



August 22, 2013

Company Profile

OTC.QB: BTHE

Last Price: \$0.44
(August 22, 2013)

Sector:
Healthcare

Industry:
Biotechnology

52 Week Range:

Low \$.15
High \$.60

Market-Cap: \$9.6 M

Shares: O/S 19.3 M

% Insider: 69.14%

1-Year Target Est.
(Mean Avg.): 1.05
Taglich Brother

David Platt, Ph.D., CEO, Boston Therapeutics said "We are focused on commercializing PAZ320 as the first compound in a new class of therapies for post-meal blood sugar, called carbohydrate hydrolyzing enzyme inhibitors (CHEI)."



Boston Therapeutics Inc.

Boston Therapeutics, Inc. (OTC.QB BTHE) is a clinical stage, publicly traded pharmaceutical company focused on developing novel drug products that potentially address areas of high unmet medical need in the treatment of diabetes and inflammatory diseases. The Company has two development stage products and an over the counter dietary supplement. The Company's product development efforts are guided by specialists in complex carbohydrate chemistry. BTHE has a unique approach that is expected to create safe and efficacious drug candidates that can be combined with existing therapies and potentially deliver valuable products in areas of high unmet medical needs. Its lead product PAZ320, is a GRAS (Generally Regarded as Safe) status product that is being developed for the reduction of post-meal elevation of blood glucose and can potentially be used in combination with Metformin, the most widely prescribed diabetes drug with more than 50 million prescriptions annually in the U.S. alone.

Carbohydrates serve a basic role in normal cell functions as well as in major disease pathologies such as cardiovascular disease, inflammatory diseases and cancer. Consider diabetes, as uncontrolled diabetes can result in micro and macrovascular complications, tighter but safe glycemic control is required.

PAZ320, Boston Therapeutics leading compound is a non-systemic, non-toxic chewable complex carbohydrate-based compound for its ability to lower post-meal elevation of blood glucose, and thus as a treatment to delay, or prevent the onset of Type 2 diabetes and related complications such as heart disease, stroke, kidney damage, retinopathy and diabetic foot. **PAZ320** is a complex polysaccharide to be taken before meals; it operates in the gastrointestinal tract to block the action of carbohydrate-hydrolyzing enzymes that break down carbs in foods during digestion, lowering the amount of available glucose absorbed via the intestine. This treatment has demonstrated positive results in a Phase II clinical trial in patients with Type 2 diabetes.

IPOXYN™ is a carbohydrate-based intravenous solution that can potentially prevent necrosis, or cell death, and treat hypoxic conditions such as diabetic foot ulcers and other vascular complications of diabetes. Hypoxia is a condition in which cells lack sufficient oxygen supply to support metabolic function. The patented IPOXYN carbohydrate molecule contains oxygen rechargeable iron which picks up oxygen in the lungs, is 5,000 times smaller than a red blood cell (RBC), and can reach hypoxic tissue more effectively than RBCs. IPOXYN is stable at room temperature, has a five year shelf life and requires no blood type matching. BTHE is planning to introduce this product in a clinical trial for hypoxic medical conditions. This is a new approach to treatment of ischemic tissue and prevention of necrosis is fundamentally different; it is a New Chemical Entity, not a biologic blood substitute.

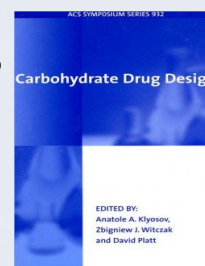
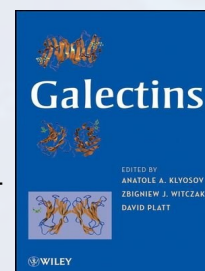
OXYFEX™, a veterinary compound, reflecting an unmet need for blood replacement and oxygen delivery to damaged or ischemic tissue due to trauma, surgery anemia and other disease conditions. Potential application, **IBD**, pectin might help decrease the inflammatory response in the colon by moderating the amounts of pro-inflammatory cytokines and immunoglobulin's, and might help to reduce inflammation in a dose-dependent manner. **BTI-9**, the polysaccharide compound has been shown to bind to tumor necrosis factor alpha (TNF- α) and thereby block immune system activation and inflammation and is being designed for colon health.

Product	Description	Indication	Development Status				
			R&D	Preclin.	Phase 1	Phase 2	Phase 3
PAZ320	Chewable tablet that manages blood sugar	Type 2 Diabetes	➔				
IPOXYN™	Injectible anti-necrosis drug	Lower-limb ischemia in diabetic patients	➔				

Complex Carbohydrate Chemistry Platform

Carbohydrates have been shown to play a fundamental role in normal cell functions as well as in major disease pathologies including cancer, cardiovascular disease and inflammatory diseases. As a class of molecules, carbohydrates have an enormous range of shape, orientation and composition. Due to this structural diversity, carbohydrate chemistry can be applied to develop a broad range of complex therapeutic molecules and drugs, including pure carbohydrates as well as protein-linked carbohydrates, or glycoproteins. However, as a consequence of their structural complexity, carbohydrates have not received as much scientific attention as nucleic acids and proteins. We view this technology gap as a unique opportunity to apply our expertise in carbohydrate engineering to develop therapeutic molecules for unmet medical needs.

Boston Therapeutics' technology platform in applied carbohydrate chemistry has been pioneered by our CEO David Platt and his scientific collaborators over the last 20 years and is summarized in two recent books that he co-edited, "Carbohydrate Drug Design (2006)" and "Galectins (2008)". Our deep domain experience in engineering complex carbohydrates has enabled us to pursue a unique pipeline of carbohydrate-based therapeutics that addresses unmet medical needs both safely and effectively for both oral and injectable applications. These proprietary formulations include modified versions of mannan and pectin, as well as a number of other proprietary and beneficial polysaccharides.



Boston Therapeutics Inc. - Investment Highlights

- BTHE's lead product, PAZ320, represents a near term commercial opportunity in the large and growing \$35B diabetes drug market.
- Potential to combine PAZ320 with Metformin, the most prescribed diabetes drug with 50M prescriptions annually, represents a compelling value creation opportunity.
- The PAZ320 profile is enhanced due to its GRAS (Generally Regarded as Safe) classification, and 505(b)(2) accelerated development pathway for FDA approval.
- BTHE's founder, David Platt, is a world renowned scientist and developed or co-developed the core technologies that are the basis of four public companies, Galectin Therapeutics (NASDAQ: GALT), SafeScience, LaJolla Pharmaceuticals, and BG Medicines who benefitted from Dr. Platt's research.
- BTHE's expertise in carbohydrate chemistry enables it to fill the development pipeline with IP protected candidates such as PAZ320 and IPOXYN with more to follow.
- Boston Therapeutics brings its expertise in complex carbohydrate chemistry to bear on the development and commercialization of prescription therapies and over-the-counter dietary supplements for diabetics. The US market for diabetes drugs is projected to grow to \$36 billion by 2017.
- The company's product pipeline is headed by PAZ320, a non-systemic enzyme inhibitor that limits after-meals glucose levels. PAZ320, a potential treatment for Type 2 diabetes is about to enter a phase III trial, and should be launched in 2017 if it clears regulatory hurdles. Preclinical work on IPOXYN, a hypoxia treatment developed for lower limb ischemia in diabetics, has been completed.
- **SUGARDOWN**, an over-the-counter enzyme inhibitor proven to manage after-meal glucose levels, is currently BTHE's only commercialized product.



Boston Therapeutics Inc. - Milestones

Product	2013	2014	2015	2016
PAZ320	Publish Phase II Data Initiate Phase II trial in France	Pivotal study initiation Initiate Phase III international trial Phase III study finalized	Clinical studies report finalized	New Drug Application (NDA)
IPOXYN	Initiate pre-clinical experiments	Short term toxicity studies Pre-IND meeting with FDA	IND application	First in human study indication

PAZ320 is a non-systemic, non-toxic, chewable drug candidate for prevention of diabetes and its complications. PAZ320 inhibits the enzymes that release glucose from complex carbohydrate in foods during digestion, reducing the amount of available glucose absorbed through the intestine. It's believed PAZ320 is a safe and effective drug compound for people with pre-diabetes and diabetes in their daily management of blood glucose levels, fulfilling an unmet medical need. This compound may provide individuals with a means by which to slow the onset of Type 2 diabetes and/or the onset of diabetes complications such as heart disease, stroke, kidney damage, retinopathy and Diabetic Foot. PAZ320 will require FDA approval for marketing as a drug and will be subject to extensive regulation by governmental authorities in the United States and other countries.

Status of Development of PAZ320

On June 22, 2012, the Company announced that it has completed enrollment in a Phase II clinical trial to evaluate the safety and efficacy of PAZ320 when added to oral agents or insulin in patients with Type 2 diabetes at Dartmouth-Hitchcock Medical Center in Lebanon, NH. PAZ320 is a non-systemic chewable tablet designed to reduce post-meal elevation of blood glucose. On April 10, 2012, the Company announced that interim data analysis of the Phase II clinical trial showed that there were no serious adverse events from PAZ320. 24 patients with Type 2 diabetes were included in the open label, dose escalation crossover trial. The patients were adults age 18-75 with Type 2 diabetes, on insulin or oral agents, with a body mass index of 25-45 kg/m² and with an A1C of less than or equal to 9%. The A1C test is a blood test that provides information about a person's average levels of blood glucose, also called blood sugar, over the past three months. The Company expects to report Phase II final results by the second quarter of 2013.

The Company continued to focus on developing the pathway to commercialization of its lead compound PAZ320 to address blood sugar management. PAZ320 addresses unmet medical needs in the large and growing diabetes drug market, which analysts estimate at \$35 billion globally per year. PAZ320 is a chewable tablet that, when taken before meals, works non-systemically in the gastrointestinal tract to block the action of carbohydrate-hydrolyzing enzymes that break down carbohydrates into glucose. This action reduces the amount of glucose available for absorption into the bloodstream.

During the second quarter of 2013 **BTHE** requested an IND application meeting with the Food & Drug Administration (FDA), and their discussions continue regarding the trial design for our international Phase III PAZ320 trial for patients with Type 2 diabetes.

BTHE will be exhibiting at American Association of Diabetes Educators (AADE) meeting in Philadelphia on August 7-9. AADE, is a multidisciplinary membership organization for healthcare professionals who specialize in teaching patients about diabetes and how to self-manage the disease. Founded in 1973, AADE works to define the practice of diabetes education, increase patients' access to the services of diabetes educators, and provide members with the support and tools to become leaders in the field of diabetes care.





Boston Therapeutics, Inc. data from their PAZ320 Phase II clinical trial is expected to be published in the July/August issue of *Endocrine Practice*, a leading peer-reviewed journal. As the Company continues to achieve its milestones, **BTHE** looks forward to furthering our drug development and commercialization pathway for therapies that address the growing diabetes market.

The Company will feature the positive results from its Phase II clinical trial evaluating the safety and efficacy of PAZ320, in which 45 percent of patients responded with a 40 percent reduction of post-meal glucose in the blood compared to baseline in a dose-dependent manner. PAZ320 is a complex carbohydrate-based drug candidate designed to reduce the elevation of post-meal blood glucose by blocking the action of carbohydrate-hydrolyzing enzymes. There were no serious adverse events in the Phase II trial conducted at Dartmouth Medical Center in NH.

Diabetes: A Growing Epidemic

- More than 33% of the U.S. population has diabetes or is pre-diabetic
- If current trends continue, by 2050, 1 of 3 U.S. adults will have diabetes
- 26mm+ have diabetes in the U.S.; 8.3% of the population
 - 460% increase since 1980
- Type 2 diabetes is incurable and is the 7th leading cause of death in the U.S.
- The American Diabetes Association estimates the total cost of diagnosed diabetes in 2012 to be \$245 billion in the United States.
- The diabetes market contains many formulations, however, many have side effects that limit their usage and/or cause serious toxicity.

PAZ 320	Other Diabetes Drugs
<p>Non-Systemic Works in the gastrointestinal tract Less risk for side effects</p> 	<p>Systemic Typical mechanisms involve interaction with liver, kidney, pancreas and cells and have side effects</p> 

Ipoxyn™

IPOXYN™, a universal oxygen carrier, is an injectable Rx for prevention of necrosis and treatment of ischemic conditions which may lead to necrosis. IPOXYN™ oxygen carriers are in pre-clinical stage of drug development.

Necrosis and Ischemia

Cell death can occur through two main mechanisms: apoptosis and necrosis. Apoptosis is a tightly regulated process in the body and many of the intracellular proteins and enzymes involved are well characterized. Necrosis has been viewed in the past as an accidental pathological mode of cell death. Recently, evidence has indicated that some forms of necrotic cell death could be related to intrinsic cellular mechanisms.

Necrosis is always the outcome of severe and acute injury. It is involved in many pathological conditions such as, heart attack, brain injuries and stroke, and neurodegenerative diseases: such as Alzheimer’s Disease, dementia and Lou Gherig’s Disease, septic shock, liver cirrhosis, chronic hepatitis, pancreatitis, muscle necrosis, diabetes mellitus, acute or critical limb ischemia, gangrene, chronic pressure ulcers, and many others.

Necrosis occurs following ischemia (shortage of oxygen supply to the tissue due to restriction in blood supply). The only treatment available at present for necrosis is providing oxygen by a high pressure facility. Thus, there is a crucial need to develop drugs for prevention and treatment of this pathology.

Limb ischemia is a chronic condition of severe obstruction of the peripheral circulation that results in severe pain in the extremities. Due to the constriction of blood vessels, especially capillaries, red blood cells are unable to flow through them and this disruption in the microcirculation leads to the deprivation of oxygen, or ischemia. Complications include gangrenous sores and wounds that won’t heal, typically in the legs and feet. If left untreated, these lesions can result in amputation of the affected limb. Lower limb ischemia is a life-threatening complication for patients with poorly-controlled diabetes and affects 10% of the diabetic population. Brem Harold, Tomic-Canic Marjana (2007).

For decades, oxygen carriers have been developed for perfusion and oxygenation of ischemic tissue. None have yet succeeded. These products were either blood-derived elements, synthetic perfluorocarbons or red blood cell modifiers. Several of the Hemoglobin-Based Oxygen Carriers (HBOC), contained nonfunctional methemoglobin impurities. These products failed to secure FDA approval based upon either poor outcomes in clinical trials or poorly formulated product.

BTHE’s New Approach

Our approach to treatment of ischemic tissue and prevention of necrosis is fundamentally different. Boston Therapeutics’ injectable drug, IPOXYN™ is a New Chemical Entity (NCE) and not a biologic blood substitute. IPOXYN™ is a modified Heme chemical structure. A significant improvement over HBOCs, IPOXYN™ prevents methemoglobin formation associated with the adverse effects of vasoconstriction and myocardial infarction. Furthermore, because of IPOXYN™’s extremely small molecular size, roughly 1/5,000th the size of a red blood cell, IPOXYN™ is able to perfuse constricted, ischemic capillaries which are inaccessible to red blood cells. This small molecular size has particular significance in treating vascular complications of diabetes since red blood cells may already be enlarged and lower limb vasculature may be compromised.

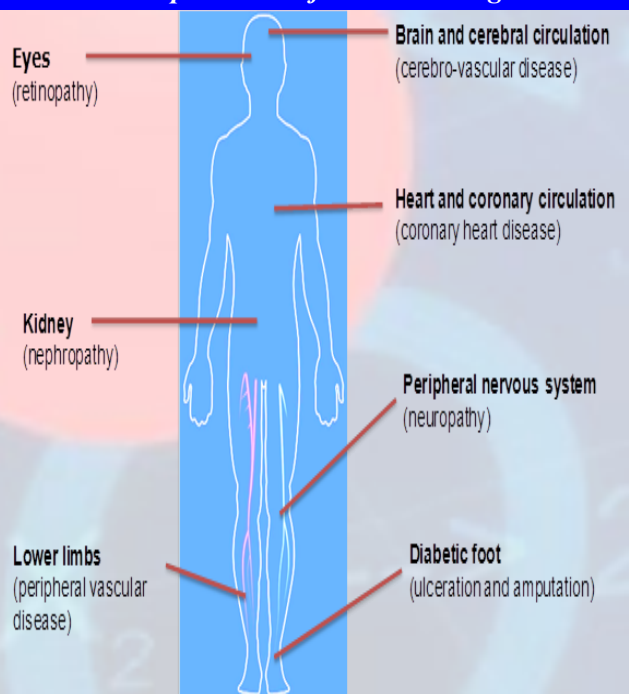
OxyFex™

OxyFex™ is the Company’s veterinary facsimile to Ipoxyn™. There is currently an unmet need in the veterinary market for blood replacement and oxygen delivery to damaged or ischemic tissue due to trauma, surgery anemia, and other disease conditions.

Ipoxyn: Market Opportunity

- **Global shortage of 110 million units of transfusion-suitable blood.**
- **The global market opportunity for anti-hypoxia or anti-necrosis technology is \$30 billion.**
- **More than 60% of non-traumatic lower-limb amputations were performed in people with diabetes.**

Complications of Diabetes Drugs



Management Team

The Company's management and advisory team has extensive expertise in complex carbohydrate chemistry, manufacturing, regulatory and clinical development, with multiple submissions and approvals to U.S. Food and Drug Administration and Environmental Protection Agency. Founders provide more than 50 years of combined expertise in public and private business management.

David Platt, Ph.D.

Chairman, Chief Executive Officer, Chief Financial Officer and Director

Dr. Platt is a world-renown expert in carbohydrate chemistry and has founded three publicly-traded companies, creating nearly \$1B for investors. He has lead two drug candidates from concept to human clinical trials. Prior to Boston Therapeutics, from 2001 to 2009, Founder, former CEO & Chairman of Pro-Pharmaceuticals, Inc. (OTC: PRWP / AMEX: PRW) Founder, former CEO, Chairman of SafeScience, Inc. He led development of two drug candidates from concept through Phase II clinical trials. Developed or co-developed core technology behind Galectin Therapeutics (Nasdaq: GALT) and LaJolla Pharmaceuticals (OTC: LJPC). Research in galectins benefitted BG Medicines (Nasdaq: BGMD).

Kenneth A. Tassej, Jr.

President and Director

Mr. Tassej has served as president of Boston Therapeutics, Inc. since November 2010. Prior to that, Mr. Tassej co-founded Boston Therapeutics, Inc. and served as Chief Executive Officer and President since its inception in June 2009 and until its merger with Avanyx Therapeutics. From 2007 to 2009, Mr. Tassej was President of TKCI, a consulting firm for commercial finance projects. Prior to TKCI, from 2005 to 2007, Mr. Tassej served as President of Liberty Shore LLC, as a consultant to businesses and to commercial and residential lenders. Mr. Tassej has a background in business management and operations.

Jonathan B. Rome

Chief Operating Officer

Mr. Rome was the Founder, President, and Chief Executive Officer of The Pharma Network, LLC, a New Jersey company focused on pharmaceutical portfolio development, licensing, sales, marketing and distribution of pharmaceuticals and active pharmaceutical ingredients, where he worked from 2000 to August 2012. Mr. Rome also was the Founder, President, and Chief Executive Officer of Ascend Laboratories, LLC, a pharmaceutical business development, sales and marketing company, selling finished products under the Ascend label to all major U.S. customers and classes of trade, where he worked from 2000 to 2012. Mr. Rome has more than 30 years of experience in the pharmaceutical industry as an executive, entrepreneur, and globally networked executive with experience throughout the global supply chain.

Anthony Squeglia

Director of Strategic Planning and Investor Relations

From 2007 to 2012, Mr. Squeglia served as Chief Financial Officer of Pro-Pharmaceuticals, Inc. (OTC: PRWP) and Galectin Therapeutics, Inc., (Nasdaq: GALT). From 2003 to 2007 Mr. Squeglia was Vice President of Investor Relations for Pro-Pharmaceuticals, Inc. and was instrumental in the Company's listing on Amex, as well as in its fund-raising activities. From 2001 to 2003, Mr. Squeglia was a Partner in JFS Advisors, a management consulting firm that delivered strategic services to entrepreneurial businesses that included raising funds, business planning, positioning, branding, marketing and sales channel development. Previously, Mr. Squeglia helped to successfully launch an IPO for Summa Four, a telecommunications switching company and held senior management positions with Unisys, AT&T, ITT and Colonial Penn. Mr. Squeglia received an M.B.A. from Pepperdine University and a B.B.A. from The Wharton School, University of Pennsylvania.



Acorn Management Partners, LLC

4080 McGinnis Ferry Rd #1101

Alpharetta, GA 30005

A Professional Relations Company

Contact: Kelly Runfola

678-736-5688

KRunfola@AcornManagementPartners.com

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