US
RESEARCH
INDEPENDENT INVESTMENT RESEARCH

Bioxytran, Inc.

(OTCMKTS: BIXT)

Initiation of Coverage

October 31, 2025

INDEPENDENT
INVESTMENT RESEARCH

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INDEPENDENT INVESTMENT RESEARCH

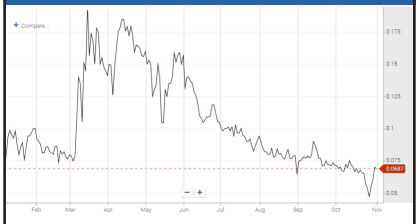
Bioxytran, Inc. (OTCMKTS: BIXT) - Initiating Coverage

Key Investment Information (as at October 31, 2025)	
Ticker	BIXT
Share Price ($)	$0.069
Shares on Issue (m)	88.9m
Options (m)	0.0m
Warrants (m)	1.3m
ATM Program (m)	0.0
Fully Diluted Shares on Issue (m)	102.4*
Market Capitalization	$6.1m
12-month Low/High	$0.039/$0.228

Board & Management	
David Platt, Ph.D.	CEO and Chairman of the Board
Ola Soderquist CPA, CMA, CM&AA	CFO
Michael Sheikh,	Chief Communications Officer
Anders N. Utter	Independent Director
Alan M. Hoberman Ph.D.	Independent Director
Dale H. Conaway DVM	Independent Director
Radka Milanova	Independent Director

Management/Director Ownership	
Total Insider Ownership	>50%

Share Price History



The investment opinion in this report is current as at the date of publication. Investors and advisers should be aware that over time the circumstances of the issuer and/or product may change which may affect our investment opinion.

ELIMINATING VIRAL THREATS FROM PANDEMIC LEVEL TO COMMON COLD

Bioxytran, Inc. (OTCQB: BIXT) is a clinical stage biotechnology company developing broad spectrum antivirals using non-toxic carbohydrate-based drugs. They are pioneers in glycovirology and stand alone in developing galectin inhibitor-based antivirals that target the conserved regions of the spike protein called the “galectin fold” and neutralize the virus. There are no approved antivirals that can treat standard risk patients across multiple families of viruses like (COVID-19, influenza, RSV). Existing antivirals like Paxlovid and Lagevrio are approved for people with underlying medical conditions which means that Bioxytrans’ leading drug candidate ProLectin-M addresses an enormous unmet medical need. Two peer-reviewed clinical trials support the non-toxic nature of the antiviral as well as its robust efficacy. The company is hoping to find a big pharma partnership to help complete their primary drug’s development program and commercialize the asset.

KEY POINTS

Robust Early Clinical Efficacy (ProLectin-M): The drug has undergone extensive early-to-mid stage trial development, completing 3 clinical trials. In a Phase 2 trial in India for mild-to-moderate COVID-19 patients, treatment with ProLectin-M almost eliminated patients’ symptoms in 24-72 hours. Viral load was reduced to undetectable levels within 3 days. **No serious adverse events or viral rebounds** were observed, suggesting a potentially better therapeutic profile than Pfizer’s Paxlovid. Their last trial was a dose optimization trial that is expected to inform the trial design of their phase 3 in India as well as their phase 1 in the USA.

Broad-Spectrum Antiviral Potential: Preclinical data shows that the company’s lead candidates, ProLectin-M and ProLectin-I, have antiviral activity against SARS-CoV-2, influenza, and RSV. The company has also completed case studies that suggest they can treat acute cases of Herpes Zosters commonly referred to as Shingles. They are also interested in investigating other viruses that include Ebola, Ebstein-Barr Virus (EBV), and Bird Flu (H5N1).

Clear Clinical Development Path: The company has a planned Phase 3 trial for COVID-19 in India and has received FDA approval for a Phase 1b/2a clinical trial for the same indication in the US. The company is advancing a universal oxygen carrier (UOC), BXT-25, for stroke and hypoxia. Its mechanism of action offers the potential to be safe in treating both ischemic or hemorrhagic stroke, which would allow for faster dosing, potentially saving hours of brain ischemia, unlike current solutions like tPA which are contraindicated in hemorrhagic stroke.

High Insider Alignment: Management and directors have significant expertise and align with shareholders, demonstrated by over 50% insider ownership and funding operations largely through stock compensation to minimize overhead cash expense. Further clinical development is, however, dependent on obtaining funding.

Investment View: BIXT is a speculative investment yet greatly derisked by the powerful galectin science that generated robust efficacy in multiple RCT’s without any adverse events. The equity is capable of creating tremendous value for shareholders contingent upon them receiving nominal funding to finish their clinical trials enabling them to check the regulatory approval boxes. The company doesn’t have sufficient operating capital and has struggled to raise capital over the past 2 years. For the most part management has kept the company moving forward with related party infusions. They own controlling interest in the company and their compensation is aligned with shareholders and tied to stock price appreciation. The fund raising risk is more pronounced than the clinical trial results. The company is seeking partnerships and collaborations for their 3 platform technologies. Big pharmas typically have 5- 10 platform technologies which make Bioxytran a notable platform technology target. Their breadth of indications means that they have a collaboration case for every big pharma. If they are unsuccessful in generating interest in a collaboration, they will likely have to raise capital which may dilute existing shareholder positions. On a comparable basis their virology platform technology is superior to many existing antiviral platforms in terms of efficacy, broad-spectrum activity, and its safety profile. The company’s market cap is a fraction of other antiviral platform technologies which represents significant upside from an investment in BIXT.

SWOT ANALYSIS

Strengths

The results from Bioxytran's Phase 2 clinical trial were positive and provide a basis for the progression to a Phase 3 trial in India or a Phase 1b/2a trial in the United States. When compared to Paxlovid (nirmatrelvir + ritonavir) and Lagevrio (molnupiravir) real-world data, ProLectin-M was able to eliminate PCR-detectable viral load in 88% of standard risk patients in 3 days, where only about 5% of patients with underlying medical conditions taking Paxlovid or Lagevrio experienced low viral burden by day 3, according to a real world study published in The Lancet. With zero observed viral rebounds and no serious adverse events, ProLectin-M has early signs of a better therapeutic profile than Paxlovid, which would be important for obtaining regulatory approval and to potentially take market share from Merck and Pfizer. Their results in standard risk patients circumvents the need for costly drug to drug interactions studies with Paxlovid which was approved in the patient population with people with underlying medical conditions. Bioxytran is pursuing academic collaborations and grants in ProLectin-M bird flu research, which could theoretically result in a follow-on approval for influenza, making ProLectin-M a drug one might take for flu-like symptoms regardless of the infection—influenza or COVID. This multi-use potential for ProLectin makes its value proposition uniquely broad compared to Paxlovid which is approved by the FDA to treat mild to moderate COVID-19 in adults who are at high risk of progression to severe COVID-19, but is not approved for use as pre-exposure, post-exposure prophylaxis, prevention, or for patients not at high risk of progression of COVID-19.

Bioxytran's expertise in carbohydrate drug design makes it one of the few companies in the world with the know-how to synthesize compounds similar to its drugs. Its other primary compounds, BXT-25, and ProLectin-I, have not shown any drug-related adverse effects in studies.

BXT-25 sets itself apart from other stroke treatments; its tolerability and mechanism of action provides the potential for it to be safe in treating ischemic or hemorrhagic stroke, as opposed to current solutions like tissue plasminogen activator (e.g. tPa – Genentech's Activase), which are contraindicated in hemorrhagic stroke. This would allow faster dosing of stroke victims with BXT-25, potentially before patients receive a scan to rule out hemorrhagic stroke, and saving on average a few hours of brain ischemia. BXT-25 also sets itself apart from other oxygenation strategies such as hyperbaric oxygen therapy (HBOT), and other drugs in development mean to improve the diffusion of soluble oxygen in the blood (rather than to increase the carrying capacity in the blood, and therefore the potential for a high diffusion concentration gradient at the oxygen's recipient tissue).

From the financial angle, Bioxytran is over half insider-owned and its team has not taken cash compensation recently. The management team is therefore highly aligned with shareholders to build shareholder value.

Weaknesses

Bioxytran's progress is hindered by its lack of cash, which slows its drug development endeavors. It also does not currently have a source of revenue and as such is subject to diluting its stock or taking on debt to fund its assets' development. It's ProLectin-M COVID clinical trials were fairly small sample sizes despite highly statistically significant results, and its history of running clinical trials in the United States under the scrutiny of the FDA is limited. Aside from ProLectin-M, its assets are early stage and are subject to

development and regulatory risks despite generating encouraging data to date.

Opportunities

Bioxytran's assets, particularly ProLectin-M, ProLectin-I, and BXT-25, could be attractive for larger pharma to purchase or in-license. Specifically, ProLectin-M's phase 2 data suggest that it could be well-tolerated and more effective COVID treatment than Paxlovid or Lagevrio, and Paxlovid is severely limited by drug interaction-induced side effects, while Lagevrio's mechanism of action causes mutations and therefore is not necessarily a good solution for widespread use due to promoting COVID-19 variants and potentially creating a more varied target for the immune system. ProLectin-M and ProLectin-I are both galectin inhibitors, where galectins such as galectin-3 are implicated as potential therapeutic targets in a wide range of chronic diseases.

While COVID-19 and influenza antiviral deals with massive upfront payments have mostly been inked for phase 3 and approved antiviral assets, promising antivirals with excellent phase 2 data have been able to garner licensing deals from big pharma companies that include substantial upfront payments with significant back-end milestone payments and royalties (i.e. "biobucks").

COVID-19 and Influenza Licensing and Acquisition Matrix					
Company Name (Licensee)	Drug Name, Phase	Drug Mechanism of Action	Licensor	Upfront Cash ($M), and Year	Total Royalties or Milestone Payments
Merck	Molnupiravir	Oral antiviral; inhibits viral RNA replication (COVID-19)	Medicines Patent Pool	N/A, 2021	Royalty-free
Pfizer	Paxlovid (Nirmatrelvir/ Ritonavir)	Oral antiviral; inhibits SARS-CoV-2 protease (COVID-19)	Medicines Patent Pool	N/A, 2021	Royalty-free
Gilead Sciences	Remdesivir (Veklury)	IV antiviral; inhibits RNA polymerase (COVID-19)	Gilead (to generics)	N/A, 2020	Royalty-free
Janssen Pharmaceuticals	VX-787 (Pimodivir), phase 2	Oral antiviral; inhibits influenza A PB2 polymerase (Influenza A)	Vertex	30, 2014	Milestones + royalties
Gilead Sciences	4-OI Derivatives (three preclinical programs)	Small molecule; inhibits influenza A PA endonuclease (Influenza A)	Novartis	Undisclosed upfront, 2019	Up to $291M milestones + royalties
Novartis	Ensovibep (MP0420), phase 2	Trispecific DARPin antiviral; binds three SARS-CoV-2 spike protein sites (COVID-19)	Molecular Partners	22 (20 CHF) upfront, 44 (40 CHF) equity investment, 2021	$163M (CHF 150M) milestone paid + 22% royalty
Merck	CD24Fc, phase 3	DAMP binding, Siglec G/10 inhibitor	OncoImmune	425, 2020	Acquisition + sales-based payments and CVRs
Roche	Baloxavir marboxil (Xofluza, influenza antiviral), FDA approved	Cap-dependent endonuclease inhibitor	Shionogi	1700, 2018	Upfront and milestone payments for global rights outside Japan
Pfizer	AT-527, phase 2	RdRp and NiRAN inhibitor	Atea	350, 2021	Upfront + royalties (undisclosed) and milestone payments (undisclosed)

Notes:

- *Royalty-free applies to COVID-19 deals during the WHO Public Health Emergency.*
- *Janssen's pimodivir was discontinued in 2020 but included as a relevant influenza antiviral deal.*
- *Novartis-Gilead deal updated with 4-OI derivatives and PA endonuclease inhibition mechanism from Nature article.*
- *Novartis-Molecular Partners deal for ensovibep included; EUA withdrawn in 2023, rights returned in 2024.*
- *Data sourced from company press releases, Nature article, and web sources.*

On the other hand, galectin-3 antagonists have demonstrated promise as enhancers to immune checkpoint inhibitor (ICI) therapies, with Galecto Biotech and Galectin Therapeutics, which competitors to Bioxytran, demonstrating favorable efficacy profiles in small scale, early-stage clinical studies, as well as in a variety of preclinical studies. Specifically in combination with PD-1 inhibitors, small molecule and larger carbohydrate-based galectin-3 antagonists have the potential to reduce non-responsiveness to ICI treatment such as PD-1 inhibitor therapies. While both types of galectin-3 inhibitors have demonstrated promise, larger molecule carbohydrate-based therapies such as Galectin's Belapectin (formerly GR-MD-02) and Bioxytran's ProLectin series of drugs have never demonstrated significant clinical adverse effects as they inhibit primarily extracellular galectin-3, whereas Galecto Biotech's small molecule galectin-3 inhibitors have shown to have adverse effects, likely due to intracellular inhibition of galectin-3, which helps prevent Cytochrome c release and caspase-mediated apoptosis during cellular stress. Therefore, larger molecule galectin-3 inhibitors, which are scarce, currently appear to have superior safety profiles, making these drugs potentially of significant value for the treatment of cancer and other (potentially a wide range of) inflammatory-fibrotic diseases.

Bioytran's BXT-25 is a unique solution to hypoxic disease and therefore may be valuable in several areas where improved oxygenation is known or suspected to provide clinical efficacy. It is well-understood that sufficient oxygenation is important for the human body to function properly, and as such, oxygenation compounds could be of significant value across a wide range of diseases, but certain applications like ischemic stroke or emergency blood transfusions are the most obvious use cases for such a compound, where oxygen is clearly the preeminent concern. Bioxytran's compound is based on heme as opposed to some other oxygenation compounds which aim to increase oxygen diffusion.

The compound has the potential to improve upon the success of hyperbaric oxygen therapy (HBOT) which has demonstrated success in several areas, most notably wound healing (sometimes covered by insurance) and carbon monoxide poisoning (FDA approved). BXT-25 also has the potential to address the weaknesses and build upon the success of Hemopure, which is a heme-based compound that transports oxygen similar to erythrocytes, but its structure able to be metabolized. When this happens, it can cause iron toxicity. Hemopure was pitched as a potential blood substitute product with a US TAM of $9.5 billion, and is currently a commercial product in South Africa and Russia, but is not available in Europe or the United States due to safety and reliability issues. BXT-25 addresses the significant drawbacks of Hemopure and with a benign safety profile demonstrated to date, has the potential to realize this value as a blood substitute as Bioxytran has launched a joint venture with the Heme Foundation for the development of this compound.

Threats

Pfizer is developing a next-generation Paxlovid already and several other companies are trying to develop new treatments for COVID infection. Of particular efficacy seem to be the 3CL protease inhibitors like nirmatrelvir (Paxlovid), but SARS-CoV-2 has shown signs of

resistance to nirmatrelvir via simple point mutations. Merck and Pfizer both have investments in their COVID antivirals to protect, so ProLectin-M might have to show a superior efficacy profile to interest either of these suitors, as opposed to others.

There are several other companies seeking to create oxygenation drugs, with companies like CervoMed (NASDAQ: CRVO) advancing molecules to improve oxygen diffusion in the boundary layer of the blood (where oxygen dissociates from heme and moves to the tissue). While the general concern is overall circulation and arterial oxygenation (hypoxemia), these approaches remain a valid competitive threat to Bioxytran. Sanguinate (Prolong Pharmaceuticals, private) is also advancing a compound called PEGylated carboxyhemoglobin bovine which is also a modified hemoglobin, stabilized by polyethylene glycol. This is a very similar approach to Bioxytran's. Prolong is also pursuing a primary indication of ischemic stroke and has completed phase 1 trials. While they are ahead of Bioxytran in development, their success would likely indicate success for Bioxytran.

COMPANY OVERVIEW

Bioxytran, Inc. ("Bioxytran" or "the Company") is a clinical stage pharmaceutical company with 3 platform technologies. The Company was established on June 9, 2018. Shortly thereafter, it underwent a restructuring via a reverse merger with U.S. Rare Earth Minerals, Inc. (USREM), which agreed to acquire Bioxytran's assets following a settlement over a defaulted secured promissory note. The company then officially rebranded as Bioxytran, Inc.

The company's foreign subsidiary, Pharmalectin BVI, was incorporated on March 17, 2021, as a British Virgin Islands Business Corporation, holding and managing Bioxytran's intellectual property, including copyrights, trademarks, patents, and licenses. Bioxytran currently employs three staff members and several consultants, and is based in Needham, Massachusetts.

The company's three technology platforms are described below.

1) The company is developing therapeutics using its glycovirology platform to develop broad-spectrum antivirals. They completed 2 randomized controlled trials (RCTs) with their leading drug candidate ProLectin-M (PLM) in Covid-19 and achieved a 100% responders' rate in both trials. There was no toxicity related to the oral chewable tablet and the results were statistically significant. While the first case study was for COVID-19, additional preclinical data demonstrated the possibility of efficacy in RSV and influenza. They recently completed enrollment in a dose optimization trial in India but the data has not been published.

2) Bioxytran also has a cancer metastasis platform in development that utilizes ProLectin-I, which is an intravenous Galectin-3 antagonist with regulatory approval to conduct a Phase 1 study in India on healthy human subjects to assess the toxicity of the drug.

3) The company also has developed a universal oxygen carrier for the treatment of hypoxic conditions and degenerative diseases, with an initial focus on ischemic, but also hemorrhagic stroke.

Bioxytran's glycovirology endeavors have been powered by its novel glycobiological discovery platform which gave rise to its ProLectin asset class. This new class of antivirals is designed to reduce viral loads via entry inhibition as well as modulate the immune system via galectin inhibition. Specifically, galectin-3 antagonists can bind with glycoproteins on a virus' outer surface, ultimately impeding virus-cell attachment and therefore viral entry into the cell.

Using its advanced carbohydrate drug discovery platform, Bioxytran is developing several therapeutic candidates for the treatment of COVID-19, including patients with or without risk factors, and for long-COVID. Bioxytran's lead asset is called ProLectin-M; it is a chewable tablet for the treatment of mild-to-moderate COVID-19. ProLectin-M binds with the SARS-CoV-2 spike protein and acts as an entry inhibitor.

Bioxytran's second asset, ProLectin-I—for cancer treatment, was also bred out of its discovery platform. The drug targets several galectins including galectin-3 with the goal of preventing metastasis and restoring endogenous immune cell function.

The company's third platform is centered around its universal oxygen carrier technology, BXT-25. BXT-25 mimics the body's natural oxygen-carrying dynamics because it is a stabilized small-molecule version of the heme in red blood cells, which carry oxygen. The manufacturing of this compound relies on the application of its proprietary carbohydrate chemistry manufacturing process to stabilize hemoglobin in a carbohydrate polymer lattice. This process creates an injectable intravenous oxygen carrier (BXT-25) that mimics the oxygen carrying function of erythrocytes while maintaining a much smaller size (~1/5000th), enabling oxygen delivery to tissues with limited or blocked blood flow, such as the brain after an ischemic stroke. Further preclinical and early clinical development of BXT-25 is contingent upon funding.

Recent Milestones

- Company has an active S1 filing (with Triton Capital) filed with the SEC for up to $1.6 million, allowing for fundraising flexibility.
- Company has entered into a collaboration with the University of Georgia to apply for federal grants to test a water soluble formulation of ProLectin-M in poultry feed ($100M HPAI Grand Challenge).
- Completed successful Techwatch Light meeting with Center for Biomedical Advanced Research and Development Agency (BARDA) and Defense Threat Reduction Agency (DTRA) with notable interest and clarity on path forward.
- Initiated business development discussions for several pipeline programs.
- Published oncology preprint on immune checkpoint inhibitor (ICI) resistance.

Upcoming Milestones

- Topline clinical trial results (phase 2 dose optimization study).
- Potential grant for HPAI Grand Challenge Innovation.
- Potential funding secured for several pipeline programs.
- Potential initiation and completion of additional in vitro or in vivo studies for virological and oxygenation indications (pending funding).
- Potential progress on business development opportunities.

Intellectual Property (IP)

Bioxytran's market competitiveness hinges on the growth and safeguarding of its intellectual property (IP) portfolio. The Company aims to leverage its existing patents and proprietary technologies to advance its technology platforms, positioning itself to license its product candidates to major pharmaceutical firms capable of navigating the regulatory landscape and overseeing product distribution.

The Company plans to strengthen its IP portfolio by pursuing additional patent filings as well as by potentially forging new licensing partnerships. Pharmalectin BVI, a wholly-owned foreign subsidiary of Bioxytran, serves as the holder and manager of the Company's copyrights, trademarks, patents, and licenses. Bioxytran currently engages international patent attorney firm Clark and Elbing, and the company holds:

- Three issued worldwide patents and one international trademark
- One issued US patent
- One provisional worldwide patent

The company is working on additional applications to further strengthen its IP position. The specific patents/trademarks are listed below.

- Pharmalectin has received an international trademark for ProLectin (WO0000001646681).
- Pharmalectin filed a provisional patent in March 2022 (Lectin-Binding Carbohydrates for Treating Viral Infections - US 63/320544); filed in March 2022.
- The International Bureau of the Patent Cooperation Treaty (PCT issued the Company a patent (Polysaccharides for IV Administration that Treat Sars-Cov-2 Infections - WO2022/099061) in 2022, and that expires in 2041.
- MDX LifeSciences has licensed a patent (Tissue Metabolic Score for Patient Monitoring - US20210153816A1) to Bioxytran, that was issued in 2021 by the International Bureau of the Patent Cooperation Treaty (PCT), and expires in 2040.
- Through its wholly owned subsidiary, NDPD Pharma, Bioxytran has a patent (Polysaccharides for Use in Treating Sars-Cov-2 Infections - WO2022/099052) that was issued in 2022 by the International Bureau of the Patent Cooperation Treaty (PCT), and expires in 2041.

Financial Position

Bioxytran had $4.3 thousand in cash as at 31 March 2025 according to their Q1 2025 10-Q. Given the Company currently generates no revenue, it will have to raise additional capital, secure grants, or find a development and commercialization partner to pursue additional clinical and preclinical studies for both ProLectin-M and BXT-25.

The Company has funded its operations through several small share offerings as well as convertible notes. Notably, the company relies almost solely on stock based compensation for its management, board, and consultants; insiders are aligned with common stockholders and the company's overhead cash expenses are minimal.

The company forecasts that it will need $8 million to advance BXT-25 through phase 1 clinical trials in 18 months, and that $3.4 million would be required to move ProLectin-M through a phase 2 clinical trial in the United States under the FDA, in 12 months. Although the company efficiently uses funds for asset development and not overhead expenses, the company does not currently have these funds and as such will need to secure the resources to advance these programs forward.

Capital Structure

At the date of this report, the Company had 89.0 million and 86.8 million shares on issue and outstanding. The Company has $1.01 million in total debt; its primary debtors are convertible noteholders and as such cash requirements for debt repayment are not a concern.

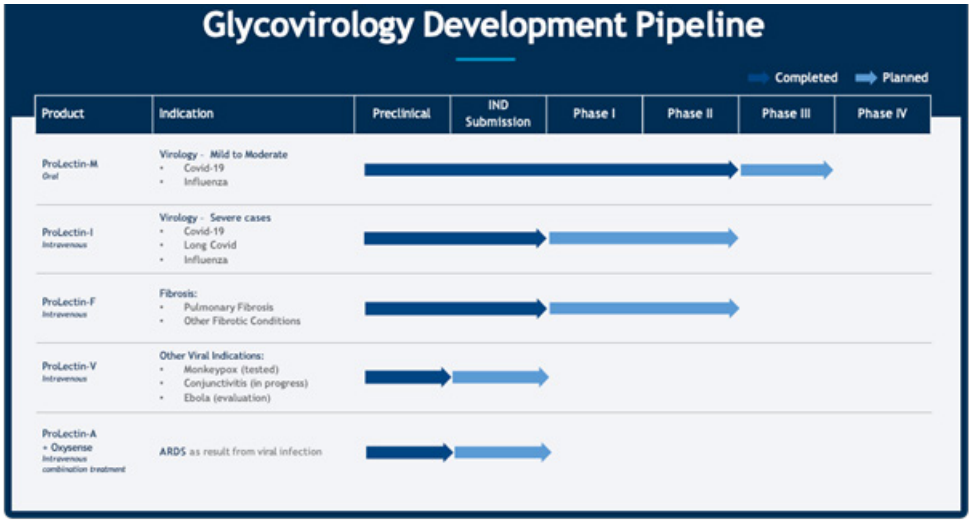
The below table shows the common shares, warrants and options on issue as well as the potential new shares that may be issued from debt to share conversion.

Capital Source	Number	Weighted Average Exercise Price
Common Shares Outstanding	88,881,859	N/A
Warrants	1,292,030	$0.22
Options	0	N/A
Convertible Notes (Potential Shares)	12,247,487	based on an $0.08 exercise price
Total Shares	102,421,376	N/A

The warrants on issue have a weighted average lifespan of 2.7 years as of 31 March 2025. The company has no options outstanding and its convertible note matured on 1 March 2025. The company has over 2,000 shareholders with majority insider ownership.

Bioxytran: Two Paradigm-Changing Pipelines

Bioxytran's two pipelines approach disease treatment in potentially paradigm-shifting ways; Viruses may be targeted with entry inhibitors that also have immune modulating capabilities as galectin-inhibitors, and which may target viruses across virus familes. The Company's degenerative disease pipeline uses galectin inhibiton and universal oxygen carrying mechanisms to address the hypoxia, inflammation, and fibrosing of tissues that accompany a wide range of degenerative diseases. This represents targeting disease at its roots, and as such these drugs are considered modifying therapies.



Glycovirology Antiviral Discovery Platform

Bioxytran's glycovirology efforts are conducted through its wholly owned subsidiary, Pharmalectin Inc. Pharmalectin's drug discovery platform utilizes advanced nuclear magnetic spectroscopy to design carbohydrate drugs that bind multiple regions on a conserved site of a virus, inhibiting viral entry. It can also be used to find drugs that will bind to viruses or even multiple viruses, thereby allowing the discovery of a broad-spectrum antiviral (targeting conserved regions between viruses and/or binding multiple viruses).

The underlying theory behind viral entry is that viruses first need to stick to the cell surface before they trick the host cell into allowing them to enter. Viruses are known hijack the upregulated galectin proteins in the extracellular space of a viral infection in order to stick to the cell surface.

Using its advanced drug discovery platform, the company has developed its lead candidate, ProLectin-M, an oral chewable tablet for COVID-19, as well as several intravenous drug candidates including ProLectin-I.

Glycovirology: New Subcategory of Glycobiology

While glycobiology is the study of glycans (sugars/carbohydrates) in the context of biology, glycovirology represents a specialty field in glycobiology research where the interactions between glycans and viruses are characterized. This can include extracellular glycans, glycoproteins, and viral and transmembrane glycans.

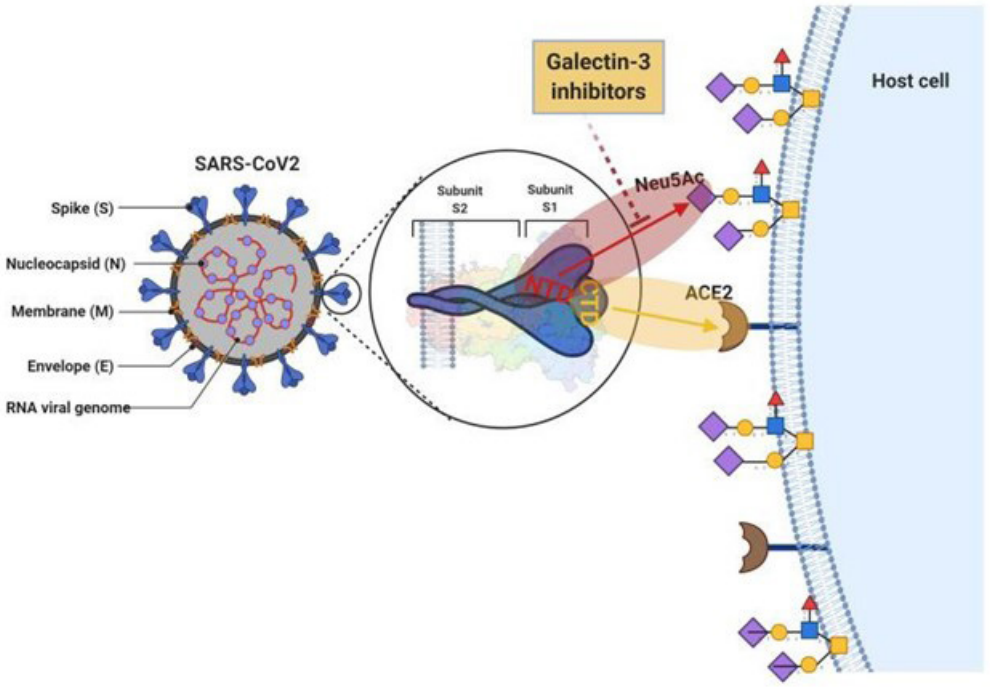
Glycans influence a wide range of biological processes, including but not limited to: inter and intracellular communication, cell recognition, immune signaling, cell growth and differentiation, the cell cycle and cell death, and even protein folding. Sugar recognition proteins called lectins, which "recognize" specific sugars, mediate the cell signaling functions of glycans.

Galectins (beta-galactoside-binding lectins, of which there are 15 types) have been shown to regulate viral infections. For viruses to bind or enter a cell, viral surface proteins (in COVID-19, the spike protein) must bind to specific cell-surface glycan, ultimately resulting in viral entry and subsequent pathways of replication. Thus, preventing a viral attachment to the cell is an antiviral method called entry inhibition. Each of Bioxytran's developed antivirals inhibit virus-cell attachment, binding with the virus surface proteins or blocking required galectins that aid in the attachment process, and therefore preventing the virus from properly attaching to the target cell.

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. While COVID-19 is no longer a new virus killing millions of Americans every year, it is still comparable to influenza with respect to winter death tolls according to CDC mortality data.

Galectin-3 inhibition is a promising antiviral strategy, and specifically a promising SARS-CoV-2 antiviral approach. While galectin-3 is produced during inflammation and cellular stress, normal galectin-3 expression in healthy tissues is highest in the lungs and gastrointestinal tract. Aside from respiratory symptoms, COVID-19 infected patients often report gastrointestinal symptoms including diarrhea, nausea, and vomiting, which may suggest increased infectivity in these tissues due to preexisting galectin-3 expression.



Immunopathology of galectin-3: an increasingly promising target in COVID-19. F1000Res. 2020 Sep 28;9:1078. Originally published 2020 Sep 1. [Version 2] doi: 10.12688/f1000research.25979.2

The use of galectin-3 inhibitors to treat COVID-19 infection was not only influenced by galectin-3's role in viral infection and inflammation, but in the SARS-CoV-2 spike protein N terminal domain's (NTD) containing morphology being almost identical to galectin-3. The COVID19 spike protein is responsible for SARS-CoV-2 viral entry as it protrudes from the viral membrane, latching onto target cells. SARS-CoV-2-S1-NTD has the ability to bind to cellular glycans, and a conserved region of the spike protein which is colloquially called the "galectin fold" is nearly identical in morphology to human galectin-3's carbohydrate recognition domain (CRD), the primary binding site of galectin-3 to glycans. Due to this striking 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 above.

There appear to be several plausible mechanisms responsible for galectin-3's role in COVID-19 infection, and therefore ProLectin's mechanism of antiviral action:

- SARS-CoV-2 S1 NTD binds to ACE-2 and potentially several other human proteoglycans.
- Galectin-3 NTD and CRD bind to SARS-CoV-2-S1, and several gal-3 inhibitors were also found to bind to the S1 RBD (ACE2 binding site).
- Galectin-3 can oligomerize around its own NTD, stabilizing the spike protein against the cellular membrane in a scaffold-like structure (by oligomerizing, and binding glycans on both the target cell and the spike protein).
- ProLectin-M may reduce any or all of these interactions that increase infectivity.

The inflammatory aspects of high galectin-3 levels may offer another therapeutic mechanism of antiviral galectin-3 inhibitors in reducing not only viral load, but also clinical symptoms and disease progression while preventing or treating infection. Cytokine release syndrome (CRS), which is the overproduciton of inflammatory cytokines, can result in COVID-19 hospitalization and fatality, acute respiratory distress syndrome (ARDS) and organ failure, and lung scarring. Galectin-3 inhibitors, particularly those which primarily bind extracellular galectin-3, have been shown significant anti-inflammatory effects when treating inflammatory diseases in vivo.

ProLectin Pipeline

Pharmalectin is using its expertise in carbohydrate chemistry to develop multiple carbohydrate-based product candidates for COVID-19 including treatment of organ damage and long-term conditions derived from the COVID-19. In addition to its COVID-19 efforts, Bioxytran is evaluating the application of its ProLectin and glycovirology technology to target influenza and other virologic diseases.

The Company is also advancing its other product candidates, ProLectin-I BXT-25, in cancer and hypoxic conditions (i.e. stroke), respectively.

ProLectin-M

Bioxytran's lead drug candidate, ProLectin-M, is able to block SARS-CoV-2 to act as an entry inhibitor antiviral. At later stages of COVID-19, galectin-3 inhibitors including ProLectin-M may also help restore adaptive immune function and reduce inflammation as an immunomodulator (galectin-3 inhibitor, reducing risk of disease progression. In severe cases of COVID-19, galectin-3 inhibition can reduce cytokine release and treat/help prevent lung fibrosis.

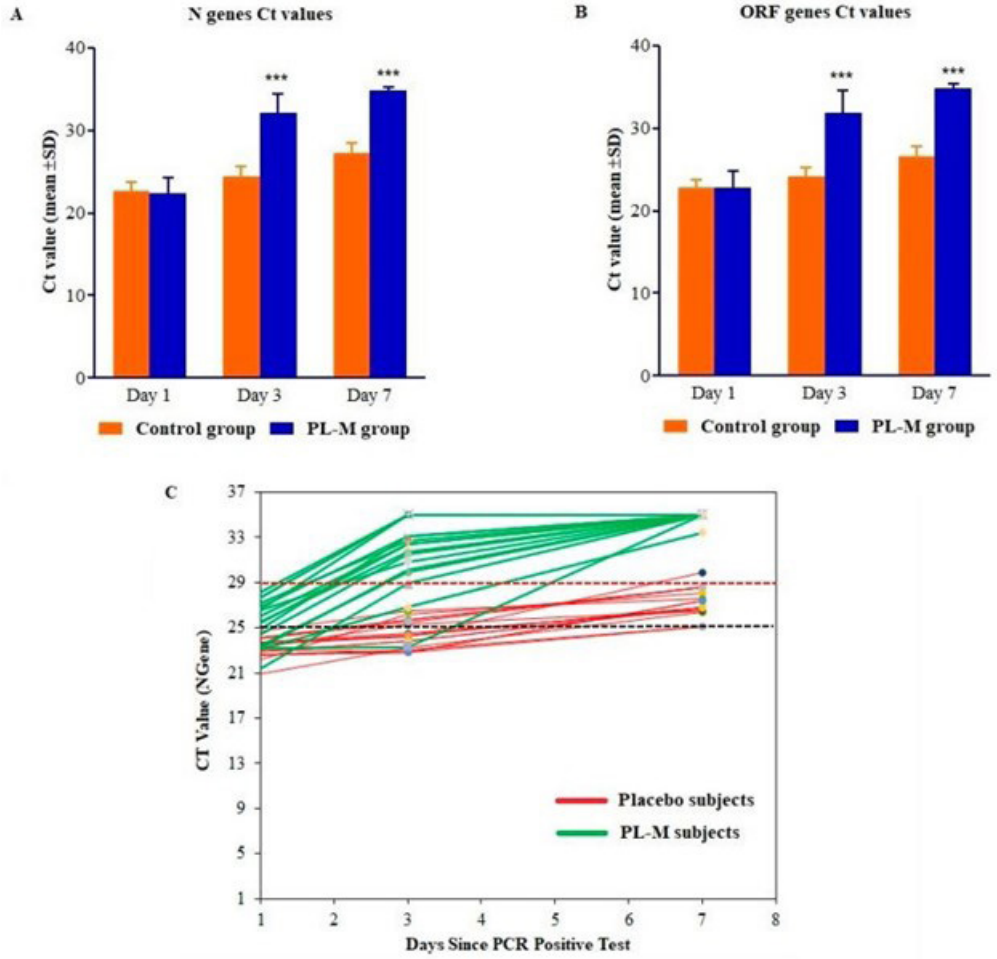
ProLectin-M, a chewable tablet exclusively licensed from a now wholly owned sister company, NDPD Pharma, Inc., was developed specifically to treat mild-to-moderate Covid-19, but has demonstrated preclinical effects as an antiviral for RSV and influenza. The company has completed phase 2 trials in India with ProLectin-M and is awaiting results from a dose optimization trial which will help inform a phase 3 design in India (or a phase 2/3 design in the United States), which will be submitted to the Central Drugs Standard Control Organisation (CDCSO), India's national regulatory most equivalent to the United States Food and Drug Administration (FDA). The company is also preparing its investigational new drug (IND) application for a Phase 1b/2a clinical trial with the FDA, which may be followed on by a Phase 2/3 submission with the EMEA.

ProLectin-M's primary mechanism of action is binding to virus' spike proteins thereby inhibiting viral entry. Bioxytran believes that ProLectin-M can simultaneously block viral entry of SARS-CoV-2 and tag it for hepatic elimination, though other clearance mechanisms are possible. The Company conducted a proof-of-concept Phase 1/2 clinical trial in India that was finalized in October 2020, with results published in the Journal of Vaccines & Vaccinations. They also published a subsequent in vitro-study to further elucidate ProLectin-M's mechanism of action. We believe that this was the first clinical trial conducted treating SARS-CoV-2 with a galectin antagonist, and that this represents a novel upper respiratory virus antiviral mechanism.

ProLectin-M Clinical Data

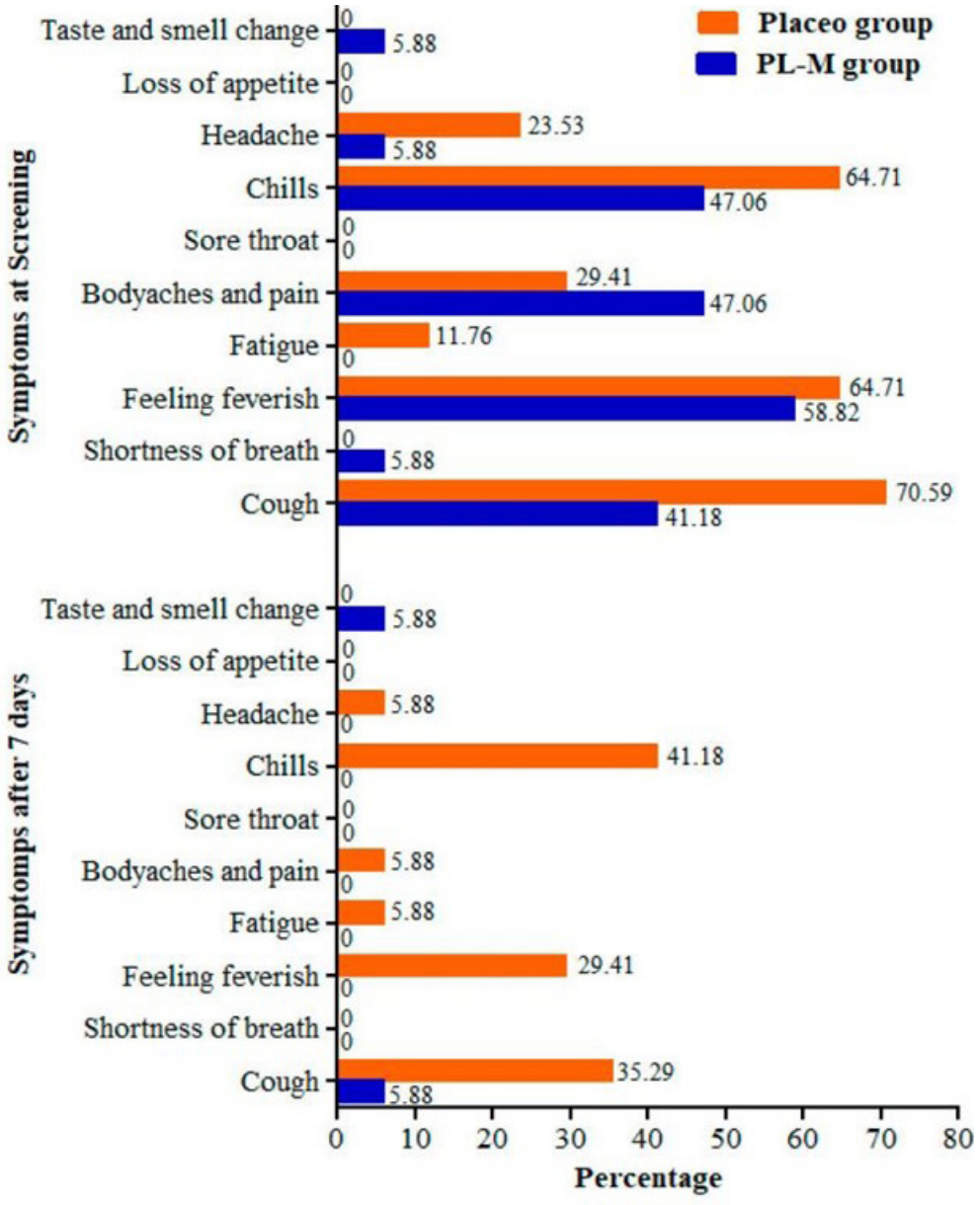
The subsequently conducted preclinical study results indicated that ProLectin-M binds fairly strongly to SARS-CoV-2, preventing entry of the virus into its target cells, resulting in a dose-dependent reduction in both viral load (treatment post infection) and cell infectivity (treatment pre infection). During the phase 1/2 study, no serious adverse events were observed, giving ProLectin a strong efficacy and safety profile. The clinical results are summarized as follows:

- The treated group's viral load declined significantly faster than the control group, with ProLectin-M treated patients experiencing viral load reduced to undetectable levels (via PCR) within 3 days, with a concomitant reduction in clinical symptoms (not statistically analyzed).



Sigamani, A.; Mayo, K.H.; Miller, M.C.; Chen-Walden, H.; Reddy, S.; Platt, D. An Oral Galectin Inhibitor in COVID-19—A Phase II Randomized Controlled Trial. Vaccines 2023, 11, 731. https://doi.org/10.3390/vaccines11040731

- All participants enrolled in the active arm were clinically asymptomatic before day 28, which supports ProLectin-M's ability to block viral replication.



The company's phase 2 results represent robust initial results (rapid reduction in viral load and symptoms) that warrant further development.

Phase 3 Trial

The Company is currently designing a Phase 3 clinical trial (clinicaltrials.gov identifier: NCT05096052) for submission under the CDCSO in India, while also preparing an IND for a Phase 1b/2a clinical trial with the FDA, with a potential follow-on Phase 3 submission with the EMEA. These trials are being designed to test the hypothesis that standard-risk COVID-19 patients receiving ProLectin-M have a faster recovery and reduced hospitalization rates compared to those receiving placebo. The completion dates of the Phase 3 trial in India and the Phase 1b/2a trial in the U.S. are dependent upon funding or a partnership.

Additional Indications: Avian Flu (H5N1)

In Bioxytran's efforts of extending ProLectin's usage as an antiviral against more than one family of viruses, it tested ProLectin-M and ProLectin-I against several other non-coronaviridae viruses, including H5N1 (avian flu) and RSV, viruses with a known profile either of galectin involvement in infection, or with certain viral entry proteins characteristics that would lend themselves to ProLectin binding. In vitro testing showed antiviral activity (albeit less potent than in SARS-CoV-2) against H5N1, and to a lesser extent, RSV. ProLectin-M and ProLectin-I both demonstrated the ability to inhibit these viruses at what are postulated to be safe equivalent human doses.

Since these in vitro tests were conducted, and presumably given the robust early results shown in COVID-19 treatment, Bioxytran signed an NDA with the University of Georgia to test its galectin antagonist against the new H5N1 strain in chickens infected with avian flu. The studies will be led by Dr. Daniel Perez, a renowned expert in virology and poultry medicine. Shortly following the NDA which was announced in March '25, Bioxytran released news that the University featured Bioxytran's technology in its submission to the U.S. Department of Agriculture's (USDA) $100M HPAI (highly pathogenic avian influenza) Poultry Innovation Grand Challenge, where it was one of a handful of molecules chosen by the University. Dubbed PHM23 in influenza, this ProLectin-M formulation's recognition by a prestigious University and leader in poultry health as a promising potential solution for Avian Flu underscores its promise more generally as a potential broad-spectrum antiviral.

Avian Flu Commercial Opportunity

Influenza, including avian flu, is a fairly large human commercial opportunity, with the global influenza treatment market estimated estimated to be $ 6.4 billion by 2030, according to Grand View Research. However, Bioxytran's current efforts with influenza are focused on treating domestic poultry, where avian flu has led to hundreds of millions of bird deaths. We estimate that each bird is worth between $1 and $25 depending on certain factors. Global economic losses from HPAI are known to be in the billions of dollars annually. In fact, according to Poultry World, the 2022 avian flu outbreak in the United States resulted in the loss of ~40 million birds with accompanying economic costs ranging from $2.5 to $3 billion. Since then, additional estimated 126 million birds have been culled.

Because HPAI has historically caused a 75-100% poultry fatality rate, a significant amount of effort is put into avian influenza mitigation. To allow for rapid response, the Animal and Plant Health Inspection Service (APHIS) is responsible for monitoring avian flu via sample collection and processing. However, since there are no poultry treatment options, once HPAI is detected at a poultry farm, the producers use ventilation shutdowns, carbon dioxide gassing, and other similar methods to kill the birds via heatstroke or suffocation.

The Department of Agriculture is the agency that bears the cost of HPAI in poultry farms. USDA mandates culling the affected flock, and in 2023, the Department of Agriculture paid over $500 million to poultry producers to compensate them for the destruction of various poultry, including turkey and egg-laying hens.

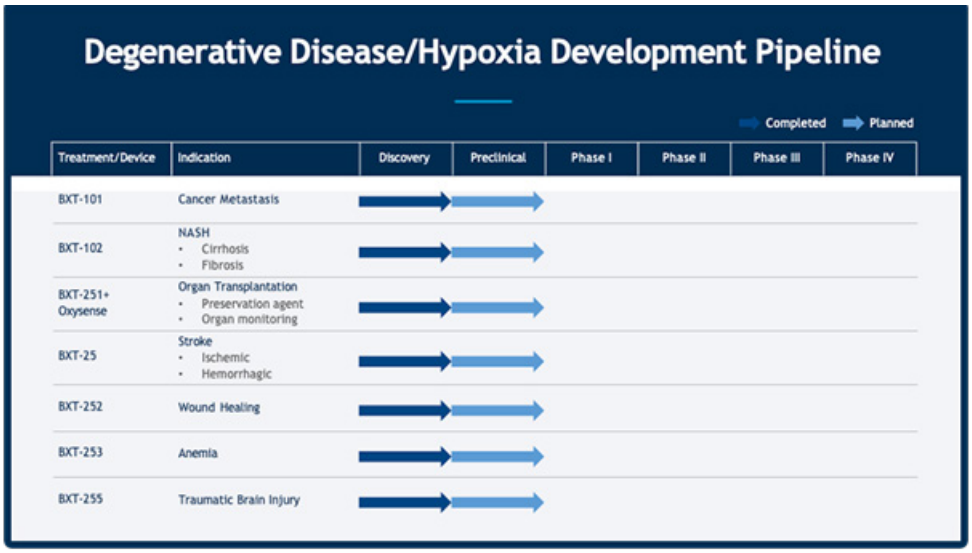
As an example, at just one layer farm housing 1 million egg-laying chickens, each producing 280 eggs per hen annually, a hypothetical 50% production loss could save ~140 million eggs, with a total worth of $7-14 million at $0.05-0.10/egg wholesale prices. With an estimated >4% risk of an HPAI outbreak at commercial poultry farms, and 110 billion eggs produced per year at these commercial operations, the TAM (as a rough estimate of potential risk mitigation) is calculated to be $220-$440 million annually.

This represents an attractive program for Bioxytran given the capex required to commercialize this solution is low compared to the capex required to advance human treatments.

ProLectin Intravenous (IV) Candidates

The company is also utilizing its glycovirology drug discovery methods to develop several intravenously-administered drugs for severe COVID-19 and the organ damage and long-term conditions that can follow: (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-A, for the treatment of Covid-related ARDS; and (3) ProLectin-F, for the treatment of patients developing lung fibrosis as a result of the use of ventilator in Covid-19 treatment. The Company is preparing a Phase 2 trial of 60 people on fibrosis of the lung in India using ProLectin-F, expected to be completed by December 2022.

Degenerative Disease/Hypoxia Pipeline



In addition to its glycovirology platform, Bioxytran is advancing an innovative technology platform of oxygen therapeutic treatments and immune modulators for hypoxic conditions, necrosis, and degenerative diseases, with an initial focus on therapeutic molecules for stroke. Bioxytran's first Universal Oxygen Carrier (UOC), BXT-25, is manufactured utilizing process technology originally developed by the Biopure Corporation (which went bankrupt in 2009), that extracts the hemoglobin molecule from red blood cells (RBCs). Once the hemoglobin molecule is separated, the Company applies its proprietary co-polymer chemistry manufacturing process to stabilize and protect the hemoglobin molecule, creating an injectable intravenous drug that can carry oxygen to tissues that have reduced blood flow or reduced oxygen availability.

Currently, BXT-25 development (preclinical and phase 1) is stayed until the company raises additional capital. Once funding is obtained, the Company plans to conduct additional pre-clinical studies in stroke using BXT-25. The company has guided $7 million in funding required to advance to phase 1-ready status, and an additional $1 million to conduct a phase 1 clinical trial. The company also has future plans to explore additional drug candidates that are derivatives of BXT-25 or structurally like it, to accelerate wound healing and treat hypoxia induced damage due to hypoxia. The company also has early plans for similar diseases or conditions including cardiovascular ischemia, dementia (including Alzheimer's Disease), anemia, cancer, and non-hypoxia induced brain trauma.

To aid in clinical management, Bioxytran garnered an exclusive license for an FDA-cleared companion diagnostic, MDXViewer, which measures tissue oxygenation and is believed to be the only FDA-approved technology for specific tissue oxygenation measurements.

Stroke

One of the most obviously valuable potential treatments for a universal oxygen carrier would be stroke, aka cerebrovascular accident (CVA). This occurs either when a blood vessel supplying blood to the brain is either blocked by a clot (ischemic stroke, accounting for 87% of all strokes in the United States) or when there is cerebrovascular rupture (hemorrhagic stroke – i.e. brain bleeding). Any stroke results in poor blood-flow and oxygenation transfer to the brain, which leads to rapid neural necrosis and glial inflammation. A stroke can rapidly cause lasting brain damage and neurological deficits, short and long-term disability, and they can be fatal.

Ischemic strokes are thrombotic, where blood clots form in the brain, or embolic, where a distant clot breaks loose and lodges in a cerebral artery, blocking blood flow. Hemorrhagic strokes, on the other hand, result from the rupture of a cerebral blood vessel. The bleeding itself can cause mechanical pressure and swelling, while the leakage of blood triggers harmful inflammatory responses that further injure or kill brain cells.

Stroke Commercial Opportunity

Global costs related to strokes are estimated at $890 billon, according to the World Health Organization (2025), with $56 billion in costs incurred in the United States alone, comprising of reatment costs and missed days of work.

According to the CDC, there are approximately 795,000 stroke cases in the United States, and over 12.2 million annual cases globally, resulting in 130,000 U.S. deaths and 7 million deaths globally. The global stroke management market was valued at $36.1 billion in 2022 and is projected to reach $74 billion by 2032 according to Allied Market Research. Pharmacological troke treatment has not advanced considerably in the last 25 years despite stroke representing the second-leading cause of death and the third-leading cause disability.

BXT-25 aims to compete with existing therapies to treat stroke, but at an earlier time frame, ideally during the "golden hour" - the first hour after a stroke occurs. For the 87% of strokes that are ischemic, tissue plasminogen activator (tPA) is used to break down clots, or mechanical thrombectomy is used to remove a clot. However, these methods often have limited efficacy in rapidly restoring blood to the brain, or they are unable to be used. tPA can only be used after hemorrhagic stroke is ruled out as it can cause additional damage by increasing bleeding in that context. Thus, treatment of stroke with tPA before arrival and diagnosis at a medical facility is a void in the treatment paradigm potentially addressable by BXT-25.

tPA also has a maximum treatment window of 4.5 hours. In a somewhat recent study, the window was more conservative at 3 hours, but only ~25% of stroke patients were able to arrive within 3 hours of stroke onset, limiting tPA administration to between 3% - 8.5% of patients (depending on location). Similarly, thrombectomy is only used in ~9% of patients.

Reducing the time between stroke onset and treatment administration (aka "time to needle") is critical to improving stroke recovery outcomes. For patients with a typical large vessel occlusion (LVO), ~120 million neurons are lost hourly, equating to 3.6 years of brain aging for each hour without treatment.

BXT-25 Overview

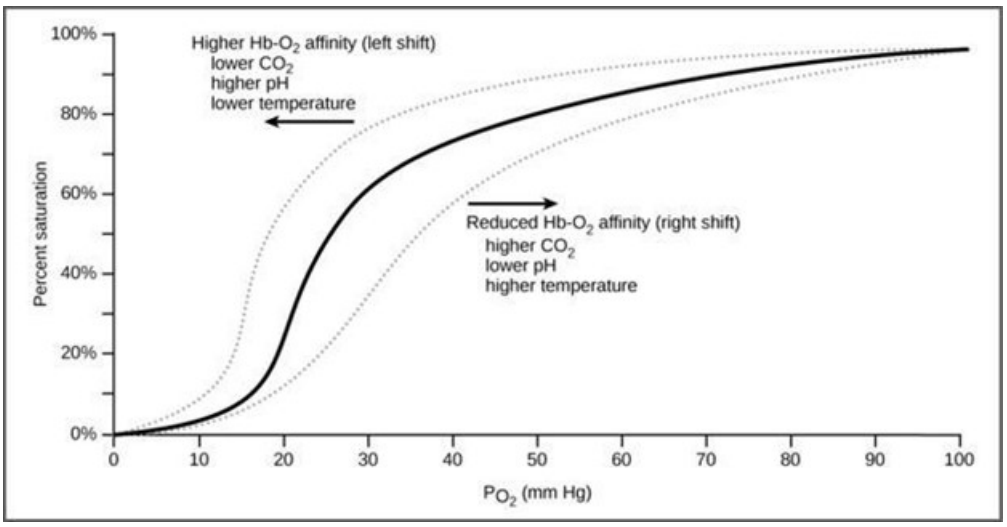
The Company's primary universal oxygen carrier, BXT-25, is a small molecule therapeutic designed to transport oxygen, and is composed of bovine hemoglobin stabilized with a proprietary co-polymer. BXT-25 integrates heme, the oxygen-carrying component of human red blood cells (RBCs), with a co-polymer to ensure stability and increase half-life within the bloodstream. The manufacturing process begins with isolating hemoglobin from bovine RBCs, followed by heme extraction. The heme is then stabilized using co-polymer.

BXT-25 molecules are approximately 5,000 times smaller than erythrocytes (red blood cells), enabling them to circulate in the blood, collect oxygen from the lungs, and release the oxygen to tissues with lower oxygen levels, just as erythrocytes do. Upon infusion, BXT-25 delivers oxygen to the brain in under three minutes. Its oxygen affinity closely resembles that of human RBCs, and as such it is not anticipated to cause adverse effects as some oxygenation treatments like hyperbaric oxygen therapy (HBOT) are known to. Without HLA matching required, BXT-25 is non-immunogenic and universally compatible with all blood types. Its low viscosity further facilitates safe oxygen delivery to the brain.

BXT-25 exhibits several critical attributes that enhance its utility and potential to improve outcomes for stroke patients:

1. Molecular Size: At 5,000 times smaller than an RBC, BXT-25 is designed to navigate blocked arteries and deliver oxygen to hypoxic tissues more effectively than RBCs, reaching oxygen-deprived areas with greater efficiency. BXT-25 is envisioned to transport oxygen to the brain during the early stages of a stroke when blood flow is obstructed and is being developed for use in both hospital and pre-hospital settings to treat brain ischemia caused by stroke.
2. Universal Compatibility: Lacking the antigens found on RBC surfaces that determine blood type, BXT-25 is potentially compatible with all blood types, simplifying its use across diverse patient populations.
3. Versatility and Storage: BXT-25's ability to be lyophilized and stored at room temperature for extended periods supports its potential inclusion in triage kits for ambulances and first responders. This "oxygen bridge" could sustain patients during the critical early hours post-stroke. Its applicability to both ischemic and hemorrhagic strokes allows for rapid administration without prior diagnostic imaging, serving as a temporary measure until comprehensive treatments are available.
4. Safety: Composed of FDA-approved heme and a benign co-polymer, BXT-25 leverages materials generally recognized as safe, supporting a favorable safety profile.

Regarding safety, other oxygenation delivery methods can cause over oxygenation which has undesirable adverse effects (such as HBOT). Since BXT-25 utilizes heme like red blood cells do, it is expected to exhibit the Bohr-Haldane effect, which describes the competitive affinities of CO2 and H+ versus O2 for hemoglobin. When oxygenated hemoglobin enters a low-oxygen environment, the low partial pressure of oxygen encourages the oxygen to dissociate from the hemoglobin and diffuse into the tissue. Because of the higher concentrations of CO2 and H+, these will bind to heme and be transported out of the tissue. The opposite effect is seen at the lungs where CO2 is dissociated and O2 is loaded for transport.



Bohr-Haldane Effect

Heme's role in managing oxygen and carbon dioxide levels is critical for respiration homeostasis, and BXT-25 is designed to mimic this core natural function. Furthermore, Bioxytran's MDXViewer is envisioned to be used to measure tissue oxygenation to potentially help tailor the the dose of BXT-25 administered by monitoring local tissue metabolism.

BXT-25: Proof of Concept

BXT-25, and compounds with similar chemistry and mechanism of action as BXT-25, have been used successfully in pre-clinical studies, providing promising proof-of-concept.

One study (Critical Care Research and Practice, Vol. 2014, Article ID 864237) investigated the effects of a highly purified hemoglobin-based oxygen carrier (HBOC) on hemodynamics, metabolic correlates of oxygen debt, and tissue oxygenation in dogs subject to controlled hemorrhagic shock. Positive effects on all variables associated with oxygen delivery and tissue oxygen tension (tPO2) were observed without any significant observed increases in pulmonary artery blood pressure. This lead to better recovery compared to control.

Further Harvard University studies yielded promising results, including absence of nitric oxide scavenging, no increased blood pressure in diabetic mice, and stroke recovery in rats. Despite HBOCs' demonstrated ability to improve blood oxygen content and tissue oxygen delivery, resulting in stroke recovery in preclinical in vivo studies, clinical use of HBOCs remain controversial due to the production of oxidative stress and vasoconstriction when HBOCs break down too quickly, and the heme binds nitric oxide (aka NO scavenging), an important vasodilator. The finding that HBOC-stabilizing co-polymer can shield the heme protein, eliminating both NO scavenging and increased blood pressure, even as the drug transported oxygen, is a very significant finding that addresses the practical shortcomings of prior un-shielded HBOCs.

MDXViewer

To support BTX-25 development, Bioxytran exclusively licensed an FDA-cleared tissue oxygenation measurement technology, MDXViewer, from MDX Lifesciences. This technology allows for real-time tissue oxygenation (not arterial oxyge) measurements, including improved oxygenation of brain tissue during BXT-25 administration. MDXViewer enables the proof of oxygen delivery to specific tissue, providing a quantitative clinical endpoint directly related to BXT-25's mechanism of action.

Competitive Landscape

There are several other companies developing galectin inhibitors, with many (rightly so) focused on galectin-3 inhibition. Few of these are complex carbohydrate drugs, and none are focused on antiviral therapy. However, these peers are generally focused on degenerative diseases and inflammatory diseases, as well as oncology.

Galectin-3 Inhibitor Competition

Galectin-3 research has exploded in recent years; accumulating evidence suggests that galectin-3 plays a major role as an amplifier of degenerative and inflammatory diseases across a wide range of human tissues, including the heart, brain, kidney, lung, and liver. Additionally, many cancers are associated with high galectin-3, which often correlates with poor prognosis, increased metastasis and cancer growth, as well as immune impairment.

The most advanced galectin-3 inhibitors are being tested in liver and lung fibrosis, as well as cancer immunotherapy and Alzheimer's Disease. Earlier stage drugs are being tested in heart disease and Alzheimer's.

Galectin-3 inhibitors fall into one of three categories:

1. protein-based inhibitors, including TrueBinding's TB006, an anti-gal-3 monoclonal antibody (mAB)
2. small molecules advanced by companies like Galecto Biotech (GB1211),
3. complex carbohydrate multivalent inhibitors such as Galectin Therapeutics' galacto-arabino-rhamnogalacturonan "belapectin" (formerly GR-MD-02).

A selection of these leading galectin inhibitor candidates are shown in a competitive matrix below.

Galectin Inhibitor Companies: Competitive Matrix				
Company	Ticker	Approximate Market Cap ($ millions)	Indication(s): (Primary) *(Secondary)*	Phase(s) (Primary) *(Secondary)*
Galectin Therapeutics	NASDAQ: GALT	225	MASH Cirrhosis *HNSCC Combination Immunotherapy*	Phase 2b/3 Completed *Phase 2*
Galecto Biotech	NASDAQ: GLTO	5	NSCLC Combination Immunotherapy *Liver Cirrhosis*	Phase 2b/3 *Phase 2*
TrueBinding	N/A	Estimate: >500	Alzheimer's *Autism* *Parkinson's*	Phase 2 *Phase 2* *Phase 2*
Bioxytran	OTCMKTS: BIXT	8	COVID-19 *Influenza*	Phase 3 (India) Phase ½ (USA) *Preclinical*

Galectin Therapeutics

Galectin Therapeutics is developing its lead galectin-3 inhibitor, belapectin, for the treatment of MASH cirrhosis with clinically significant portal hypertension (CSPH). MASH cirrhosis is an advanced stage of metabolic associated steatohepatisis (MASH), where the liver becomes inflamed due to metabolic stress and the accumulation of fat (within hepatocytes). Over time, chronic inflammation and regenerative responses can cause liver scarring (fibrosis). Significant and arguably irreversible scarring of the liver is referred to as cirrhosis.

Galectin's phase 2b/3 NAVIGATE clinical trial evaluated the effects of belapectin in treating MASH cirrhosis with CSPH, for which there are no approved therapies aside from a liver transplant. The company's previous phase 2 clinical trial suggested that belapectin may prevent the development of esophageal varices in patients with compensated NASH (now referred to as MASH) cirrhosis.

Variceal development is caused by increased portal pressure, and they eventually are prone to bleed. Variceal bleeds are a life threatening event and represent liver decompensation, which also leads to death.

Galectin Therapeutics is also exploring its galectin inhibitors in combination immunotherapy clinical trials. Initial cancer studies evaluated belapectin in combination therapy for the treatment of advanced melanoma as well as head and neck squamous cell carcinoma (HNSCC). The company also conducted a successful exploratory phase 2a trial of belapectin (formerly GR-MD-02) in patients with plaque psoriasis.

Galecto Biotech

Galecto Biotech AB, with collaborators Syneos Health and bioRASI, conducted a phase 2 trial using GB0139, a galectin-3 inhibitor, to evaluate its utility in treating idiopathic pulmonary fibrosis (IPF). GB0139 (formerly TD139) was administered by dry powder inhalation over 52 weeks. Unfortunately, the patients given GB0139 fared worse than placebo and as such GB0139 was discontinued.

It is likely that intracellular binding of galectin-3 by small molecule galectin-3 inhibitors rather than larger carbohydrate-based extracellular galectin-3 inhibitors may be attributable for the decrease the tolerability profile of this small molecule galectin-3 inhibitor compared to the pristine safety profile of other extracellular galectin-3 inhibitors like belapectin and ProLectin-M.

Galectin-3 blocking intracellularly, as Galecto does, might be specifically problematic in chronic diseases such as IPF or MASH cirrhosis due to significant fibrosis, inflammation, and hypoxia causing cellular stress. This would predispose liver cells toward cell death (apoptosis), resulting in cells upregulating cell survival pathways, which include intracellular galectin-3, an inhibitor of apoptosis due to cytochrome c release due to interactions with Bcl-2 and Bax proteins. When intracellular galectin-3 is blocked by such small molecule inhibitors like GB0139, or even the latest inhibitor in Galecto's pipeline, GB1211, under conditions of chronic stress, it may lead to increased cell death.

The most direct mechanism of cell death signaling through hypoxia is protected by intracellular galectin-3, as inhibiting intracellular galectin-3 may release Bax to begin cytochrome c-mediated apoptosis.

Due to these safety concerns, Galecto's phase 2 trial of GB1211 in liver cirrhosis is at risk of a similar outcome as its prior phase 2 IPF trial, and these safety concerns could account for the company's very low market capitalization.

TrueBinding

TrueBinding is pursuing the development of its lead candidate, TB006, a monoclonal antibody (mAB) that binds galectin-3. The company is private but has puportely raised over $200 million since its inception, and has completed a phase 1b/2 trial where patients were dosed for a short 5 weeks. The company reported several statistically significant or near statistically significant findings, including improved cognition well after the treatment period concluded.

Since these results, the FDA has renewed the company's expanded access program for Alzheimer's, and the company has started an investigator initiated trial using TB006 to treat adult autism spectrum disorder. Furthermore, the FDA accepted the company's investigation new drug (IND) application for testing TB006 in Parkinson's Disease.

Projections

In our revenue projection model for ProLectin, we assume that ProLectin-M garners development and commercialization milestone payments as well as back-end royalties on net sales (8%), with an overall probability of success of 16%. We estimate a current 3.5 million U.S. COVID-19 prescriptions, noting current drug-drug interactions limiting the potential use of Paxlovid in at-risk patients, and its lack of use in otherwise healthy patients. We assume a market penetration of 15% and we model U.S. sales of $981 million in 2034.

We also assume that BXT-25 garners development an commercialzation milestone payments as well as single digit royalties (7%) on net sales, with an overall probability of success of 10%. We estimate a current 795 thousand strokes annually, with a 20% market penetration in 2034 resulting in $1.88 billion in U.S. net sales.

Not included in our valuation projections are potential revenues from galectin inhibitor use as an antiviral against avian flu, delivered potentially by adding to poultry feed. This represents revenue potential of up to $220-440 million annually in the United States alone, with low development costs and high margins.

Financials

Below we provide the estimated financials for Bioxytran as the company currently stands (without development and commercialization partnerships). In contrast, our valuation model incorporates a partnership that fully supports Bioxytran's development of BXT-25 and ProLectin-M. The financials below represent Bioxytran's estimated financials before any development and commercialization partnership or lincesing activities take place. In these estimated figures, we assume Bioxytran continues funding its operatins with financings.

Income Statement							
December Year-End (US$m)	2024A	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Product Sales	-	-	-	-	-	-	-
Grants	-	-	-	-	-	-	-
Upfront & Milestone Payments	-	-	-	-	-	-	-
Royalties	-	-	-	-	-	-	-
Operating Expenses	2.4	2.5	2.6	2.8	2.9	3.0	3.2
Operating Income	(2.4)	(2.5)	(2.6)	(2.8)	(2.9)	(3.0)	(3.2)
Income Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income	(2.4)	(2.5)	(2.6)	(2.8)	(2.9)	(3.0)	(3.2)

Balance Sheet						
December Year-End (US$m)	2024A	2025E	2026E	2027E	2028E	2029E
ASSETS						
Current Assets:						
Cash & Cash Equivalents	0.0	0.0	0.0	0.0	*0.0*	0.0
Prepaid Expenses	0.0	0.0	0.0	0.0	0.0	0.0
Total Current Assets	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.1	0.2	0.2	0.2	0.2	0.2
TOTAL ASSETS	0.14	0.13	0.15	0.16	0.18	0.20
LIABILITIES & SHAREHOLDERS' EQUITY						
Current Liabilities:						
Accounts Payable & Accrued Expenses	0.4	0.4	0.4	0.4	0.4	0.4
Other	1.5	1.5	1.5	1.5	1.5	1.5
Total Current Liabilities	1.9	1.9	1.9	1.9	1.9	1.9
Other	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL LIABILITIES	1.9	1.9	1.9	1.9	1.9	1.9
Common Stock	0.1	0.1	0.1	0.1	0.1	0.1
Additional Paid-In Capital	17.0	17.0	17.0	17.0	17.0	17.0
Accumulated Deficit	(18.9)	(18.9)	(18.9)	(18.9)	(18.9)	(18.9)
TOTAL SHAREHOLDERS' EQUITY	(1.8)	(1.8)	(1.8)	(1.8)	(1.8)	(1.8)

Cash Flow Statement						
December Year-End (US$m)	2024A	2025E	2026E	2027E	2028E	2029E
Operating Activities						
Net Profit/(Loss)	(2.4)	(2.5)	(2.6)	(2.8)	(2.9)	(3.0)
Adjustments:	0.0	0.0	0.0	0.0	0.0	0.0
Share-based Compensation	0.3	0.3	0.3	0.4	0.4	0.5
Share-based Payments to Vendors	0.3	0.4	0.4	0.5	0.5	0.6
Other	0.5	0.0	0.0	0.01	0.0	0.0
Changes in Assets & Liabilities:						
Prepaid Expenses	0.0	0.0	0.0	0.0	0.0	0.0
Accounts Payable & Accrued Expenses	1.2	0.0	0.0	0.0	0.0	0.0
Other						
OPERATING CASH FLOW	(0.1)	(1.8)	(1.9)	(1.9)	(2.0)	(2.0)
Investing Activities						
Acquisition of property, plant & equipment	0.0	0.0	0.0	0.0	0.0	0.0
Other	0.0	0.0	0.0	0.0	0.0	0.0
INVESTING CASH FLOW	0.0	0.0	0.0	0.0	0.0	0.0
Financing Activities						
Proceeds from issue of shares	0.1	1.8	1.9	1.9	2.0	2.0
Proceeds from registered Direct offering	-	-	-	-	-	-
Pre-funded warrant exercise	-	-	-	-	-	-
FINANCING CASH FLOW	0.06	1.8	1.9	1.9	2.0	(2.0)
Net change in cash						
Cash at Beginning of period	0.0	0.0	0.0	0.0	0.0	0.0
Cash at end of period	0.0	0.0	0.0	0.0	0.0	0.0

Board and Management

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 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 expert 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 analysts on Wall Street. He is also the founder of an Investor Relations Firm.

Independent Board of Directors

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, D.V.M., 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 D.V.M. degree from Tuskegee Institute and an M.S. degree in pathology from the College of Veterinary Medicine at Michigan State University.

Radka Milanova, Director

Dr. Milanova led five Investigational New Drug Applications (IND) and two successful New Drug Applications (NDA). She was instrumental in a number of research and development programs that ultimately led to eight granted patents and seventeen publications. Dr. Milanova has unique insight in practical pharmaceutical development as well as a deep background in business development and licensing which will be beneficial for Bioxytran. She holds a PhD in Organic Chemistry form Simon Fraser University, in Canada. During her career she has held a number of executive positions in various biotechnology companies.

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