

December 21, 2022

## 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

- On November 16<sup>th</sup>, the Company announced positive topline safety and efficacy results of its randomized, placebo-controlled Phase 2 clinical trial in 34 patients with mild-to-moderate COVID-19. During the 7 days of treatment, an orally administered Galectin Antagonist in the form of a chewable tablet was administered 8 times per day on an hourly basis. The trial met its endpoint with a 100% response rate by day 7 versus 6% in placebo, which was statistically significant (p-value=.001) and something that has only ever been accomplished by one other drug in the past decade. The Company’s analysis also revealed an 88% response rate by day 3, which was statistically significant (p-value=.001).
- Bioxytran announced on December 8<sup>th</sup> that it had received an Investigational New Drug (IND) authorization letter from India’s Central Drugs Standard Control Organization (CDSCO) to optimize dosage in COVID-19 patients. The trial’s objective is to provide guidance for a 408 patient Phase III trial.
- The Company announced that it had established an Indian subsidiary (Pharmalectin India Private Limited), with a purpose to launch commercial product sales of ProLectin-M should the company receive Central Drugs Standard Control Organization (CDSCO) approval. The Indian manufacturing plant is an FDA-approved facility that is capable of supporting the Indian market with a population of 1.4 billion people.
- Bioxytran has developed what it believes to be a potential cure for COVID. The Company believes that its drug can be used as a method of prophylaxis (a first line of defense against all mutation of coronaviruses) to prevent an individual from getting infected with the virus.
- The Company’s cash position as of September 30, 2022 was \$374,190.

**BioXyTran® Inc.**  
 Tissue Regeneration For Life

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**BIXT (NASDAQ) One-Year Chart**



Ticker (Exchange)	(BIXT-OTCBB)
Recent Price (12/21/2022)	\$0.40
52-week Range	\$0.0034 to 1.25
Shares Outstanding	116.4 million
Market Capitalization	\$49 million
Avg. 10-day Volume	60,500
EPS (Qtr. ended 09/30/2022)	(\$0.00)
Employees	4

## RECENT DEVELOPMENTS

**December 14, 2022**—Bioxytran, Inc. (BIXT) announced that it has established an Indian subsidiary (Pharmalectin India Private Limited). The purpose of the subsidiary is to launch commercial product sales of ProLectin-M should the company receive Central Drugs Standard Control Organization (CDSCO) approval. The Indian manufacturing plant is an FDA-approved facility that is capable of supporting the Indian market with a population of 1.4 billion people. The Company has not yet identified a distributor.

**December 12, 2022**—The Company announced that Bioxytran CMO, Michael Sheikh, was to present the latest clinical trial results on the Emerging Growth Conference on December 14, 2022.

**December 8, 2022**—Bioxytran announced the receipt of an Investigational New Drug (IND) authorization letter from India's Central Drugs Standard Control Organization (CDSCO) to optimize dosage in COVID-19 patients. The trial's objective is to provide guidance for a 408 patient Phase III trial.

**On November 16, 2022**—The Company announced positive topline safety and efficacy results of its randomized, placebo-controlled Phase 2 clinical trial in 34 patients with mild-to-moderate COVID-19.

During the 7 days of treatment, an orally administered Galectin Antagonist in the form of a chewable tablet was administered 8 times per day on an hourly basis. The endpoint was a statistically significant reduction in viral load measured by the number of patients reaching a below threshold PCR value (Ct value  $\geq$  29) by day 7. The trial met its endpoint with a 100% response rate by day 7 versus 6% in placebo, which was statistically significant (p-value=.001). The Company's analysis also revealed an 88% response rate by day 3, which was statistically significant (p-value=.001). There were no drug-related serious adverse events (SAE's) in the patient population or viral rebounds by day 14 in the patient population. The data from this clinical trial provided the rationale of dosing and protocol design for study in an upcoming phase 2/3 registrational trial.

Nuclear Magnetic Resonance (NMR) testing was used to elucidate the Mechanism of Action of the specific Galectin Antagonist. Tests concluded that ProLectin-M binds relatively strongly to galectin-3 with micromolar affinity down to 2 $\mu$ M. While the Galectin Antagonist does bind to the S1 Spike Protein, the study showed that it could bind in 2 different orientations with galectin-3. The NMR binding data indicate that 5 molecules of galectin-3 are required to saturate one spike protein. These findings on the mechanism of action supported the decisions on dosing, duration, and ingestion.

Bioxytran expects to explore not only COVID-19, but also other viruses and indications. The underlying concept of glycovirology is that viral membranes are glycosylated and the conserved binding regions, called the galectin fold, are unique to each virus. The Company is challenged with identifying the structure on each virus and then the specific complex carbohydrate chemical structures that will bind to the galectin fold to achieve complete binding and inhibition of viral entry. The latest journal articles have demonstrated the utility of using high power resolution of NMR mathematical calculations to rapidly assess the binding affinity in theory. Based on this, Bioxytran believes the Company has a significant platform technology that could be relevant to other serious viral diseases.

## COMPANY BACKGROUND

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. 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.

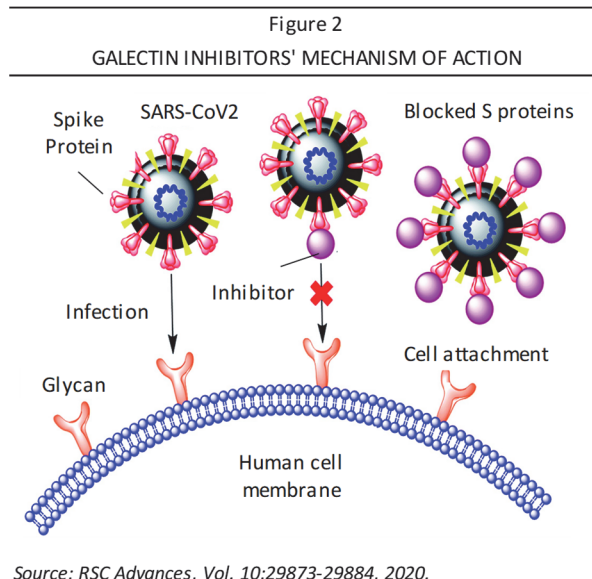
Within the lectin protein family, one type of lectins, specifically galectins, have been found to play multiple roles in regulating virus infections. For a virus to gain access to a cell, proteins on the virus' surface must bind to certain glycans on a cell surface, allowing them to enter the cell, and 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 December 2022, more than 650 million cases have been reported worldwide, resulting in over 6.6 million deaths. The U.S. is still considered one of the epicenters of the disease, with roughly 100 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).

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 has received approval for a Phase 2 trial with The Central Drugs Standard Control Organisation (CDSCO), 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 first quarter 2023.

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 and also a Phase 2 trial in India, finalized in June 2022 an on-line pre-print published at MedRxiv. To Bioxytran's knowledge, this was the first clinical trials 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.

A second Phase 2 trial, also in India, was conducted in June 2021 as a randomized double-blind placebo controlled clinical trial of 34 mild-to-moderate COVID-19 patients, soon to be published, but currently available as a pre-print on MedRxiv. The aim of the study was to measure the incidence of adverse events in the treated and placebo arms. The efficacy end point was an absolute change in RT-PCR Cycle Threshold (Ct) values on days 3 and 7. The results showed a statistically significant change ( $p=.001$ ) in Ct values in the N or ORF gene test on day 3 and day 7, indicating the patient was no longer contagious and completely cleared the virus. The average Ct value of the treated group was PCR negative (over 29) on days 3 and 7 while none of the of the placebo group were negative on day 3 or 7. On the day three, 88% of the treated group was PCR negative versus 0% in the control. On day 7, 100% of the treated group was PCR negative versus 6% in control.

The Company also used NMR spectroscopy to elucidate the Mechanism of Action. The journal article revealed that PL-M binds to Galectin-3 in a very similar fashion that Galectin-3 binds to the SARS-CoV-2 S1 subunit.

#### *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 first quarter 2023.

#### *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 March 2023.



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## **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 desired 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 BXT-25 starts with the isolation of hemoglobin from RBCs of bovine sources, and the extraction of heme from the hemoglobin. 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.* BXT-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.

A laboratory production-line has been developed and an initial batch GLP material of the BXT-25 has been manufactured. Pre-clinical trials are pending.

#### *MDXViewer*

In order to support its BXT-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 BXT-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. Bioxytran's foreign subsidiaries; Pharmalectin BVI 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. Pharmalectin India was organized on September 7, 2022 as a Private Limited company under the laws of India and is to be the sponsor of the Company's clinical trials and commercialize the Company's products in India. The Company currently has 4 employees and is headquartered in Needham, Massachusetts.

## INVESTMENT HIGHLIGHTS

- ***Bioxytran, Inc. 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 as 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.
- ***Bioxytran announced in December the receipt of an Investigational New Drug (IND) authorization letter from India's Central Drugs Standard Control Organization (CDSCO) to optimize dosage in COVID-19 patients.*** The trial's objective is to provide guidance for a 408 patient Phase III trial. The Company is also preparing a Phase 1/2 trial on fibrosis of the lung in India using ProLectin-F.
- ***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 September 30, 2022 was \$374,190.***

## Risks and Disclosures

This Company Update 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 Update 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 10-K, 10-Q, and 8-K as well as other 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, Annual Reports, and U.S. Securities and Exchange Commission (SEC) 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 will have been compensated by the Company in cash of forty-five thousand dollars and two hundred thousand warrants for its services in creating the base report and for quarterly updates.

Investors should carefully consider the risks and information about Bioxytran’s business. Investors should not interpret the order in which considerations are presented in its SEC filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in Bioxytran’s SEC filings 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, and the trading price of the Company’s shares could decline.

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