to control, as determined by rRT-PCR. Pre-treatment (Protocol 1) of Vero cells with ProLectin-M reduced viral load over 90% in doses higher than 7 µg/mL, with the greatest reductions being observed at 8 µg/mL (94.4%). Figure 19 (page 28) displays the reduction of viral load (circles) and viral particles (squares) for protocol 1 (A); and the viral presence (circles) and viral particles (squares) for protocol 2 (B). Furthermore, cytotoxic tests demonstrated that ProLectin-M does not exhibit cytotoxic effects on Vero cells at concentrations up to 100 µg/mL. In fact, the compound appeared to increase cell viability, with maximal effects on cell proliferation observed at doses of 50 µg/mL when compared to control.

Figure 19
REDUCTION OF VIRAL LOAD IN VERO CELLS



Source: Bioxytran, Inc.

The study, which outlines and further defines ProLectin-M's mechanism of action (MOA), confirms and expands on the preliminary clinical data results from Bioxytran's Phase 1/2 trial published in the *Journal of Vaccines & Vaccination* (referenced above), whereby human clinical trial results showed elimination of viral load to undetectable levels within a few days.

Phase 3 Trial (ClinicalTrials.gov Identifier: NCT05096052)

The Company has applied for an IND with the CDCSO in India for a Phase 3 clinical trial and is preparing its IND for a Phase 2 clinical trial with the FDA, soon to be followed by a Phase 3 submission with the EMEA. The trials are designed to test the Company's hypothesis that patients receiving ProLectin-M, irrespective of their vaccination status or underlying medical conditions, will have a faster recovery from COVID-19 compared to those receiving its matching placebo.

The Phase 3 double blind randomized controlled clinical trials will include 408 participants. Bioxytran plans to recruit participants following a broad inclusion criterion. For example, vaccination status of participants is irrelevant. The primary measures are change in seropositivity at day 14, and proportion of patients reporting improvement in their disease on a WHO Clinical Progression Scale measured daily over the course of the study. Secondary measures include time to discharge, duration of hospitalization, and mortality/serious adverse events—all at 29 days. The trial is expected to be completed by fourth quarter 2022.

ProLectin-M Benefits

- *Eliminates virus*: ProLectin-M shows a rapid reduction of viral load in the blood and eliminates the virus completely within a few days. The theory behind the Mechanism of Action (MOA) is that the drug prevents the virus from entering the human cell and is eventually eliminated by the liver.

- *Stops the spread*: ProLectin-M has the potential to reduce the viral load quickly to viral levels that are considered non-contagious. Lowering viral levels can also lower the infectivity of the virus and help prevent people from spreading the virus to others by reducing the time that they are contagious, whereas vaccinated people can still infect others.

- *Promotes immunity*: The adaptive immune system creates Immunoglobulin G (IgG) antibodies resulting in long term immunity.

- *Prophylactic characteristics*: If ProLectin-M can slow the spread of the virus to other parts of the body then it gives rise to the possibility that people who are not infected by the virus might be able to use ProLectin-M as a preventative measure.

- *Universally compatible with all mutations*: By targeting lectins, ProLectin-M binds to the part of the spike protein resistant to change regardless of how the SARS-CoV-2 mutates.

- *Easy to transport and administer*: ProLectin-M tablets can be stored at any temperature. They are easy to administer and people can treat themselves at home.

ProLectin-I

The Company is also preparing an IND with the CDCSO for a second drug candidate, ProLectin-I, for the treatment of lung fibrosis. Pharmalection is about to begin an initial human research study with a group of five hospitals in Bangalore, India.

ProLectin-A

The Company is further developing ProLectin-A, an IV treatment of COVID-related Acute Respiratory Distress Symptom (ARDS). A significant problem related to the COVID-19 pandemic is that an increasing number of COVID-19 patients are developing life-threatening complications, such as ARDS, shock, kidney failure, acute cardiac injury, and secondary bacterial infections. The underlying cause for these complications is often cytokine release syndrome (CRS) that results in a massive, systemic inflammatory response, leading to the damage of vital organs such as the lungs, heart, and kidneys, and ultimately multiple organ failure and death in many cases. For this purpose, Bioxytran is developing ProLectin-A that aims to deliver oxygen to damaged organs and at the same time fight infection.

ProLectin-F

The fourth drug in this series is ProLectin-F, developed to treat patients developing lung fibrosis as a result of the use of ventilator in COVID-19 treatment. Increasing evidence from experimental and clinical studies suggests that mechanical ventilation, which is necessary for life support in patients with ARDS, can cause lung fibrosis, which may significantly contribute to morbidity and mortality. According to a review of medical records of 22,350 admissions, the cost of treating patients who were put on a ventilator was four times higher than for those treated without a ventilator and that the death rate of pulmonary fibrosis patients who were put on a hospital ventilator was seven times higher than those treated without a ventilator. The Company is preparing a Phase 1/2 trial of 60 people on fibrosis of the lung in India using ProLectin-F, expected to be completed by November 2022.

PROLECTIN FUTURE RESEARCH—DEVELOPMENT OF A MULTIPLE-TARGET COMPOUND

Current drug design protocols normally start by determining a target (often times a protein receptor) responsible or involved in the biological process that results in a disease, and then creating an inhibitor to block that interaction of the protein and the receptor in order to stop the resulting negative consequences. Whether it is a monoclonal antibody or a small molecule, the intended target normally remains a single receptor or protein. While current advances in drug design and discovery have been focused on improving or optimizing the interaction between the target and the therapeutic compound (e.g., strengthening or fine tuning the binding between both), the next step in the evolution of drug design would be the creation of a single molecule that targets multiple receptors responsible for different aspects of the disease. This approach can result in eliminating the need for using combinations of therapeutic compounds to treat all aspects of a disease, which could lead to increased side effects and drug-drug interaction (DDI) issues.

A recent study, sponsored by Bioxytran and co-authored by the Company's CEO David Platt, has shown a methodology using Nuclear Magnetic Resonance (NMR) imaging that can optimize drug design to target multiple receptors. Although the study's main objective was to assess the potential of PLG-007 (a combination of galactomannans GMα and GMβ) as an adjunct treatment for diabetes and inflammatory-related diseases, more relevant to Bioxytran's operations (and carbohydrate drug development in general) is the article's research methodology and description of a new process using NMR imaging that allows for the advancement of carbohydrate drugs development by achieving two key benefits: (1) fine tuning the interaction of carbohydrate drugs with target glycoproteins; and (2) providing a methodology to create a single compound that target multiple receptors *(Source: International Journal of Molecular Sciences,* Vol. 23 (14): 7739, 2022).

Fine Tune

The research created a tool which is expected to empower drug designers with a means to test molecules in the lab and fine tune the interaction of carbohydrate drugs with target glycoproteins. For instance, a complex carbohydrate galectin inhibitor, such as ProLectin-M, could be designed specifically to strongly bind to the conserved carbohydrate recognition domain-like fold on the SARS-CoV-2 spike protein. After a target is selected, a carbohydrate drug may be designed using the NMR binding technique as the next evolution of the drug design process.

Multiple Targets

The journal article also utilizes a methodology using NMR imaging that can optimize drug design to target multiple receptors. The use of this improved NMR technology could translate into the design of antivirals that target different receptors or proteins. After the targets are selected, a carbohydrate drug may be designed using the NMR binding technique resulting in a therapeutic agent that binds with multiple targets.

This is important for glycovirological conditions where multiple galectins might be involved in the pathology of the disease. Developing one antagonist capable of binding multiple target galectins is the ideal use case in drug development because it would target multiple key aspects of the disease instead of just one part of the disease. Furthermore, the same process could be used for the regulation of different galectins implicated in different viral infections, resulting in a single customized antiviral that can treat different viral conditions.

Bioxytran believes that this methodology provides a blueprint that could allow the creation of carbohydrate drugs that can treat the entire disease instead of singular targets. For example, in a disease that is caused by the upregulation of different biological pathways involving galectins, NMR could be used to screen different agents that create the desire effect, resulting in a single molecule that would inhibit all galectins involved, treating all aspects of the disease and eliminating the need for multiple drugs to achieve the same result.

Additional Implications for Multiple Component Drug Design

The researchers of this publication combined two molecules to make a single drug candidate that they knew behaved in a certain way and expected even better performance. NMR testing of both the formulation's carbohydrate components (GMα & GMβ) revealed that both were proven to block the enzyme of interest that breaks starch apart in the digestive process. If GMα worked independently from GMβ then it follows that the combination would likely be more powerful. However, results of the experiment showed that the drug candidate allowed more starch, not less, to be broken apart.

Researchers believe that the reason for this discrepancy is the fact that GMα does not work in conjunction with the other component to block the enzyme at its active site, in which case more components would achieve better results. GMα is an allosteric inhibitor, which means the molecule effectively disables the enzyme by binding to a site other than the enzyme's active site and changing the enzyme's shape. In this case, at the specific dosage and GMα:GMβ molecule ratio, both components interfered with one another resulting in the opposite effect than the one desired. When allosteric inhibition is present, it complicates clinical trial development as higher doses might not necessarily lead to better outcomes. However, understanding this information before a trial is conducted, including the MOA of each component (i.e., active or allosteric inhibition), could result in an optimal point for dosing, the right combination of component ratio and dosage levels.

This case study highlights why NMR Spectroscopy could be useful in carbohydrate drug design. Research into glycovirology and the role of galectins in human disease, although relatively new compared to other medical approaches, is growing with over 3,800 research papers over the past 30 years published on galectin-3 alone. There are at least 100 disease indications and untold number of viruses that could be targeted by galectin inhibition. NMR spectroscopy can speed up research and development of carbohydrate drugs, making the task of developing compounds more efficient.

BXT-25—HYPOXIA AND DEGENERATIVE DISEASE

Bioxytran is developing an innovative technology platform of oxygen therapeutic treatments for hypoxic conditions, necrosis, and degenerative diseases. The Company's technology platform seeks to deliver oxygen to affected areas with an initial focus on therapeutic molecules for stroke, wound healing, and traumatic brain injury (TBI), with additional applications in other related conditions, such as dementia, Alzheimer's disease, and anemia.

The Company's hypoxia/degenerative disease technology platform uses a technology developed by the Biopure Corporation—which separates the hemoglobin molecule from red blood cells (RBCs). Biopure filed for bankruptcy in 2009 and the manufacturing technology the Company uses from Biopure is in the public domain. Once the hemoglobin molecule is extracted, the Company applies its proprietary manufacturing process, based on Dr. Platt's prior research, to enhance the hemoglobin molecule, creating an injectable intravenous drug that prevents cell death by carrying oxygen to human tissue or brain cells that have limited or blocked blood flow. Bioxytran's lead candidate in this research area, BXT-25, is an oxygen-carrying small molecule consisting of bovine hemoglobin stabilized with a co-polymer, intended to treat hypoxic conditions in the brain resulting from stroke. BXT-25 is designed to be an injectable anti-necrosis drug specifically designed to diffuse oxygen into the brain tissue to treat a person immediately after an ischemic stroke.

The Company plans to begin pre-clinical studies on this indication, with future plans to explore additional drug candidates using chemical structures that are a sub-class of BXT-25 to treat wound healing due to hypoxia, cardiovascular ischemia, anemia, cancer conditions, and trauma. At this time, BXT-25 development is on hold until the Company secures additional capital.

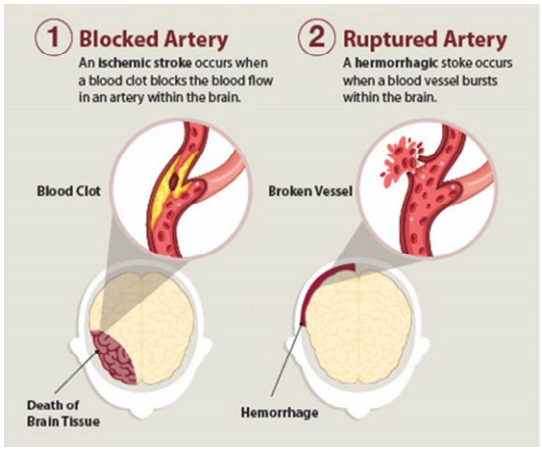
Bioxytran also has an exclusive license for an FDA approved companion diagnostics—MDXViewer—that allows the Company to detect oxygen delivery to brain tissue. To Bioxytran's knowledge, the diagnostic device is the only technology approved by the FDA that allows for measurement of oxygenation of a specific tissue, as opposed measurements of arterial oxygen levels.

STROKE OVERVIEW

Stroke, also known as cerebrovascular accident (CVA) or brain attack, occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked by a clot or ruptures. A stroke results in poor blood-flow to the brain, which leads to brain cells necrosis (cell death). A stroke can cause lasting brain damage and neurological deficits, long-term disability, or even death.

Strokes can be classified into two major categories: ischemic and hemorrhagic (illustrated in Figure 20). Ischemic strokes, composing 87% of all total strokes, are caused by interruption of the blood supply to the brain; an ischemic stroke may be thrombotic, which occurs when diseased or damaged cerebral arteries become blocked by the formation of a blood clot within the brain, or embolic, which occurs when a clot formed originally somewhere outside the brain—typically in the heart—travels into a cerebral artery.

Figure 20
STROKE



Source: CDC.gov.

Hemorrhagic strokes result from the rupture of a blood vessel or an abnormal vascular structure. The leaked blood puts too much pressure on brain cells, which damages them. High blood pressure and aneurysms—balloon-like bulges in an artery that can stretch and burst—are examples of conditions that can cause a hemorrhagic stroke.

There are approximately 795,000 new or recurrent cases of stroke in the U.S. each year, of which 610,000 are new cases and 185,000 are recurrent cases, resulting in 130,000 deaths (one every four minutes). Stroke is a leading cause of serious long-term disability in the U.S., at a cost of roughly $53 billion each year—including the cost of healthcare services, medications to treat the stroke, and lost productivity (Source: Centers for Control Disease and Prevention [CDC]). Worldwide, there were 12.2 million cases of stroke and 6.55 million deaths in 2019, representing the second-leading cause of death and the third-leading cause disability. Global costs related to strokes are estimated at $500 billon, as shown in Figure 21 (Source: *The Lancet*, Vol. 20 (10): 795-820, 2021).

Figure 21

STROKE STATISTICS

	Strokes	Population	Survivors	Direct Cost	Indirect Cost
US	0.8 million	330 Million	5.8 Million	$44 Billion	$22 Billion
EU	1.1 million	515 Million	3.4 Million	$28 Billion	$15 Billion
CN	2.5 million	1,402 Million	7.5 Million	Estimated $74 Billion	
World (Total)	12.2 million	7,700 Million	33 Million	Estimated $500 Billion	

Source: The Lancet Neurology, Vol 20 (10), 2021.

Bioxytran's injectable drug candidate, BXT-25, may compete with existing therapies to treat stroke, hypoxia, and anti-necrosis. The global stroke management market was valued at $31.7 billion in 2020 and is projected to reach $67.8 billion by 2030 (Source: Allied Market Research's *Stroke Management Market by and Application: Global Opportunity Analysis and Industry Forecast, 2021–2030*, 2022).

Treatment and Therapy Options for Stroke

The only FDA approved treatment for ischemic strokes is **tissue plasminogen activator (tPA or rTPA)**, given through an intravenous therapy (IV)—a medical technique that administers fluids, medications, and nutrients directly into a person's vein. tPA works by dissolving the clot and improving blood flow to the part of the brain being deprived of blood. If administered within 3 hours (and up to 4.5 hours in certain cases), tPA may improve the chances of recovering from a stroke. However, only about 25% of stroke patients arrive for treatment within that time period (Source: Seeking Alpha's *Time Is Brain: Bioxytran's Tissue Oxygenation Therapy May Breathe New Life Into Stroke Victims*, 2019). Another treatment option is a mechanical **thrombectomy**, in which the blood clot is removed by threading a wired-caged device, called a stent retriever, through an artery in the groin up to the blocked artery in the brain. The stent opens and grabs the clot, enabling the removal of the stent with the trapped clot.

The stroke market represents a significant opportunity. Existing treatments are limited. In contrast to breakthroughs in many disease categories over the past two decades, stroke treatment, especially development of therapeutic drugs, has had minimal improvement for the past several decades. This can be seen by four of the most advanced drug candidates to treat a stroke (Figure 22 [page 33]). Abciximab from Eli Lilly is a platelet aggregation inhibitor. Clinical trials show little advantage over placebo and could lead to dangerous side effects, including more bleeding in patients. Cerovive from AstraZeneca is a Nitrone-based neuro protectant currently in Phase III clinical trials, showing no significant benefit over placebo with respect to changes in neurological impairment as measured by the national institute of health stroke scale. Candesartan, from AstraZeneca, is an angiotensin receptor blocker, which was used to control blood pressure. Its efficacy in stroke patients still must be proven. Ancod from Knoll Pharmaceuticals is an anti-coagulant that acts by breaking down the fibrinogen. It increases the risk of hemorrhage similar to those associated with tPA. There is currently a large unmet medical need for safe and efficacious therapy, as current treatments are either time-dependent, limited to certain clot types, or both. Of note, according to the Company, there are no therapeutic agents available that actively deliver oxygen to the brain.

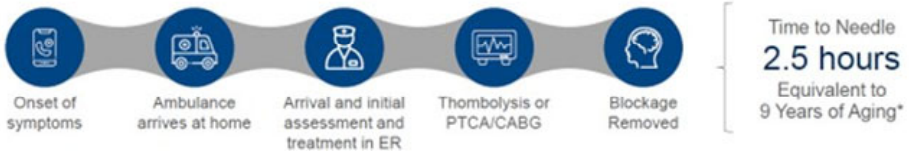
Figure 22
STROKE TREATMENT OPTIONS

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

Source: Bioxytran, Inc.

Importantly, the time it takes from the onset of a stroke to the time treatment starts (also known as "Time to Needle") is key to the effective recovery from the condition (Figure 23). In patients experiencing a typical large vessel ischemic stroke, 120 million neurons, 830 billion synapses, and 714 km (447 miles) of myelinated fibers are lost each hour. Compared with the normal rate of neuron loss in brain aging, the ischemic brain ages 3.6 years each hour without treatment (Source: *Stroke,* Vol.37(1):263-266, 2006).

Figure 23
STROKE TIME TO TREATMENT



Source: Bioxytran, Inc.

DEGENERATIVE DISEASE/HYPOXIA PIPELINE

Oxygen is indispensable to the life of all human tissues. Hemoglobin, a protein normally contained within RBCs, is the molecule responsible for carrying and releasing oxygen to the body's tissues. Hemoglobin's protein structure is similar in many different animal species, including humans. Under normal conditions, hemoglobin contained within RBCs carry approximately 98% of the body's oxygen and the remaining 2% is dissolved in the blood plasma. Oxygen therapeutics describe a class of agents that are administered intravenously to enhance the oxygen delivery capability of blood. These oxygen transporting agents may be perfluorocarbon (PFC) emulsions or modified hemoglobin solutions. Bioxytran's technology involves the development of **hemoglobin-based oxygen carriers (HBOC)**.

The Company's lead pharmaceutical therapeutic candidate, BXT-25, is an oxygen-carrying small molecule consisting of bovine hemoglobin stabilized with a co-polymer. This modified hemoglobin will be designed to be an injectable intravenous drug to prevent necrosis, or cell death, by carrying oxygen when blood flow to the brain is blocked during the initial stages of stroke.

Bioxytran is also exploring the use of additional drug candidates using chemical structures that are a sub-class of BXT-25, which share the same physical properties, to treat wound healing due to hypoxia, cardiovascular ischemia, anemia, cancer conditions, and trauma. Figure 24 (page 34) provides an overview of the Company's degenerative disease/hypoxia development pipeline. BXT-25 development, however, is on hold until the Company raises additional capital.

Figure 24

BIOXYTRAN'S DEGENERATIVE DISEASE PIPELINE

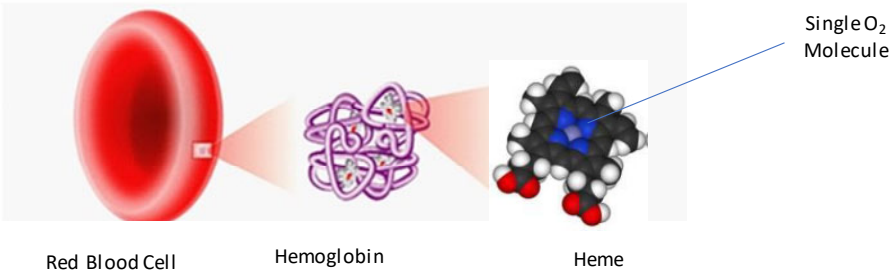
Source: Bioxytran, Inc.

BXT-25 Overview

BXT-25 is a hemoglobin-based polymer that is simply a combination of heme, derived from hemoglobin, and a co-polymer designed to stabilize it in the blood system. The production of BTX-25 starts with the isolation of hemoglobin of red blood cells (RBCs) from bovine sources, and the extraction of heme (the oxygen carriers of human blood cells) from the hemoglobulin. The Company then applies its proprietary co-polymer chemistry manufacturing process to stabilize and modify the heme (Figure 25). This modified molecule is designed to be an injectable intravenous drug to prevent necrosis, or cell death, by carrying oxygen when blood flow to the brain is blocked during the initial stages to treat patients with ischemia of the brain resulting from a stroke.

Figure 25

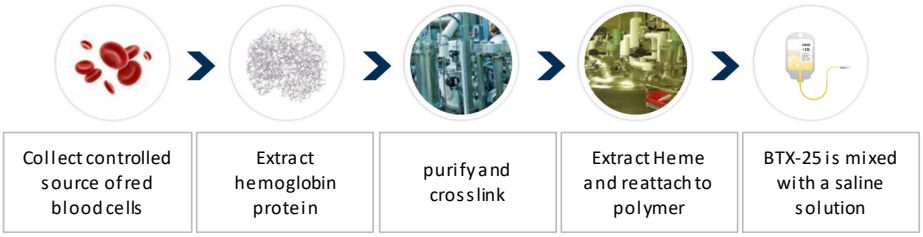
BTX-25



Source: Bioxytran, Inc.

BTX-25's proprietary manufacturing process involves the extraction of heme from hemoglobulin and the attachment of the heme molecule to a co-polymer. Despite its oxygen carrying capabilities, if heme is injected directly into the bloodstream, it would be filtered out by the liver. Bioxytran avoids this shortcoming by combining the heme with a co-polymer that mimics natural carbohydrates on blood cells. New blood has a surface sugar that is recognized by the liver. As the blood cell ages, the sugar breaks down to the point where the liver decommissions the cell and filters it out. BXT-25 is comprised of molecules of heme bonded to a co-polymer stabilizer that mimics the sugars found on a blood cell surface, preventing it from being filtered out by the liver. Figure 26 (page 35) provides an overview of the proprietary manufacturing process.

Figure 26
PROPRIETARY MANUFACTURING PROCESS FOR BTX-25



Source: Bioxytran, Inc.

Current medical procedures for ischemic stroke aim to dissolve the clot using rtPA, or to remove the clot surgically, neglecting the injured brain. Bioxytran's treatment is intended to reduce brain tissue damage, recovery time, and patient suffering, minimizing direct and indirect healthcare costs. The small synthetic molecule carries oxygen from the lungs to the brain, prolonging the "Time to Needle" window and allowing for other medical procedures to take place. BXT-25 offers an "Oxygen Bridge" to ensure survival in the critical hours immediately after ischemic stroke and prevent necrosis of brain tissue.

BXT-25 molecules are 5,000 times smaller than RBCs. BXT-25 circulates in the blood collecting oxygen from the lungs and releases the oxygen molecules where the tissue has developed ischemia, or lack of oxygen. The oxygen is delivered to the brain immediately upon infusion (less than 3 minutes). BXT-25 has oxygen affinity that mimics human RBCs and is not expected to cause adverse effects. BXT-25 is non-immunogenic and universally compatible with all blood types. It is recognized by the blood-brain barrier (BBB) and has low viscosity, allowing it to safely deliver oxygen to the brain.

BXT-25 Key Attributes

BXT-25 displays the following key attributes that contribute to its effectiveness and help the pre-clinical drug candidate potentially improve the outcome of stroke victims.

Molecule Size

The BXT-25 molecule is designed to be 5,000 times smaller than an RBC, which the Company believes will enable it to reach hypoxic tissue more effectively than RBCs as its size allows the therapeutic molecule to transport oxygen through blocked arteries and into oxygen-deprived tissue. Brain blood clots resulting in strokes are not an impermeable barrier but are porous. However, the size of RBCs makes them too big to pass through, trapping even more blood cells in its structure. Rather than dissolving or breaking up the clot, Bioxytran intends to use an oxygen delivery vehicle that is small enough to pass through the clot, allowing for the delivery of oxygen to brain tissue that is receiving inadequate numbers of RBCs.

Blood Type Compatibility

Surfaces of RBCs include different antigens, which determine the blood type as A, B, AB, or O. Because BXT-25 is a single, modified hemoglobin molecule stabilized with a co-polymer which, unlike a RBC, has neither antigens nor a Rh factor, the Company believes that its therapeutic candidate is compatible with all blood types.

Flexibility

BXT-25 is envisioned to be administered by first responders while they transport the stroke patient or ER personnel while the patient is awaiting imaging results to prevent or reduce cell death in the brain while a treatment course of action is developed. Due to BXT-25's stable shelf life, a triage kit for ambulances can be developed for rapid deployment, working as an "Oxygen Bridge" to ensure survival in the critical hours immediately after a stroke.

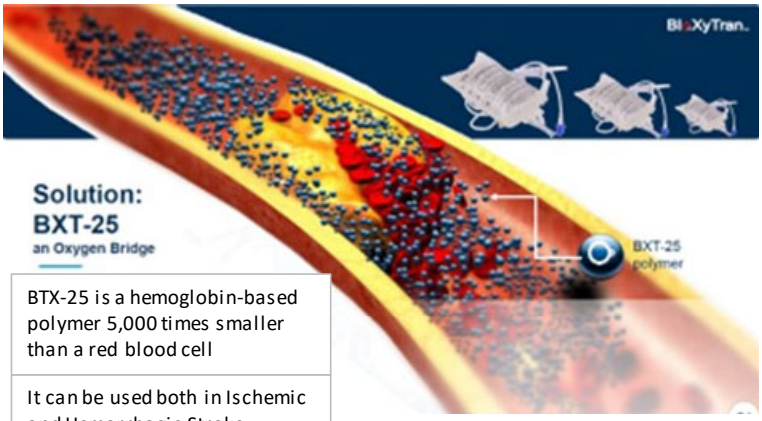
In addition, since BXT-25 can be used both in ischemic and hemorrhagic stroke, the Company believes that it can be safely administered to any stroke patient quickly, even before any diagnostic or imaging test is conducted, working as a bridge until more robust options can be implemented.

Safety Profile

BXT-25 is made up of two components—heme and the co-polymer—that the FDA generally regards as safe. Heme is an FDA approved material that identifies and delivers oxygen, and the co-polymer is an FDA approved sugar that stabilizes heme in blood and eliminates **nitric oxide (NO)** scavenging. Some blood substitutes can cause **NO scavenging**, which has been shown to cause changes in vascular function (e.g., vasoconstriction).

Figure 27 provides an overview of the BXT-25 molecule.

Figure 27
BTX-25 OVERVIEW



Source: Bioxytran, Inc.

Proof of Concept

BXT-25, or compounds with similar chemistry as BXT-25, have been used in pre-clinical tests as proof-of-concept studies. One animal study determined the effects of increasing circulating concentrations of a highly purified hemoglobin-based oxygen carrier (HBOC) on hemodynamics, metabolic correlates of oxygen debt, and tissue oxygenation in a dog model of controlled hemorrhagic shock. Administration of this compound with similar chemistry to BTX-25 in conjunction with a colloid resulted in positive effects on all variables associated with oxygen delivery and tissue oxygen tension (tPO_2) without producing significant increases in pulmonary artery blood pressure, leading to better recovery after hemorrhage compared to control (Source: *Critical Care Research and Practice*, Vol. 2014, Article ID 864237).

Further studies conducted in Harvard University also provided promising results. Despite HBOCs demonstrated ability to improve blood oxygen content and tissue oxygen delivery, actual use of the compounds in a clinical setting remains controversial based upon the potential for most HBOCs to produce oxidative stress and vasoconstriction. The latter is primarily attributed to the binding of hemoglobin or heme molecules to NO (a vasodilator), a process known as NO scavenging. One study conducted in rat models indicated that the co-polymer shielded the heme protein, eliminating NO scavenging and resulting in no increased blood pressure, as the drug acted as a universal carrier of oxygen. In further experiments, compounds with similar chemistry as BXT-25 were also found to improved oxygen delivery and brain recovery in stroke induced rats. Figure 28 (page 37) provides an overview of results of these studies.

Figure 28

PROOF-OF-CONCEPT STUDIES

Absence of nitric oxide scavenging, no increased blood pressure in diabetic mice (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)	Oxygen delivery and brain recovery in stroke induced rats with similar chemistry to BXT-25 (Harvard Medical School, 2013)

Source: Bioxytran, Inc.

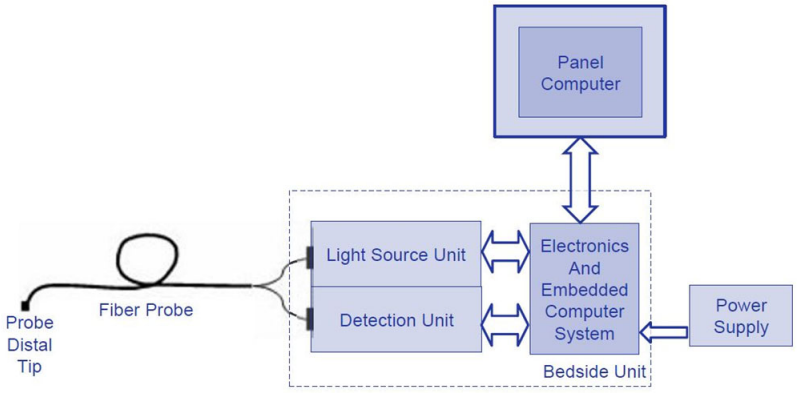
MDXVIEWER

In order to support its BTX-25 development, Bioxytran obtained an exclusive license for MDXViewer, an FDA cleared technology that allows for real-time measurements of tissue oxygenation and oxygen supply to the brain, developed by MDX Lifesciences, Inc. Bioxytran obtained the license for the use of the technology for clinical monitoring of oxygen delivery through oxygen carriers. MDXViewer allows the Company to prove oxygen delivery to tissue, providing a clinical end-point for measuring oxygen supply to the brain in real-time in order to support BTX-25 clinical trials. To the Company's knowledge, the diagnostic device is the only technology cleared by the FDA that allows for measurement of oxygenation of a specific tissue, as opposed to the measurement of arterial oxygen levels.

The MDXViewer device consists of three components (shown in Figure 29): (1) the Main Unit, which contains the light sources, optical detectors, and the main signal processing components; (2) the Monitor Unit, which displays the tissue monitored parameters and contains the MDXViewer's operating user interface; and (3) the Probe Accessory, which includes the optical sensing flexible fiber bundle, connected to the main unit through an optical connector. The probe is integrated into an adapted 3-way urinary (Foley) catheter.

Figure 29

MDXVIEWER COMPONENTS



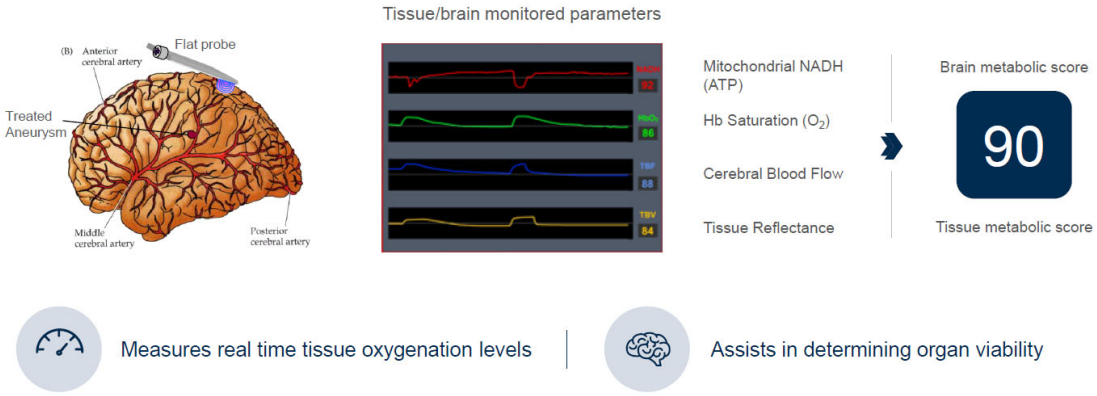
Source: MDX Lifesciences Inc.

MDXViewer illuminates tissue by low power light and detects light that is subsequently emitted or reflected from the tissue. The light is guided to the tissue by a bundle of flexible optical fibers and emitted from the tissue both by reflection and fluorescence. The emitted light from the tissue is analyzed by various detectors and the signals are transferred to the monitor's central processing unit.

MDXViewer is a multi-parametric/multivariate patient monitoring system providing real-time continuous information on a patient's systemic metabolic state through the measurement of four physiological parameters, sensed at the tissue level: mitochondrial NADH redox state via surface fluorometry/reflectometry; blood oxygenation and hemoglobin saturation via spectroscopy; cerebral blood flow via laser doppler flowmetry; and tissue blood volume (TBV) via reflectometry.

These parameters are then combined with additional hemodynamic, cardiovascular, and respiratory measurements, including heart rate, systemic blood pressure, respiratory rate, systemic hemoglobin saturation, and body core temperature to provide a tissue or brain metabolic score reflecting tissue oxygenation levels. The MDXViewer operational process is illustrated in Figure 30.

Figure 30
MDXVIEWER - FDA APPROVED COMPANION DIAGNOSTICS



Source: Bioxytran, Inc.

Investment Highlights

- ***Bioxytran, Inc. ("Bioxytran" or "the Company") is a clinical stage pharmaceutical company developing platform technologies in the fields of glycovirology, hypoxia, and degenerative diseases.*** Using its platform technologies, the Company is initially developing therapeutics in two medical areas: (1) glycovirology and anti-viral therapeutics, with an initial focus on COVID-19; and (2) hypoxic conditions and necrosis, with an initial focus on brain conditions resulting from stroke.

- ***Bioxytran's glycovirology efforts are conducted through its subsidiary, Pharmalectin Inc.*** Pharmalectin is developing a novel technology platform—ProLectin—designed to reduce the viral load and modulate the immune system using galectin inhibitors. Galectin-3 inhibitors have the capability to bind with proteins on the virus surface, preventing the virus from attaching to a cell and entering the cell.

- ***While the initial focus of the Company is the SARS-CoV-2 virus, Bioxytran believes that its technology can be used to create antiviral therapeutics targeting a considerable number of viral pathogens***, as well as the potential creation of a multiple-antagonist single molecule that can target multiple biological pathways responsible for various aspects of a disease, such a single customized antiviral that can treat different viral conditions.

- ***Using its ProLectin technology platform, Bioxytran is developing an end-to-end solution for COVID-19, including treatment for severe conditions derived from the disease.*** The Company's lead candidate, ProLectin-M, is a chewable tablet for the treatment of mild-to-moderate COVID-19, which binds with proteins on the virus' surface and acts as cell-entry inhibitor.

- ***ProLectin-M complements the Company's intravenous drug candidates:*** ProLectin-I, for the treatment of severe cases of COVID-19; ProLectin-F, for the treatment for COVID-related lung-fibrosis; and ProLectin-A, for the treatment of COVID-related Acute Respiratory Distress Symptom (ARDS).

- ***To Bioxytran's knowledge, Pharmalectin is the only company using a galectin inhibitor to create an end-to-end viable solution to COVID-19***. The Company's pipeline candidates can block viral entry and act as an antiviral in the early stage of the disease, restore adaptive immune function to help eradicate the virus and prevent progress to severe disease, and can interrupt the process leading to the cytokine storm believed to be responsible for many of the fatal cases of the disease and treat COVID-related lung fibrosis.

- ***During proof-of-concept studies, ProLectin-M was found to bind strongly to the COVID-19 virus, preventing entry of the virus into its target cells.*** Treatment with ProLectin-M resulted on symptom-free patients within 24 to 72 hours, with a significant reduction of viral load, completely eliminated in 5 to 7 days, while displaying no serious adverse events.

- ***The Company is currently working on a Phase 3 clinical trial with the CDCSO in India and is preparing its IND application for a Phase 2 clinical trial with the FDA for ProLectin-M.*** The Company is also preparing a Phase 1/2 trial on fibrosis of the lung in India using ProLectin-F. Bioxytran expects all three trials to be completed by the fourth quarter 2022.

- ***Bioxytran's second technology platform—its hypoxia program—relies on the application of its proprietary co-polymer chemistry manufacturing process to enhance the hemoglobin molecule, creating an injectable drug that prevents necrosis by carrying oxygen to brain cells that have limited or blocked blood flow***.

- ***Bioxytran's lead candidate in this research area is BXT-25, an oxygen-carrying small molecule intended to treat hypoxic conditions in the brain resulting from stroke***. BXT-25 development is on hold pending additional capital being raised. Once funding is obtained, Bioxytran plans to begin pre-clinical studies for this indication.

- ***The BXT-25 molecule is designed to be 5,000 times smaller than a red blood cell (RBC), enabling the therapeutic molecule to transport oxygen through blocked arteries and into oxygen-deprived tissue more effectively than RBCs.*** The Company believes that BXT-25 is non-immunogenic, universally compatible with all blood types, and is recognized by the blood-brain barrier (BBB)—allowing it to deliver oxygen to the brain.

- ***Additionally, Bioxytran has an exclusive license for an FDA-cleared companion diagnostic—MDXViewer—that allows the Company to detect oxygen delivery to brain tissue in real-time, providing a clinical endpoint to support BTX-25 clinical trials***. To the Company's knowledge, the diagnostic device is the only technology cleared by the FDA that allows for measurement of oxygenation of a specific tissue, as opposed to measurements of arterial oxygen levels.

- ***The Company's management and scientific advisory team holds extensive expertise in complex carbohydrate chemistry (CCC) and regulatory and clinical development, with multiple submissions and approvals to the FDA***.

- ***The Company's cash position as of June 30, 2022 was $500,677.*** On August 15, 2022, Bioxytran entered into a subscription agreement for the issuance of 1,400,000 shares of the Company's Common Stock, resulting in the Company receiving net cash in the amount of $576,000.

Competition

As the Company continues to develop its product candidates and expand the application of its technologies, targeting diverse viral and hypoxic conditions, it may encounter competition from pharmaceutical and biotechnology companies as well as research institutions that commercialize or seek to commercialize new treatments for the same indications the Company is targeting.

Bioxytran believes it can utilize its technology platform capabilities to target a number of viral conditions, including the possibility of creating a multiple-antagonist molecule that can treat different viruses. As such, in the long term, the Company would enter a space that includes large cap pharmaceutical companies, including Gilead Sciences, Inc. (GILD-NASDAQ), GSK plc (GSK-NYSE), AbbVie Pharmaceuticals (ABBV-NYSE), Johnson & Johnson (JNJ-NYSE), and Merck & Co. (MRK-NYSE), among others.

In the shorter term, the Company's initial focus is on the creation of an end-to-end solution to treat COVID-19. In this space, Bioxytran would face competition from other oral drugs designed to treat COVID-19. Currently there are three oral drugs approved to treat COVID-19: Paxlovid (Pfizer) and Lagevrio (Merck), authorized for patients with mild-to-moderate COVID-19, with strong scientific evidence they can reduce the risk of progressing to severe disease, including hospitalization and death; and Olumiant (Eli Lilly) approved to treat certain adults who are hospitalized with COVID-19. Figure 31 provides and overview of oral therapies to treat COVID-19 (approved and under development).

Figure 31
SELECTED ORAL THERAPIES FOR COVID-19

APPROVED			
Drug	**Company**	**Description**	
Paxlovid (Nirmatrelvir with Ritonavir)	Pfizer Inc.	Emergency approval in December 2021 for mild-to-moderate COVID-19 in people ages 12 and older who are at high risk for severe illness	
Lagevrio (Molnupiravir)	Merck Sharp & Dohme Corp.	Alternative option for treating COVID-19 in adults at high risk of severe illness. It appears to be less effective than Paxlovid	
Olumiant (baricitinib)	Eli Lilly and Company.	Approved in May 2022 for the treatment of certain adults who are hospitalized with severe COVID-19	
UNDER DEVELOPMENT			
Candidate	**Company**	**Description**	Phase
Tollovir	Todos Medical Ltd.	For treatment of hospitalized (severe and critical) COVID-19	Phase 2/3
Tempol	Adamis Pharmaceuticals	For treatment of COVID-19	Phase 2/3
Bemnifosbuvir	Atea Pharmaceuticals Inc.	Missed primary endpoints in Phase 3 study	Phase 3
Brequinar	Clear Creek Bio Inc.	For treatment of COVID-19	Phase 2

Sources: GoodRx Health and Bioxytran, Inc.

Companies Developing Galectin-3 Inhibitors

Bioxytran may also face competition from other companies involved in the development of galectin inhibitors, specifically those working with galectin-3. Research into the part that galectin-3 plays in various major human diseases is promising. Interest in galectin-3 has expanded significantly over the past decade, specifically for its role in cancer and heart disease, with additional attention being shown to the brain, kidney, lung, and liver. Drug development has progressed the most with fibrosis in both the liver and lungs, though cancer immunotherapy and heart disease are also targets for drug development. It is expected that galectin-3 will remain an important area of focus for medical research as its role in the disease process is better understood along with how its presence can be used as a biomarker for disease progression or a target for effective therapies.

The most popular of galectin-3 inhibitors fall into one of three categories:

(1) peptide-derived inhibitors, perhaps headed by the sixteen amino acid long peptide "G3-C12" obtained from phage display;

(2) carbohydrate-derived multivalent inhibitors, represented mostly by the pectin derivatives, examples of which are the citrus-pectin derived "GBC-590" and "GCS-100" (both by Safescience, Inc.); or

(3) galactomannan "GM-CT-01" (Davanat™) and galactoarabino-rhamnogalacturonan "GR-MD-02" (both by Galectin Therapeutics, formerly Pro-Pharmaceuticals, Inc.). Inhibitors from these two categories are undergoing Phase II clinical trials.

A selection of these development candidates is summarized in Figure 32 and detailed in the accompanying section.

Figure 32
COMPANIES DEVELOPING GALECTIN-3 INHIBITORS

Organ System	Company	(TICKER-EXCHANGE)	Indication	Phase
Liver	Galectin Therapeutics	GALT-NASDAQ	NASH cirrhosis	Phase 3
	MandalMed, Inc.	Closely-held	Liver fibrosis	Pre-clinical
Heart	G3 Pharmaceuticals	Closely-held	Diastolic heart failure, also known as heart failure with preserved ejection fraction or HFpEF	Pre-clinical
	MandalMed, Inc.	Closely-held	Prevent and treat harmful remodeling after myocardial infarction	Pre-clinical
Kidneys	Angion Biomedica	ANGN-NASDAQ	Primary focal segmental glomerulosclerosis (FSGS), a form of chronic kidney disease	Pre-clinical
Skin	Galectin Therapeutics	GALT-NASDAQ	Psoriasis, Atopic dermatitis	Phase 2
Cancer	Galectin Therapeutics	GALT-NASDAQ	Combination immunotherapy therapy with KEYTRUDA in advance melanoma and head and neck cancer	Phase 2
	GlycoMimetics, Inc.	GLYC-NASDAQ	Cancer	Discovery
Lung	Galecto Biotech/BMS	GLTO-NASDAQ	IPF (idiopathic pulmonary fibrosis)	Planned Phase 2/3
Fibrosis	GlycoMimetics, Inc.	GLYC-NASDAQ	Fibrosis	Discovery

Source: Pharma IQ, a division of IQPC and Crystal Research Associates, LLC.

Angion Biomedica
https://angion.com

Angion Biomedica is a clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of novel small molecule therapeutics to address fibrotic diseases and acute organ injuries. Currently, the company's primary focus is chronic fibrotic conditions in the lung and kidney, where effective treatments with more limited off-target toxicities are needed.

G3 Pharmaceuticals
https://www.g3therapeutics.com

G3 Pharmaceuticals (G3T) has identified and genetically validated an entirely novel biological mechanism and potential drug target to treat both cardiovascular disease as well as non-alcoholic fatty liver disease that does not rely on lowering LDL-cholesterol. This genetically validated asset is currently in preclinical development.

Galectin Therapeutics
https://galectintherapeutics.com

Galectin Therapeutics has a lead drug compound that inhibits binding of galectin-3 in an attempt to treat diseases (in particular NASH cirrhosis and cancer) that are dependent on the action of galectin-3. NASH is the form of nonalcoholic fatty liver disease (NAFLD) in which a patient has inflammation of the liver and liver damage, in addition to fat in the liver. The inflammation and liver damage of NASH can cause fibrosis, or scarring, of the liver. NASH may lead to cirrhosis, in which the liver is scarred and permanently damaged. Galectin's NAVIGATE clinical trial is the Phase 2b/3 study of belapectin for the treatment of NASH cirrhosis, for which there are no approved

therapies aside from a liver transplant. A previous clinical trial showed belapectin may prevent the development of esophageal varices in patients with compensated NASH cirrhosis. Varices are an early sign for the development of serious complications in NASH cirrhosis. Approximately 50% of cirrhotic NASH patients with portal hypertension do not have varices when first diagnosed. Based on studies in animal models, Galectin Therapeutics is also exploring its galectin inhibitors in combination immunotherapy clinical trials. The initial cancer indication is advanced melanoma, the deadliest form of skin cancer. The company has also conducted an exploratory Phase 2a clinical trial of belapectin in patients with moderate to severe plaque psoriasis based on the improvement of psoriasis seen in a patient in the Phase 1 clinical trial.

Galecto Biotech AB
https://galecto.com

Galecto Biotech currently has two galectin-3 inhibitors in its pipeline: GB0139, in Phase 2 for the treatment of pulmonary fibrosis; and Gb1211, in Phase 2 trials for fibrotic indications (liver cirrhosis) and non-small lung cancer. Sponsored by Galecto Biotech AB (with collaborators Syneos Health and bioRASI, LLC), the GB0139 study is designed to evaluate the efficacy and safety of the product candidate, administered by dry powder inhalation, over 52 weeks. Previously known as TD139, GB0139 (given once per day) will be compared to placebo. All subjects eligible for the study will be randomized into one of the two treatment arms: (1) GB0139 3 mg once a day, or (2) placebo once a day. The 426 participants in this study will be double-blinded, with the blinding to be maintained throughout the study. The company also announced the completion of enrollment for its Phase 1b/2a GULLIVER-2 trial of GB1211 in liver cirrhosis (March 2022) and the first patient enrollment in its Phase 2 trial of GB1211 in combination with Atezolizumab for first-line treatment of NSCLC (June 2022).

GlycoMimetics, Inc.
https://glycomimetics.com

GlycoMimetics is applying its comprehensive understanding of carbohydrate biology (“glycobiology”), including knowledge of the bioactive conformations and molecular interactions of functional carbohydrates, to rationally design, develop, and commercialize highly-potent, small-molecule therapeutics that selectively target molecular mechanisms known to be centrally involved in the causes and progression of various human diseases. Each of the company’s drug candidates have been discovered internally, leveraging GlycoMimetics’ specialized synthetic chemistry platform. The company’s initial research and development efforts have focused on drug candidates targeting selectins, which are adhesion molecules that are principally involved in the inflammatory component and progression of a wide range of conditions. The company’s expertise in glycobiology has enabled it to advance several highly-potent selectin antagonists into clinical development to treat individuals with sickle cell disease and acute myeloid leukemia. In addition, GlycoMimetics is developing several other glycomimetic drug candidates that may address unmet medical needs in a variety of solid tumor and fibrotic diseases. The company’s product candidates are rationally designed to function more like traditional therapeutics (e.g., exhibiting good bioavailability and pharmacokinetics) and to enhance the key biological activity over the native carbohydrate structures. By delivering on highly-differentiated product profiles, GlycoMimetics’ drug candidates have the potential to address significant unmet medical needs. In addition to its drug candidates in the clinic, which target AML and other cancers, GlycoMimetics is researching therapies for other diseases.

MandalMed
(https://www.mandalmed.com

MandalMed’s lead product, MM-003, is a human protein that is an inhibitor of galectin-3, which is being developed to prevent and treat harmful remodeling after myocardial infarction (MI or heart attack) and, thus, to improve cardiac function and reduce mortality from subsequent heart failure. MandalMed is also seeking to develop MM-003 for chronic use in heart failure by performing biomarker-directed clinical studies. Elevated levels of galectin-3 in the serum have identified a subset of individuals with heart failure that have more progressive disease. Galectin-3 is a key mediator of cardiac fibrosis and timely inhibition of galectin-3 after MI could improve the functionality of the heart and patient outcomes. MandalMed scientists and collaborators are also testing MM-003, a dominant negative protein inhibitor of galectin-3, in animal models of liver disease to determine whether treatment can prevent and reverse liver fibrosis.

Historical Financial Results

Figures 33, 34, and 35 (pages 44-46) provide a summary of Bioxytran's most recent key financial statements for the three and six months ended June 30, 2022.

Figure 33
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
For the three and six months ended June 30, 2022 and 2021
(unaudited)

	Three months ended		Six months ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Operating expenses:				
Research and development	$ 43,141	$ 718,652	$ 283,266	$ 1,065,685
General and administrative	447,360	272,614	1,003,941	839,934
Stock based compensation expense	46,723	51,050	69,123	825,608
Total operating expenses	537,224	1,042,316	1,356,330	2,731,227
Loss from operations	(537,224)	(1,042,316)	(1,356,330)	(2,731,227)
Other expenses:				
Interest expense	(54,480)	(84,217)	(106,515)	(171,627)
Debt discount and intangible amortization	(42,336)	(17,103)	(134,581)	(17,103)
Total other expenses	(96,816)	(101,320)	(241,096)	(188,730)
Net loss before provision for income taxes	(634,040)	(1,143,636)	(1,597,426)	(2,919,957)
Provision for income taxes	—	—	—	—
NET LOSS	(634,040)	(1,143,636)	(1,597,426)	(2,919,957)
Net loss attributable to the non-controlling interest	11,691	246,935	62,807	401,549
NET LOSS ATTRIBUTABLE TO BIOXYTRAN	$ (622,349)	$ (896,701)	$ (1,534,619)	$ (2,518,408)
Loss per Common share, basic and diluted	$ (0.01)	$ (0.01)	$ (0.01)	$ (0.02)
Weighted average number of Common shares outstanding, basic and diluted	110,840,998	103,371,579	110,840,998	101,753,891

Source: Bioxytran, Inc.

Figure 34
CONDENSED CONSOLIDATED BALANCE SHEETS
As of June 30, 2022 and Decembert 31, 2021
(unaudited)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 500,677	$ 72,358
Total current assets	500,677	72,358
Intangibles, net	67,548	46,932
Total assets	$ 568,225	$ 119,290
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable and accrued expenses	$ 556,835	$ 624,316
Accounts payable related party	1,062,000	531,000
Un-issued shares liability	60,150	—
Un-issued shares liability related party	56,240	—
Convertible notes payable, net of premium and discount	3,593,650	2,122,181
Total current liabilities	5,328,875	3,277,497
Total liabilities	5,328,875	3,277,497
Commitments and contingencies	—	—
Stockholders' deficit:		
Preferred stock, $0.001 par value; 50,000,000 shares authorized, nil issued and outstanding	—	—
Common Stock, $0.001 par value; 300,000,000 shares authorized; 110,840,998 issued and outstanding	110,841	110,841
Additional paid-in capital	5,876,859	5,881,876
Non-controlling interest	(460,063)	(397,256)
Accumulated deficit	(10,288,287)	(8,753,668)
Total stockholders' deficit	(4,760,650)	(3,158,207)
Total liabilities and stockholders' deficit	$ 568,225	$ 119,290

Source: Bioxytran, Inc.

Figure 35
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
For the three and six months ended June 30, 2022 and 2021
(unaudited)

	Six months ended	
	June 30, 2022	June 30, 2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (1,597,426)	$ (2,919,957)
Adjustments to reconcile net loss to net cash used in operating activities:		
Debt discount amortization, incl. issuance of warrants	132,759	17,103
Amortization	1,822	—
Stock-based compensation	69,123	825,608
Changes in operating assets and liabilities:		
Pre-paid expenses	—	(224,586)
Accounts payable and accrued expenses	(67,481)	217,851
Accounts payable related party	531,000	674,290
Net cash used in operating activities	(930,203)	(1,409,691)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Investment in intangibles	(22,438)	(8,954)
Net cash used in investing activities	(22,438)	(8,954)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from subsidiary stock transactions	—	600,000
Proceeds from issuance of convertible notes payable	1,380,960	1,165,000
Net cash provided by financing activities	1,380,960	1,765,000
Net increase in cash	428,319	346,355
Cash, beginning of period	72,358	41,688
Cash, end of period	$ 500,677	$ 388,043
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION		
Interest paid	$ 69,900	$ —
Income taxes paid	$ —	$ —
NON-CASH INVESTING & FINANCING ACTIVITIES		
Issuance of warrants	$ 42,250	$ —
Forfeiture of stock options	47,267	$ —
Debt discount on convertible note	$ 86,040	$ 102,747
Common shares issued for the conversion of principal and accrued interest	$ —	$ 1,107,906
Forgiveness of related party debt recorded to additional paid-in capital	$ —	$ 1,020,323

Source: Bioxytran, Inc.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Bioxytran, Inc. ("Bioxytran" or "the Company") with the assistance of Crystal Research Associates, LLC ("CRA") based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Bioxytran's statements on forms filed from time to time.

The content of this report with respect to Bioxytran has been compiled primarily from information available to the public released by the Company through news releases and other filings. Bioxytran is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Bioxytran or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its agreement, CRA has been compensated by the Company in cash of forty-five thousand U.S. dollars and two hundred thousand warrants for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about Bioxytran's business, as described below. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in the accompanying section are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Bioxytran or that it currently believes to be immaterial may also adversely affect the Company's business. If any of such risks and uncertainties develops into an actual event, Bioxytran's business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved in an investment in the Company as well as for copies of this report, please contact Bioxytran by calling (617) 454-1199.

RISKS RELATED TO THE COMPANY'S BUSINESS

Bioxytran's plan relies upon its ability to obtain additional sources of capital and financing. If the amount of capital the Company is able to raise from financing activities, together with its revenues from operations, is not sufficient to satisfy Bioxytran's capital needs, the Company may be required to cease operations.

To become and remain profitable, Bioxytran must succeed in developing and commercializing products that generate significant income. This will require the Company to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of its drug candidates, discovering additional drug candidates, obtaining regulatory approval for these drug candidates, manufacturing, marketing and selling any products for which the Company may obtain regulatory approval, and establishing and managing Bioxytran's collaborations at various stages of each candidate's development. The Company is only in the preliminary stages of these activities. It may never succeed in these activities and, even if it does, may never generate income that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, Bioxytran is unable to accurately predict the timing or amount of increased expenses or when, or if, the Company will be able to achieve profitability. If Bioxytran is required by the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA) to perform studies in addition to those currently expected, or if there are any delays in completing Bioxytran's clinical trials or the development of any of its drug candidates, the Company's expenses could increase, and revenue could be further delayed.

Even if the Company does achieve profitability, Bioxytran may not be able to sustain or increase profitability on a quarterly or annual basis. The Company's failure to become and remain profitable would depress its value and could impair its ability to raise capital, expand its business, maintain the research and development efforts, diversify its product offerings, or continue operations. A decline in the value of Bioxytran could also cause an investor to lose all or part of his/her investment.

Bioxytran has incurred losses since inception and expects to incur losses for the foreseeable future and may never achieve or maintain profitability.

As at December 31, 2021, the Company has incurred losses since inception and has an accumulated deficit of $8,753,668. The report of the Company's independent registered public accountants as of and for years ending December 31, 2021 and 2020, contained an explanatory paragraph regarding substantial doubt about Bioxytran's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent upon its ability to generate revenue and raise capital from financing transactions. Management anticipates that the Company's cash resources are not sufficient to continue operations until additional cash investments are secured. The future of the Company is dependent upon its ability to obtain financing and upon future profitable operations from the development of its new business opportunities. There can be no assurance that Bioxytran will be successful in accomplishing its objectives. Without such additional capital, the Company may be required to curtail or cease operations.

Bioxytran has a limited operating history, which makes it difficult to evaluate its current business and future prospects.

The Company has limited operating history, and its operations are subject to all of the risks inherent in establishing a new business enterprise. The likelihood of success must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with the formation of a new business, the development of new technologies or those subject to clinical testing, and the competitive and regulatory environment in which Bioxytran will operate. The Company may never obtain FDA or EMA approval of its products in development and, even if they do and are also able to commercialize its products, Bioxytran may never generate revenue sufficient to become profitable. Its failure to generate revenue and profit would likely cause the Company's securities to decrease in value or become worthless.

The Company will require additional financing to implement its business plan, which may not be available on favorable terms or at all, and Bioxytran may have to accept financing terms that would place restrictions on it.

Bioxytran believes that the Company must raise not less than $3.7 million in the current offering in addition to current cash on hand to be able to continue its business operations for approximately the next 15 month, however, funding at any level lower than $5.3 million over the next year will delay the development of the Company's technology and business. Bioxytran will need to continue to conduct significant research, development, testing, and regulatory compliance activities, together with projected general and administrative expenses, the Company expects will result in operating losses for the foreseeable future. Bioxytran may not be able to obtain equity or debt financing on acceptable terms or at all to implement its growth strategy. As a result, adequate capital may not be available to finance its current development plan, take advantage of business opportunities, or respond to competitive pressures. If the Company is unable to raise additional funds, they may be forced to curtail or even abandon its business plan.

Until such time, if ever, as Bioxytran can generate substantial product income, the Company expects to finance its cash needs through a combination of equity offerings, debt financings, and license and collaboration agreements. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. In addition, the terms of any future financings may impose restrictions on the Company's right to declare dividends or on the manner in which Bioxytran conducts its business. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting Bioxytran's ability to take specific actions, such as

incurring additional debt, making capital expenditures, declaring dividends, or making acquisitions or significant asset sales.

If Bioxytran raises additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, the Company may have to relinquish valuable rights to its technologies, future revenue streams, research programs, or drug candidates or grant licenses on terms that may not be favorable to the Company and/or that may reduce the value of its common stock.

Bioxytran's products are based on novel, unproven technologies.

The Company's drug candidates in development are based on novel, unproven technologies using proprietary co-polymer compounds in combination with similar FDA approved drug for veterinary use. Co-polymers are difficult to synthesize, and Bioxytran may not be able to synthesize co-polymer that will be usable as delivery vehicles for the anti-hypoxia drugs it is working with or other therapeutics it intends to develop. Clinical trials are expensive, time-consuming, and may not be successful. They involve the testing of potential therapeutic agents, or effective treatments, in humans, typically in three phases, to determine the safety and efficacy of the products necessary for an approved drug. Many products in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if Bioxytran's products progress successfully through initial or subsequent human testing, they may fail in later stages of development. The Company may engage others to conduct its clinical trials, including clinical research organizations and, possibly, government-sponsored agencies. These trials may not start or be completed as the Company forecasts or may not achieve desired results.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. Bioxytran may incur additional costs or experience delays in completing, or ultimately be unable to complete the development and commercialization of its drug candidates.

Bioxytran's drug candidates are unproven and its risk of failure is high. It is impossible to predict when or if its current or any future drug candidates will receive regulatory approval or prove effective and safe in humans. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, the Company must conduct extensive clinical trials and, in the case of BXT-25, first complete preclinical development, to demonstrate the safety and efficacy of its drug candidates in humans.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failed clinical trial can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

Bioxytran may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent its ability to receive marketing approval or commercialize the Company's drug candidates, including:

- regulators or institutional review boards may not authorize Bioxytran or its investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- the Company may experience delays in reaching, or fail to reach, an agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- clinical trials of Bioxytran's drug candidates may produce negative or inconclusive results, and the Company may decide, or regulators may require it to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of Bioxytran's drug candidates may be larger than the Company anticipates, enrollment in these clinical trials may be slower than anticipated, or participants may drop out of these clinical trials at a higher rate than anticipated;

- Bioxytran's third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to it in a timely manner, or at all;

- The Company may have to suspend or terminate clinical trials of its drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;

- regulators or institutional review boards may require that Bioxytran or its investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of Bioxytran's drug candidates may be greater than anticipated;

- the supply or quality of the Company's drug candidates or other materials necessary to conduct clinical trials of its drug candidates may be insufficient or inadequate;

- Bioxytran's drug candidates may have undesirable side effects or other unexpected characteristics, causing the Company or its investigators, regulators, or institutional review boards to suspend or terminate the trials; and

- regulators may revise the requirements for approving the Company's drug candidates, or such requirements may not be as anticipated.

If Bioxytran is required to conduct additional clinical trials or other testing of its drug candidates beyond those that it currently contemplates, if it is unable to successfully complete clinical trials of its drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, the Company may:

- be delayed in obtaining marketing approval for its drug candidates;

- not obtain marketing approval at all, which would seriously impair its viability;

- obtain marketing approval in some countries and not in others;

- obtain approval for indications or patient populations that are not as broad as intended or desired;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;

- be subject to additional post-marketing testing requirements; or

- have the product removed from the market after obtaining marketing approval.

Bioxytran plans to initiate pre-clinical studies of BXT-25 and clinical studies of ProLectin. The Company applied for an IND for ProLectin-M in March 2022, and is currently awaiting FDA's response. However, it cannot provide any assurance that the Company will successfully initiate or complete those planned trials and be able to initiate any other clinical trials for BXT-25, ProLectin, or any future drug candidates that may be developed. The results of any clinical trials could yield negative or ambiguous results. Such results could adversely affect future development plans, collaborations, and Bioxytran's stock price.

Bioxytran's product development costs will increase if the Company experiences delays in clinical testing or marketing approvals. The Company does not know whether any of its intended preclinical studies or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which Bioxytran may have the exclusive

right to commercialize its drug candidates or allow its competitors to bring products to market before the Company does, potentially impairing its ability to successfully commercialize its drug candidates and harming its business and results of operations.

A fast track, breakthrough therapy, or other designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

Bioxytran may seek fast-track, breakthrough therapy, or similar designation for its drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, and even if the Company believes a particular drug candidate is eligible for this designation, Bioxytran cannot assure investors that the FDA would decide to grant it. Even if the Company does receive fast track designation, it may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from its clinical development program.

Additionally, Bioxytran may in the future seek a breakthrough therapy designation for some of its product candidates that reach the regulatory review process. A breakthrough therapy is a drug candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and that, as indicated by preliminary clinical evidence, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies by the FDA are eligible for accelerated approval and increased interaction and communication with the FDA designed to expedite the development and review process.

As with fast-track designation, designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if the Company believes one of its product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and may determine not to grant such a designation. Even if Bioxytran receives a breakthrough therapy designation for any of its product candidates, the designation may not result in a materially faster development process, review, or approval compared to conventional FDA procedures. Further, obtaining a breakthrough therapy designation does not assure or increase the likelihood of the FDA's approval of the applicable product candidate. In addition, even if one or more of the Company's product candidates qualifies as a breakthrough therapy, the FDA could later determine that those products no longer meet the conditions for the designation or determine not to shorten the time period for FDA review or approval.

Bioxytran will rely on third parties to conduct its clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

The Company intends to use third-party clinical research organizations, or CROs, to conduct its planned clinical trials and does not plan to independently conduct clinical trials of BXT-25 or any future drug candidates. Bioxytran relies on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage its clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If the Company needs to enter into alternative arrangements, this will delay its product development activities.

The Company's reliance on these third parties for research and development activities reduces its control over these activities but does not relieve Bioxytran of its responsibilities. For example, the Company remains responsible for ensuring that each of its clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires the Company to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials with which the Company must comply.

Bioxytran is also required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or conduct its clinical trials in accordance with regulatory requirements or the Company's stated protocols, Bioxytran will not be able to obtain, or may be delayed in obtaining, marketing approvals for its drug candidates and will not be able to, or may be delayed in its efforts to successfully commercialize its drug candidates.

Bioxytran also expects to rely on other third parties to store and distribute drug supplies for its clinical trials. Any performance failure on the part of its distributors could delay clinical development or marketing approval of the Company's drug candidates or commercialization of its products, producing additional losses, and depriving Bioxytran of potential product revenue.

If Bioxytran experiences delays or difficulties in the enrollment of patients in clinical trials, the Company's receipt of necessary regulatory approvals could be delayed or prevented.

The Company may not be able to initiate or continue clinical trials for its drug candidates if it is unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the U.S., such as the EMA. In addition, some of Bioxytran's competitors have ongoing clinical trials for drug candidates that treat the same indications as its drug candidates, and patients who would otherwise be eligible for its clinical trials may instead enroll in clinical trials of competitors' drug candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the drug candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- Bioxytran's payments for conducting clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Bioxytran is unable to forecast with precision its ability to enroll patients. The Company's inability to enroll a sufficient number of patients for its clinical trials would result in significant delays and could require it to abandon one or more clinical trials altogether. Enrollment delays in Bioxytran's clinical trials may result in increased development costs for its drug candidates, which would cause the value of the Company to decline and limit its ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of the Company's drug candidate or Bioxytran observes limited efficacy, the Company may need to abandon or limit its development of some of its drug candidates.

If Bioxytran's drug candidate is associated with undesirable side effects in clinical trials, has limited efficacy or has characteristics that are unexpected, the Company may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. The Company has not commenced pre-clinical trials of BXT-25, which even if it proves successful, may later be found to cause side effects that will prevent further development of the compounds.

Even if Bioxytran's drug candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payers, and others in the medical community necessary for commercial success.

Even if the Company's drug candidate receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payers, and others in the medical community. If Bioxytran's drug candidate does not achieve an adequate level of acceptance, the Company may not generate significant product revenues and may not become profitable. The degree of market acceptance of its drug candidate, if approved for commercial sale, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- Bioxytran's ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for the Company's drug candidate;
- the prevalence and severity of their side effects;
- any restrictions on the use of Bioxytran's products together with other medications;
- interactions of the Company's products with other medicines patients are taking; and
- inability of certain types of patients to take Bioxytran's products.

If the Company is unable to address and overcome these and similar concerns, its business and results of operations could be substantially harmed.

If Bioxytran is unable to establish effective sales, marketing, and distribution capabilities or enter into agreements with third parties with such capabilities, the Company may not be successful in commercializing its drug candidate if and when they are approved.

Bioxytran does not have a sales or marketing infrastructure and has limited experience in the sale, marketing, or distribution of its products. To achieve commercial success for any product for which the Company obtains marketing approval, Bioxytran will need to successfully establish and maintain relationships with third parties to perform sales and marketing functions.

Factors that may inhibit the Company's efforts to commercialize its products on its own include:

- Bioxytran's inability to recruit, train, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of the Company's products;
- the lack of complementary products to be offered by sales personnel, which may put Bioxytran at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization;
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

Bioxytran will rely on third parties to sell, market, and distribute its drug candidate. The Company may not be successful in entering into, or maintaining arrangements with such third parties or may be unable to do so on terms that are favorable to the Company. In addition, Bioxytran's product revenues and profitability, if any, may be lower if the Company relies on third parties for these functions than if they were to market, sell, and distribute any products that it develops itself. The Company will likely have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market its products effectively. If the Company does not establish sales, marketing, and distribution capabilities successfully, either on its own or in collaboration with third parties, they will not be successful in commercializing their drug candidate.

If Bioxytran is unable to convince physicians as to the benefits of its proposed products, the Company may incur delays or additional expense in its attempt to establish market acceptance.

Broad use of Bioxytran's proposed products may require physicians to be informed regarding its proposed products and the intended benefits. Inability to carry out this physician education process may adversely affect market acceptance of the Company's proposed products. Bioxytran may be unable to timely educate physicians regarding its proposed products in sufficient numbers to achieve its marketing plans or to achieve product acceptance. Any delay in physician education may materially delay or reduce demand for Bioxytran's products. In addition, the Company may expend significant funds toward physician education before any acceptance or demand for its proposed products is created, if at all.

Bioxytran faces substantial competition, which may result in others discovering, developing, or commercializing competing products before or more successfully than the Company does.

The development and commercialization of new drug products is highly competitive. Bioxytran faces competition and will face competition with respect to any drug candidates that the Company may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products in the field of oxygen therapeutics for the treatment of a variety of conditions and any of such products may target the stroke. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

A substantial number of the companies against which Bioxytran is competing or against which the Company may compete in the future have significantly greater financial resources, established presence in the market, and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than the Company. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of competitors.

Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with Bioxytran in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, the Company's programs.

The Company's commercial opportunity could be reduced or eliminated if its competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that Bioxytran may develop. Competitors also may obtain FDA or other regulatory approval for their products more rapidly than Bioxytran may obtain approval, which could result in its competitors establishing a strong market position before the Company is able to enter the market. In addition, Bioxytran's ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

Bioxytran may be unable to compete in its target marketplaces, which could impair its ability to generate revenues, thus causing a material adverse impact on the Company's results of operations.

Bioxytran's success depends upon its ability to retain key executives and to attract, retain, and motivate qualified personnel, and the loss of these persons could adversely affect the Company's operations and results.

The Company is highly dependent on the principal members of its management, scientific and clinical team, including Dr. David Platt, its Chairman, President, and Chief Executive Officer; Mike Sheikh, its Executive Vice President; and Ola Soderquist, its Chief Financial Officer. The Company does not have a "key person" insurance for any of Dr. Platt, Mr. Sheikh, or Mr. Soderquist, and even if such policies were to be obtained, such insurance policies may not adequately compensate the Company for the loss of their services.

The loss of the services of any of the Company's executive officers or of any members of its scientific and medical advisory board, could impede the achievement of the Company's research, development, and commercialization objectives and seriously harm Bioxytran's ability to successfully implement its business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in its industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of, and commercialize products.

Competition to hire from this limited pool is intense, and Bioxytran may be unable to hire, train, retain, or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. The Company also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, Bioxytran relies and expect to continue to rely to a significant degree on consultants and advisors, including scientific and clinical advisors, to assist it in formulating its research, development, and commercialization strategy. The Company's consultants and advisors may be employed by employers other than Bioxytran and may have commitments under consulting or advisory contracts with other entities that may limit their availability. If Bioxytran is unable to continue to attract and retain high quality personnel, its ability to pursue its growth strategy will be limited.

Bioxytran's lack of operating experience may cause it difficulty in managing its growth, which could lead to the Company's inability to implement its business plan.

Bioxytran has limited experience in marketing and selling of pharmaceutical products. Any growth will require the Company to expand its management, operational, and financial systems and controls. If Bioxytran is unable to do so, its business and financial condition would be materially harmed. If rapid growth occurs, it may strain the Company's operational, managerial, and financial resources.

The Company depends on third parties to manufacture and market its products and to design trial protocols, arrange for and monitor the clinical trials, and collect and analyze data.

Bioxytran does not have, and does not intend to develop, facilities for the manufacture of any of its products for clinical or commercial production. In addition, the Company is not a party to any long-term agreement with any of its suppliers, and accordingly, has its products manufactured on a purchase-order basis from one of two primary suppliers. The Company will need to develop relationships with manufacturers and enter into collaborative arrangements with licensees or have others manufacture its products on a contract basis. Bioxytran expects to depend on such collaborators to supply it with products manufactured in compliance with standards imposed by the FDA and foreign regulators.

Moreover, as Bioxytran develops products eligible for clinical trials, the Company contracts with independent parties to design the trial protocols, arrange for and monitor the clinical trials, collect data, and analyze data. In addition, certain clinical trials for its products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. Bioxytran's dependence on independent parties and clinical sites involves risks, including reduced control over the timing and other aspects of its clinical trials.

Bioxytran is exposed to product liability, pre-clinical, and clinical liability risks, which could place a substantial financial burden upon the Company should it be sued.

The Company's business exposes it to potential product liability and other liability risks that are inherent in the testing, manufacturing, and marketing of pharmaceutical formulations and products. Such claims may be asserted against it. In addition, the use in Bioxytran's clinical trials of pharmaceutical formulations and products that its potential collaborators may develop and the subsequent sale of these formulations or products by Bioxytran or its potential collaborators may cause the Company to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against it could have a material adverse effect on its business, financial condition, and results of operations.

Since Bioxytran does not currently have any FDA-approved products or other formulations, it does not have any other product liability insurance covering commercialized products. The Company may not be able to obtain or maintain adequate product liability insurance, when needed, on acceptable terms, if at all, or such insurance may not provide adequate coverage against the Company's potential liabilities. Furthermore, Bioxytran's potential partners with whom the Company intends to have collaborative agreements, or our future licensees, may not be willing to indemnify the Company against these types of liabilities and may not themselves be sufficiently insured or have sufficient liquidity to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by Bioxytran could have a material adverse effect on its business, financial condition, and results of operations.

In addition, the Company may be unable to obtain or to maintain clinical trial liability insurance on acceptable terms, if at all. Any inability to obtain and/or maintain insurance coverage on acceptable terms could prevent or limit the commercialization of any products that are developed.

If users of the Company's proposed products are unable to obtain adequate reimbursement from third-party payers or if new restrictive legislation is adopted, market acceptance of Bioxytran's proposed products may be limited, and the Company may not achieve revenues.

The continuing efforts of government and insurance companies, health maintenance organizations, and other payers of healthcare costs to contain or reduce costs of healthcare may affect Bioxytran's future revenues and profitability, and the future revenues and profitability of its potential customers, suppliers, and collaborative partners, as well as the availability of capital. For example, in certain international markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of healthcare, the U.S. Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals, and on the reform of the Medicare and Medicaid systems. While the Company cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm Bioxytran's business, financial condition, and results of operations. The Company's ability to commercialize its proposed products will depend, in part, on the extent to which appropriate reimbursement levels for the cost of its proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers, and other organizations, such as HMOs. Third-party payers are increasingly challenging the prices charged for medical drugs and services. Additionally, the trend toward managed healthcare in the U.S. and the concurrent growth of organizations, such as HMOs, which could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may all result in lower prices for or rejection of Bioxytran's products.

There are risks associated with the Company's reliance on third parties for marketing, sales, and distribution infrastructure and channels.

Bioxytran intends to enter into agreements with commercial partners to engage in sales, marketing, and distribution efforts around its products in development. The Company may be unable to establish or maintain these third-party relationships, or establish new relationships, on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with its competitors. If Bioxytran does not enter into or maintain relationships with third parties for the sales and marketing of its proposed products, it will need to develop its own sales and marketing capabilities. Furthermore, even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to the Company;
- fail to adequately market the Company's products;
- cease operations with little or no notice to the Company; or
- offer, design, manufacture, or promote competing formulations or products.

If Bioxytran fails to develop sales, marketing, and distribution channels, the Company could experience delays in generating sales and incur increased costs, which would harm its financial results.

Bioxytran will be subject to risks if the Company seeks to develop its own sales force.

If the Company chooses at some point to develop its own sales and marketing capability, its experience in developing a fully integrated commercial organization is limited. If Bioxytran chooses to establish a fully integrated commercial organization, it will likely incur substantial expenses in developing, training, and managing such an organization. The Company may be unable to build a fully integrated commercial organization on a cost-effective basis, or at all. Any such direct marketing and sales efforts may prove to be unsuccessful. In addition, Bioxytran will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Its marketing and sales efforts may be unable to compete against these other companies. Bioxytran may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

RISKS RELATED TO ITS INDUSTRY

The Company will need regulatory approvals to commercialize its products as drugs.

In offering BXT-25, ProLectin, or any other product as a drug, Bioxytran is required to obtain approval from the FDA to sell its products in the U.S. and from foreign regulatory authorities to sell its products in other countries. The FDA's review and approval process is lengthy, expensive, and uncertain. Extensive pre-clinical and clinical data and supporting information must be submitted to the FDA for each indication for each product candidate to secure FDA approval.

Before receiving FDA clearance to market the Company's proposed products, Bioxytran will have to demonstrate that its products are safe and effective on the patient population and for the diseases that are to be treated. Clinical trials, manufacturing, and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution, and promotion of drugs and medical devices. As a result, regulatory approvals can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial, and other resources. The FDA could reject an application or require the Company to conduct additional clinical or other studies as part of the regulatory review process. Delays in obtaining or failure to obtain FDA approvals would prevent or delay the commercialization of Bioxytran's product candidates, which would prevent, defer, or decrease receipt of revenues. In addition, if the Company receives initial regulatory approval, its product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation.

Data obtained from clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory clearances.

Data obtained from Bioxytran's planned pre-clinical studies and clinical trials will not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical and clinical data is susceptible to varying interpretations, which could delay, limit, or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the potential drug, resulting in delays to commercialization, and could materially harm the Company's business. Bioxytran's clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for its drugs, and thus the Company's proposed drugs may not be approved for marketing.

Bioxytran's competitive position depends on protection of its intellectual property.

Development and protection of the Company's intellectual property is critical to its business. All of Bioxytran's intellectual property has been invented and/or developed or co-developed by Dr. David Platt; and other intellectual property that is important to the development of BXT-25 is in the public domain. If the Company does not adequately protect its intellectual property, or if competitors develop technologies incorporating the same or similar technologies that already are in the public domain, those competitors may be able to practice Bioxytran's technologies. The Company's success depends, in part, on its ability to obtain patent protection for its products or processes in the U.S. and other countries, protect trade secrets, and prevent others from infringing on its proprietary rights.

Since patent applications in the U.S. are maintained in secrecy for at least portions of their pendency periods (published on U.S. patent issuance or, if earlier, 18 months from earliest filing date for most applications) and since other publication of discoveries in the scientific or patent literature often lags behind actual discoveries, Bioxytran cannot be certain that it is or will be the first to make the inventions to be covered by its patent applications. The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents.

The patent applications the Company files, including applications that will follow the filing of Provisionals, may not issue as patents or the claims of any issued patents may not afford meaningful protection for its technologies or products. In addition, patents issued to Bioxytran or to any future licensors may be challenged and subsequently narrowed, invalidated, or circumvented. Patent litigation is widespread in the biotechnology industry and could harm the Company's business. Litigation may be necessary to protect Bioxytran's patent position or to determine the scope and validity of third-party proprietary rights, and the Company may not have the required resources to pursue such litigation or to protect its patent rights.

Although Bioxytran will require its scientific and technical employees and consultants to enter into broad assignment of inventions agreements, and all of its employees, consultants, and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored. Currently, Bioxytran does not have any scientific or technical employees.

Products the Company develops could be subject to infringement claims asserted by others.

Bioxytran cannot assure that products based on its patents or intellectual property that it licenses from others will not be challenged by a third-party claiming infringement of its proprietary rights. If the Company were not able to successfully defend patents that may be issued to it, that the Company may acquire, or that it may license in the future, Bioxytran may have to pay substantial damages, possibly including treble damages, for past infringement.

The Company faces intense competition in the biotechnology and pharmaceutical industries.

The biotechnology and pharmaceutical industries are intensely competitive. The Company faces direct competition from U.S. and foreign companies focusing on pharmaceutical products, which are rapidly evolving. Its competitors include major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations, than Bioxytran. In addition, academic and government institutions are increasingly likely to enter into exclusive licensing agreements with commercial enterprises, including its competitors, to market commercial products based on technology developed at such institutions. The Company's competitors may succeed in developing or licensing technologies and products that are more effective or less costly than that of Bioxytran or succeed in obtaining FDA or other regulatory approvals for product candidates before the Company does. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing, and other resources.

The market for the Company's proposed products is rapidly changing and competitive, and new drugs and new treatments, which may be developed by others, could impair Bioxytran's ability to maintain and grow its business and remain competitive.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render the Company's proposed products noncompetitive or obsolete, or Bioxytran may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities, and others diversifying into the field is intense and is expected to increase.

As a pre-revenue company engaged in the development of drug technologies, Bioxytran's resources are limited, and the Company may experience technical challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to the Company's proposed products. Bioxytran's competitors may develop drugs that are safer, more effective or less costly than its proposed products and, therefore, present a serious competitive threat.

The potential widespread acceptance of therapies that are alternatives to Bioxytran's may limit market acceptance of its proposed products, even if commercialized. Many of the Company's targeted diseases and conditions can also be treated by other medication. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for the Company's technologies, formulations, and products to receive widespread acceptance if commercialized.

Healthcare cost containment initiatives and the growth of managed care may limit the Company's returns.

Bioxytran's ability to commercialize its products successfully may be affected by the ongoing efforts of governmental and third-party payers to contain the cost of healthcare. These entities are challenging prices of healthcare products and services, denying or limiting coverage and reimbursement amounts for new therapeutic products, and for FDA-approved products considered experimental or investigational, or which are used for disease indications without FDA marketing approval.

Even if the Company succeeds in bringing any products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, Bioxytran may not be able to maintain price levels sufficient to realize an appropriate return on its investment in research and product development. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to the Company before or after any of its proposed products are approved for marketing.

RISKS RELATED TO THE COMPANY'S INTELLECTUAL PROPERTY

If Bioxytran is unable to obtain and maintain patent protection for its products, or if the scope of the patent protection obtained is not sufficiently broad, competitors could develop and commercialize products similar or identical to the Company's, and its ability to successfully commercialize its products may be impaired.

The Company's plan for the development of BXT-25 is based, in part, on a technology developed by the Biopure Corporation, which separates hemoglobin from RBCs. Biopure filed for bankruptcy in 2009 and the technology Bioxytran uses from Biopure is in the public domain. The Company plans to apply its proprietary chemistry to break down and augment a bovine hemoglobin molecule producing a co-polymer-based molecule the Company calls BXT-25. Bioxytran faces competitors and other entities who are engaged in the further development of some or all of that public-domain technology for the purpose of creating products that may compete directly with its products.

Among such competitors and other entities is Boston Therapeutics, Inc. (OTCQB: BTHE). Bioxytran's chairman, David Platt, was founder, and until April 1, 2015, Chief Executive Officer of Boston Therapeutics; and that entity is a pharmaceutical company focused on developing, manufacturing, and commercializing novel compounds based on complex carbohydrate chemistry to address unmet medical needs in diabetes. According to its website, products Boston Therapeutics seeks to develop include an anti-necrosis glyco-protein based therapeutic agent that consists of a stabilized glycoprotein composition containing oxygen-rechargeable iron, targeting both human and animal tissues and organ systems deprived of oxygen and in need of metabolic support. The Boston Therapeutic development efforts are, like the efforts of the Company, based in part on Biopure technology that is now in the public domain. While Boston Therapeutics is focused on medical conditions that are different from the conditions that will be addressed by the Company, and while the Company's proprietary technology is very different from the technology under development at Boston Therapeutics at the time of Dr. Platt's departure from that entity, a refocus of Boston Therapeutics to treat conditions that are central to the Company's focus may make it a direct competitor.

Currently there are four drug candidates to treat a stroke. Abciximab from Eli Lilly is a platelet aggregation inhibitor. Clinical trials show little advantage over placebos and could lead to dangerous side effects, including more bleeding in patients. Cerovive from AstraZeneca is a Nitrone-based neuro protectant currently in Phase III clinical trials, which shows no significant benefit over placebos with respect to changes in neurological impairment as measured by the national institute of health stroke scale. Candesartan from AstraZeneca is an angiotensin receptor blocker, which was used to control blood pressure. Its efficacy in stroke patients still must be proven.

Ancod from Knoll Pharmaceuticals is an anti-coagulant that acts by breaking down the fibrinogen. It increases the risk of hemorrhage similar to those associated with tPA.

Bioxytran's success depends in large part on its ability to obtain and maintain patent and other intellectual property protection in the U.S. and other countries with respect to its proprietary products. The Company seeks to protect its proprietary position by filing patent applications in the U.S. and abroad related to its drug candidates.

The patent prosecution process is costly and time-consuming, and Bioxytran may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. It is also possible that the Company will fail to identify patentable aspects of its research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. In addition, the laws of foreign countries may not protect the Company's rights to the same extent as the laws of the U.S. and Bioxytran may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all.

Therefore, the Company cannot know with certainty whether they were the first to make the inventions claimed in its owned patents or pending patent applications, or that it was the first to file for patent protection of such inventions, nor can they know whether those from whom the license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability, and commercial value of Bioxytran's patent rights are highly uncertain. Its pending and future patent applications may not result in patents being issued which protects its technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of the Company's patents or narrow the scope of its patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of the Company's patent applications and the enforcement or defense of its issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office, or U.S. PTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of Bioxytran's business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of its patent applications and the enforcement or defense of its issued patents, all of which could have a material adverse effect on the Company's business and financial condition.

Even if the Company's patent applications issue as patents, they may not issue in a form that will provide Bioxytran with any meaningful protection, prevent competitors from competing with it, or otherwise provide the Company with any competitive advantage. Bioxytran's competitors may be able to circumvent its owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and Bioxytran's patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit the Company's ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of its products.

Given the amount of time required for the development, testing, and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, Bioxytran's patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to the Company's.

Bioxytran may become involved in lawsuits to protect or enforce its patents or other intellectual property, which could be expensive, time-consuming, and ultimately unsuccessful.

Competitors may infringe the Company's issued patents or other intellectual property. To counter infringement or unauthorized use, Bioxytran may be required to file infringement claims, which can be expensive and time-consuming. Any claims the Company asserts against perceived infringers could provoke these parties to assert counterclaims against it, alleging that Bioxytran infringes their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of Bioxytran's is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that its patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of the Company's patents at risk of being invalidated or interpreted narrowly, which could adversely affect Bioxytran.

Third parties may initiate legal proceedings alleging that Bioxytran is infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of the Company's business.

Bioxytran's commercial success depends upon its ability to develop, manufacture, market, and sell its drug candidates without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against Bioxytran and the Company has not been held by any court to have infringed a third party's intellectual property rights, it cannot guarantee that its products or use of its products do not infringe third-party patents.

It is also possible that Bioxytran has failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the U.S. remain confidential until patents issue. Patent applications in the U.S. and elsewhere are published approximately 18 months after the earliest filing, which is referred to as the priority date. Therefore, patent applications covering the Company's products or technology could have been filed by others without Bioxytran's knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover its technologies, products, or the use of its products.

Bioxytran may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to its products and technology, including inter parties review, interference, or derivation proceedings before the U.S. PTO and similar bodies in other countries. Third parties may assert infringement claims against it based on existing intellectual property rights and intellectual property rights that may be granted in the future.

If Bioxytran is found to infringe a third party's intellectual property rights, the Company could be required to obtain a license from such third party to continue developing and marketing its products. However, the Company may not be able to obtain any required license on commercially reasonable terms or at all. Even if the Company were able to obtain a license, it could be non-exclusive, thereby giving competitors access to the same technologies licensed to Bioxytran. The Company could be forced, including by court order, to cease commercializing the infringing technology or product.

In addition, Bioxytran could be found liable for monetary damages, including treble damages and attorneys' fees, if the Company is found to have willfully infringed a patent. A finding of infringement could prevent the Company from commercializing its drug candidates or force it to cease some of its business operations, which could materially harm the Company's business. Claims that Bioxytran has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business.

RISKS RELATING TO OWNERSHIP OF COMMON STOCK

The Company has a limited public market for its shares of common stock and investors may not be able to resell shares at or above the price paid, or at all.

There is a limited public market for the Company's common stock. Bioxytran intends to apply for quotation on the OTCQB through a market maker; however, there can be no assurance that its common stock will ever be quoted on any quotation service. In order to be eligible for trading on the OTCQB, the Company must file a market maker application with FINRA to have its common stock quoted on the OTCQB and remain current in its filings with the Securities and Exchange Commission. In order to be eligible for the OTCQB, Bioxytran must have a minimum bid price of $0.01, have at least 50 beneficial stockholders, each owning at least 100 shares, have a freely traded public float of at least 10% of issued and outstanding shares of Common Stock, or qualify from an exemption thereof and pay initial listing fees. On March 30,2022, the Company received the FINRA Clearance Letter and is currently awaiting the removal of the Caveat Emptor issued by OTC Market Group. The Company cannot assure investors that an active public market for its common stock will develop or that the market price of its shares will not decline below the public offering price. The public offering price of its shares may not be indicative of prices that will prevail in the trading market following the offering.

Because Bioxytran is subject to the "Penny Stock" rules, the level of trading activity in its stock may be reduced.

Penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. In addition, the penny stock rules generally require that prior to a transaction in a penny stock, the broker-dealer make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written agreement to the transaction. These disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for a stock that becomes subject to the penny stock rules, which may increase the difficulty Purchasers may experience in attempting to liquidate such securities.

The Company does not expect to pay dividends in the foreseeable future. Any return on investment may be limited to the value of its common stock.

Bioxytran does not anticipate paying cash dividends on its common stock in the foreseeable future. The payment of dividends on its common stock will depend on earnings, financial condition, and other business and economic factors affecting it at such time as the board of directors may consider relevant. If the Company does not pay dividends, its common stock may be less valuable because a return on an investment will occur only if the Company's stock price appreciates.

Provisions in the Nevada Revised Statutes and Company Bylaws could make it very difficult for an investor to bring any legal actions against Bioxytran's directors or officers for violations of their fiduciary duties or could require the Company to pay any amounts incurred by its directors or officers in any such actions.

Members of the Company's board of directors and its officers will have no liability for breaches of their fiduciary duty of care as a director or officer, except in limited circumstances, pursuant to provisions in the Nevada Revised Statutes and Bylaws as authorized by the Nevada Revised Statutes. Specifically, Section 78.138 of the Nevada Revised Statutes provides that a director or officer is not individually liable to the company or its shareholders or creditors for any damages as a result of any act or failure to act in his or her capacity as a director or officer unless it is proven that (1) the director's or officer's act or failure to act constituted a breach of his or her fiduciary duties as a director or officer and (2) his or her breach of those duties involved intentional misconduct, fraud, or a knowing violation of law.

Future sales of substantial amounts of the shares of common stock by existing shareholders could adversely affect the price of the Company's common stock.

If Bioxytran's existing shareholders sell substantial amounts of the shares, the market price of its common stock could fall. Such sales by existing shareholders might make it more difficult for the Company to issue new equity or equity-related securities in the future at a time and place deemed appropriate. If any existing shareholders sell a substantial number of shares, the prevailing market price for the Company's shares could be adversely affected.

Financial and operational projections that the Company may make from time to time are subject to inherent risks.

The projections that the Company provides from time to time (including, but not limited to, those relating to potential peak sales amounts, clinical and regulatory timelines, production and supply matters, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to specific as well as general business, regulatory, economic, market, and financial conditions and other matters, all of which are difficult to predict and many of which are beyond its control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There may be differences between actual and projected results, and actual results may be materially different from than those contained in the projections.

The Company's Certificate of Incorporation permits "blank check" preferred stock, which can be designated by Bioxytran's Board of Directors without stockholder approval.

Bioxytran has 50,000,000 authorized shares of preferred stock. The shares of its preferred stock may be issued from time to time in one or more series, each of which shall have a distinctive designation or title as is determined by the Company's Board of Directors prior to the issuance of any shares thereof. The preferred stock may have such voting powers, full or limited, or no voting powers, and such preferences and relative, participating, optional or other special rights and such qualifications, limitations or restrictions thereof as adopted by the Board of Directors. Because the Board of Directors is able to designate the powers and preferences of the preferred stock without the vote of a majority of its stockholders, stockholders will have no control over what designations and preferences its preferred stock will have. If preferred stock is designated and issued, then depending upon the designation and preferences, the holders of the preferred stock may exercise voting control over the Company. As a result, its stockholders will have no control over the designations and preferences of the preferred stock and as a result the operations of the Company.

Company management collectively owns a substantial majority of its common stock.

Collectively, Bioxytran's officers, directors, and one other stockholder own or exercise voting and investment control of approximately 77.4% of our outstanding common stock. As a result, investors may be prevented from affecting matters involving the Company, including:

- the composition of Bioxytran's Board of Directors and, through it, any determination with respect to its business direction and policies, including the appointment and removal of officers;
- any determinations with respect to mergers or other business combinations;
- acquisition or disposition of assets; and
- corporate financing activities.

Furthermore, this concentration of voting power could have the effect of delaying, deterring, or preventing a change of control or other business combination that might otherwise be beneficial to the Company's stockholders. This significant concentration of share ownership may also adversely affect the trading price for its common stock because investors may perceive disadvantages in owning stock in a company that is controlled by a small number of stockholders.

If the Company fails to establish and maintain an effective system of internal control or disclosure controls and procedures are not effective, it may not be able to report financial results accurately and timely or to prevent fraud. Any inability to report and file the Company's financial results accurately and timely could harm its reputation and adversely impact the trading price of its common stock.

Effective internal controls are necessary for the Company to provide reliable financial reports and effectively prevent fraud. Section 404 of the Sarbanes-Oxley Act of 2002 requires Bioxytran to evaluate and report on its internal controls over financial reporting and, depending on its future growth, may require the Company's independent registered public accounting firm to annually attest to its evaluation, as well as issue their own opinion on the Company's internal controls over financial reporting. The process of implementing and maintaining proper internal controls and complying with Section 404 is expensive and time consuming. Bioxytran cannot be certain that the measures it will undertake will ensure that the Company will maintain adequate controls over its financial processes and reporting in the future. Furthermore, if Bioxytran is able to rapidly grow its business, the internal controls that it will need may become more complex and significantly more resources will be required to ensure its internal controls remain effective.

Failure to implement required controls or difficulties encountered in their implementation, could harm the Company's operating results or cause it to fail to meet its reporting obligations. If Bioxytran's auditors or the Company discovers a material weakness in its internal controls, the disclosure of that fact, even if the weakness is quickly remedied, could diminish investors' confidence in its financial statements and harm its stock price. In addition, non-compliance with Section 404 could subject the Company to a variety of administrative sanctions, including the suspension of trading, ineligibility for future listing on one of the Nasdaq Stock Markets or national securities exchanges, and the inability of registered broker-dealers to make a market in the Company's common stock, which may reduce Bioxytran's stock price.

Glossary

Acute Respiratory Distress Symptom (ARDS)—A life-threatening lung injury that allows fluid to leak into the lungs. Breathing becomes difficult and oxygen cannot get into the body. Most people who contract ARDS are already at the hospital for trauma or illness.

ß-galactoside—A type of glycoside (a molecule in which a sugar is bound to another functional group) containing galactose. ß-galactoside is recognized as the binding sites of galectin proteins.

Blood-Brain Barrier (BBB)—A network of blood vessels and tissue that is made up of closely spaced cells and helps keep harmful substances from reaching the brain. The blood-brain barrier lets some substances, such as water, oxygen, carbon dioxide, and general anesthetics, pass into the brain.

Carbohydrate Recognition Domain (CRD)—A carbohydrate-binding structure present in a large group of proteins that are part of the lectin protein family. CRD mediate the interactions between lectins and carbohydrate.

Chimeric—Proteins created through the joining of two or more genes which are originally coded for separate or same proteins.

Co-Polymer—A polymer is a substance that has a molecular structure consisting of a large number of similar units (monomers) bonded together. A co-polymer is a polymer derived from more than one species of monomer.

Complex Carbohydrate Chemistry (CCC)—Complex carbohydrates, also known as polysaccharides, are long chains of simple sugar units bonded together in long, complex chains. Chemically, they usually are comprised of three or more linked sugar molecules.

COVID-19—Coronavirus disease 2019, also known as COVID-19, is an a highly contagious respiratory disease caused by the SARS-CoV-2 virus. In March 2020, the World Health Organization (WHO) declared the COVID-19 outbreak a pandemic.

Cycle Threshold (Ct)—A measurement to quantify relative levels of a specific pathogen. The cycle threshold is defined as the thermal cycle number at which the fluorescent signal exceeds that of the background and, therefore, passes the threshold for positivity. Ct value is inversely related to the quantity of target nucleic acid in the sample, with lower Ct values reflecting higher viral loads.

Cytokines—Small proteins secreted by certain cells of the immune system that are crucial in controlling the growth and activity of other immune system cells and blood cells. Some cytokines stimulate the immune system and others slow it down.

Cytokine Release Syndrome (CRS)—Sometimes called cytokine storm, CRS is a severe immune reaction in which the body overproduces too many pro-inflammatory cytokines into the blood, leading to a surge of more immune cells to the site of infection. This translates into an inflammatory cycle that is not easily brought back to homeostasis.

Fibrosis—The thickening and scarring of connective tissue, usually as a result of injury or disease.

Galectins—Galectins are carbohydrate-binding proteins, part of the lectin protein family, that bind specifically to β-galactoside sugars. Galectins are involved in many physiological functions, such as inflammation, immune responses, cell migration, and signaling. They are also linked to diseases, such as fibrosis, cancer, heart disease, and viral infections.

Galectin-3—A member of the lectin family that plays an important role in cell-cell adhesion, cell-matrix interactions, cell growth, apoptosis, and inflammation. Galectin-3 is involved in the development of many diseases, including cancer, as well as brain, kidney, lung, and liver disease. Galectin-3 has also been found to mediate key interactions at the virus-host interface, playing a key role in controlling viral spread.

Glycans—Complex carbohydrate (sugar) molecules found on the surface of cells from most organisms. Glycans are essential biomolecules serving structure, energy storage, and system regulatory purposes, including a key role in intercellular communication and transmission of immune response signals.

Glycovirology—A new field of molecular biology research that aims to characterize the interactions between viruses and glycans. Cell-surface glycans play central roles in mediating the cell attachment and entry of many viruses, including a number of human pathogens. The emerging field of "glycovirology" aims to provide direct insight into biophysical mechanisms that regulate glycan-virus binding, and to ultimately provide a platform from which novel glycan-based antiviral strategies can be launched.

Heme—An iron-containing compound which forms the nonprotein part of hemoglobin and some other biological molecules. The heme part of hemoglobin is the substance inside red blood cells (RBCs) that binds to oxygen in the lungs and carries it to the tissues.

Hemoglobin—A protein inside RBCs that carries oxygen from the lungs to tissues and organs in the body and carries carbon dioxide back to the lungs.

Hemoglobin-Based Oxygen Carrier (HBOC)—A type of artificial blood substitute made from molecules of hemoglobin (Hb)—the oxygen-carrying protein in RBCs—that are chemically modified or developed through genetic engineering.

Hypoxic—Related or affected by hypoxia, a deficiency in the amount of oxygen reaching the tissues.

Ischemia—An inadequate blood supply to an organ or part of the body.

Lectins—Carbohydrate-binding proteins that are highly specific to receptors on cell surfaces, including glycans. The interaction and binding between lectins and glycans play a role in numerous biological processes, including cell movement, signaling, and intracellular communications. Lectins also mediate attachment and binding of bacteria, viruses, and fungi to their intended targets.

Necrosis—The death of most or all of the cells in an organ or tissue due to disease, injury, or failure of the blood supply.

Nitric Oxide (NO)—A toxic compound formed by the oxidation of nitrogen. Despite its toxic nature, NO performs important chemical signaling functions in humans, including acting as a vasodilator and controlling blood flow to tissues.

Nitric Oxide Scavenging—A reaction between nitric oxide (NO) and different compounds in the body that could lead to NO depletion, leading to changes in vascular function (e.g., vasoconstriction). For example, the clinical use of artificial hemoglobin-based blood substitutes and oxygen carriers' has been hampered by vasoconstriction caused by NO scavenging.

Nuclear Magnetic Resonance (NMR)—Nuclear magnetic resonance is a physical phenomenon in which nuclei in a strong constant magnetic field are perturbed by a weak oscillating magnetic field and respond by producing an electromagnetic signal with a frequency characteristic of the magnetic field at the nucleus.

Polymerase Chain Reaction (PCR)—*See Real Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR).*

Real Time Reverse Transcriptase Polymerase Chain Reaction (rRT-PCR)—A laboratory technique combining reverse transcription of RNA (using an enzyme called reverse transcriptase to change a specific piece of RNA into a matching piece of DNA) and amplification of the DNA by another enzyme called DNA polymerase. It is primarily used to measure the amount of a specific RNA. rRT-PCR may be used to study the RNA of certain viruses and to help diagnose and monitor an infection.

Red Blood Cells (RBCs)—Also known as erythrocytes, red blood cells (RBCs) are a type of blood cell that is made in the bone marrow and found in the blood. RBCs contain a protein called hemoglobin, which carries oxygen from the lungs to all parts of the body.

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)—A member of a large family of viruses called coronaviruses, SARS-CoV-2 is the virus that causes COVID-19.

Stroke—A condition that occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked by a clot (ischemic stroke) or ruptures (hemorrhagic stroke). Strokes result in poor blood-flow to the brain, which leads to brain cells necrosis (cell death). A stroke can cause lasting brain damage and neurological deficits, long-term disability, or even death.

Time to Needle—The time interval from the onset of stroke symptoms to initiation of treatment in a medical setting.

Thrombectomy—Surgery to remove a thrombus (blood clot) from a blood vessel.

Tissue Plasminogen Activator (tPA or rTPA)—An enzyme made in the body that helps dissolve blood clots. A form of this enzyme is made in the laboratory to treat heart attacks, strokes, and clots in the lungs.

Vero cells—A cell line taken from the kidneys of the African green monkey. Vero cells are widely used for screening purposes for bacterial toxins, viruses, and for parasite studies.

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About Our Firm: For the past decade, Crystal Research Associates, LLC (www.crystalra.com) has successfully articulated the exceptional stories of small- and mid-cap companies to the Wall Street investor community. Our methods are well-established and diverse, from compiling and disseminating objective, factual information for both institutional and retail investor audiences to capitalizing on our expansive line of targeted distribution channels, which include industry-leading financial data and information providers. Our distribution efforts are accompanied by the use of prominent social media channels and by strategic and targeted appearances on national news programs and print media.

Crystal Research Associates is led by Wall Street veterans, Jeffrey Kraws and Karen Goldfarb. Together, Kraws and Goldfarb have built a unique business model, capitalizing on decades of experience as an award-winning sell-side analyst team to produce institutional-quality industry and market research in a manner that is easily understood by investors and consumers. Our firm's approach has been proven successful over the years as our products are published and available on Bloomberg, Thomson Reuters/First Call, Capital IQ, FactSet, Yahoo! Finance, and scores of other popular forums.