



**QUARTERLY UPDATE: August 22, 2014**

**Company Description**

Boston Therapeutics, Inc. (“the Company”) addresses the diabetes and inflammatory disease markets using complex carbohydrate chemistry (CCC) technology. The Company’s portfolio includes two development-stage pharmaceutical candidates as well as a marketed over-the-counter (OTC) dietary supplement. The OTC product, SugarDown®, is a chewable tablet designed to support healthy blood sugar levels. It is available and generating revenue in the U.S. and overseas markets. The lead pharmaceutical candidate, BTI-320, is a Phase II, non-systemic, non-toxic, carbohydrate-based tablet being evaluated as a therapy for Type 2 diabetes in patients currently taking metformin. The compound inhibits enzymes that release glucose from complex carbohydrates in foods during digestion—reducing the amount of glucose released from digested complex carbohydrates. Boston Therapeutics’ second pipeline candidate (currently in preclinical development) is Ipxoxyn (and a veterinary analog of Ipxoxyn, called OxyFex), which is a carbohydrate-based intravenous solution in development to treat hypoxic conditions caused by a lack of oxygen to living tissue, such as lower-limb ischemia stemming from severe diabetes. The Ipxoxyn molecule, which is 5,000 times smaller than a red blood cell (RBC), works by picking up oxygen in the lungs and offloading it to tissue that has been oxygen-deprived. The Company is positioned to benefit from two simultaneous paths to market—OTC and pharmaceutical drug development.

**Key Points**

- In August 2014, Boston Therapeutics reported revenue of \$65,218 for the six months ended June 30, 2014, which was an increase over revenue of \$25,454 for the comparable period a year ago. The improvement was due to an increase in sales in the second quarter 2014 versus the second quarter 2013 as well as a marketing incentive previously granted to a customer in 2013 that offset revenue during the first quarter 2013.
- During the second quarter 2014, Boston Therapeutics has made progress in several important areas. The Company is working to increase awareness and sales of SugarDown® by leveraging the product’s clinical trial data, which has included entering into a strategic marketing relationship with Benchworks SD, LLC as well as commencing a Phase IIb confirmation study in Type 2 diabetes patients. The study measures the impact of two doses of SugarDown® (versus a placebo) taken after meals for five weeks. Results are expected in 2014.
- The Company has also strengthened its core competency as an R&D organization by adding people to leadership and advisory boards who are skilled in biotechnology R&D, diabetes research, and carbohydrate chemistry. New additions include a past president of the Canadian Diabetes Association, the chair of the Department of Pharmaceutical Sciences at Wilkes University, and a past president of the American Diabetes Association, among others.
- Boston Therapeutics further advanced its development efforts for BTI-320 by securing a supply of pharmaceutical-grade BTI-320 tablets in support of a 2015 Investigational New Drug (IND) filing and forthcoming Phase III trial. A Phase IIb study of BTI-320 in the U.S. completed patient enrollment in August 2014, with data expected by late 2014.
- At June 30, 2014, the Company had a cash position of over \$1.5 million, and currently seeks to raise up to \$10 million.



**Boston Therapeutics, Inc.**  
1750 Elm Street, Suite 103  
Manchester, NH 03104  
Phone: (603) 935-9799  
Fax: (603) 685-4784  
[www.bostonti.com](http://www.bostonti.com)

Ticker (Exchange)	BTHE (OTC)
Recent Price (8/22/2014)	\$0.45
52-week Range	\$0.38 - \$1.67
Shares Outstanding	~38.4 million
Market Capitalization	~\$17.3 million
Average 3-mo. Volume	27,592
Insider Ownership +>5%	67%
Institutional Ownership	—
EPS (Qtr. ended 6/30/14)	(\$0.03)
Employees	7

**BTHE One-Year Stock Chart**



## Recent Events and Financial Results

### Recent Events

Boston Therapeutics' recent news announcements are summarized below, with full press releases available from the Company at [www.bostonti.com/news/press-releases](http://www.bostonti.com/news/press-releases).

- *On August 20, 2014*, Boston Therapeutics announced that it had completed enrollment of its Phase IIb clinical study on BTI-320 in the U.S. The study, SD-002, is being conducted by Accumed Research Associates in Garden City, NY. The U.S. trial enrolled patients with Type 2 diabetes who are currently being treated with metformin. The patients were administered BTI-320 using a randomized, double-blind, placebo-controlled, dose-ranging, three-way crossover study design. Patients' blood glucose levels were monitored and their postprandial (after-meal) blood glucose levels were measured following a test meal. The primary endpoint of the study is the evaluation of the effect of BTI-320 compared to placebo in the area under the curve (AUC) of glucose. A secondary endpoint is effect on insulin levels in the blood for four hours following intake of the meal.
- *On August 18, 2014*, Boston Therapeutics appointed noted diabetes specialist Jaime A. Davidson, M.D. to its Medical Advisory Board (biography on page 9).
- *On August 5, 2014*, Boston Therapeutics announced that it had expanded its Medical Advisory Board with the appointments of noted diabetes experts, Meng H. Tan, M.D., Philip Raskin, M.D., and Charles M. Clark, Jr., M.D., as advisors. Biographies for these individuals are provided on page 9.
- *On July 30, 2014*, Boston Therapeutics announced that it was sponsoring a symposium to be held at the American Chemical Society's Fall National Meeting in San Francisco on Monday, August 11. The symposium, titled "Rearrangement and Domino Reactions in Carbohydrate Chemistry," was organized by the American Chemical Society's Division of Carbohydrate Chemistry, and highlighted recent developments that make using a novel methodology for connecting molecules, via domino-rearrangement reactions, successful and important in studies related to the discipline of glyco-science.
- *On July 29, 2014*, the Company appointed an individual with decades of research experience, Zbigniew J. Witczak, Ph.D. (biography on page 8), to its Scientific Advisory Board (SAB). This brings the total number of Scientific Advisory Board members to six, and the addition of Dr. Witczak is anticipated to provide valuable expertise to Boston Therapeutics' future endeavors.
- *On July 9, 2014*, Boston Therapeutics appointed Benjamin Rivnay, Ph.D. (biography on page 8) to serve as its chief scientist, a newly created position. In this role, Dr. Rivnay is responsible for the development of the Company's science and technology and serves as the primary liaison to the Company's Medical Advisory Board. Dr. Rivnay reports to Rom E. Eliaz, Ph.D., chairman of the Board of Directors' Scientific Advisory Committee.

### Second Quarter 2014 Financial Results

On August 8, 2014, Boston Therapeutics reported results for its second quarter ended June 30, 2014. During this quarter, the Company reported revenue of \$21,391 versus revenue of \$2,118 for the year-ago quarter ended June 30, 2013. The growth in revenues was largely due to shipping SugarDown® to a customer during the current quarter. Gross margin also improved from the second quarter 2013 to the second quarter 2014, from a deficit of (\$5,853) in the year-ago term to a deficit of only (\$595) in the current term.

- *Research and development (R&D) expense* increased from \$19,822 in the second quarter 2013 to \$412,255 in the second quarter 2014 due to clinical trial expenses for BTI-320's Phase II.

- *Sales and marketing expense* also increased in the second quarter 2014 versus the year-ago quarter, from \$67,170 to \$84,821 due to hiring activities in support of greater sales and marketing initiatives for SugarDown® and previously engaging a marketing company.
- *General and administrative (G&A) expense* for the second quarter 2014 was \$708,436 versus \$421,570 for the second quarter 2013.

Boston Therapeutics' second quarter 2014 net loss was approximately \$1.2 million, or (\$0.03) per share, versus a net loss of \$519,238, or (\$0.03) per share, in the second quarter 2013. Weighted average shares outstanding increased by roughly 19 million from the 2013 period to the 2014 period.

### **Six Months Ended June 30, 2014, Financial Results**

On August 8, 2014, Boston Therapeutics reported results for the six-month period ended June 30, 2014. For the first six months of 2014, the Company reported revenue of \$65,218 versus revenue of \$25,454. The difference is due in part to a reduction in revenue that occurred in early 2013 when Boston Therapeutics granted a \$20,600 marketing incentive to one customer for SugarDown® product. Gross margin deficit was (\$11,326) for the first half of 2014 versus a deficit of (\$30,454) in the first half of 2013.

- *R&D expense* for the six months ended June 30, 2014, was \$681,689 versus \$48,483 for the comparable period of 2013 as a result of Phase II clinical trial activities for BTI-320.
- *Sales and marketing expense* in the first six months of 2014 were \$257,556 versus \$148,396 for the same period in 2013.
- *G&A expense* for the six months ended June 30, 2014, was over \$1.8 million versus \$949,740 for the six months ended June 30, 2013. The increase was due to a number of factors, including accounting, financial, and legal professional fees related to increased legal services, the indemnification of Dr. Platt's legal costs associated with his arbitration (which was concluded in favor of Dr. Platt in July 2014), and engaging a finance professional to manage accounting and financial reporting matters, as well as an increase in non-cash, stock-based compensation, payroll and payroll-related expenses, consulting and professional services, and severance costs associated with the resignation of the Company's former president, Kenneth A. Tassej, Jr., effective June 30, 2014.

Boston Therapeutics' net loss as of the first six months of 2014 was nearly \$2.8 million, or (\$0.07) per share, versus a net loss of close to \$1.2 million, or (\$0.06) per share, for the first six months of 2013.

The Company held cash and cash equivalents of over \$1.5 million as of June 30, 2014, versus cash and cash equivalents of roughly \$3.4 million as of December 31, 2013. Boston Therapeutics has stated that it believes its cash resources are sufficient to fund planned operations into the fourth quarter 2014. On August 15, 2014, the Company filed a preliminary Form S-1 with the U.S. Securities and Exchange Commission (SEC) for the potential raise of up to \$10 million in equity financing.

## Company Background

Boston Therapeutics, Inc. (“Boston Therapeutics” or “the Company”) is a pharmaceutical company addressing the diabetes and inflammatory disease markets. The Company is developing novel compounds based on complex carbohydrate chemistry (CCC). Its portfolio includes two pipeline candidates and a marketed over-the-counter (OTC) dietary supplement. Boston Therapeutics’ approach is to develop safe and efficacious drug formulations that can be used alone as well as in combination with currently available therapies in areas of high unmet medical need.

The Company’s most advanced pharmaceutical candidate, BTI-320, is a non-systemic, non-toxic, plant-based tablet being evaluated as a therapy for Type 2 diabetes in patients taking metformin. The drug works by inhibiting the enzymes that release glucose from complex carbohydrates in foods during digestion in order to reduce the amount of available glucose absorbed through the intestine. Importantly, the product is not intended to lower blood sugar, but rather to reduce or keep post-meal blood sugar from spiking. The Company currently markets an OTC dietary supplement, called SugarDown®, with the product indicating in its functional claims to support healthy blood sugar and indicating in preliminary studies to moderate post-meal blood glucose.

Boston Therapeutics’ preclinical-stage product candidate, Ipoxy (and veterinary analog, OxyFex), is a carbohydrate-based intravenous solution in development for prevention of necrosis (cell death) and treatment of hypoxic conditions (which occur when there is a deficiency in the amount of oxygen reaching body tissues). Ipoxy is being initially evaluated to relieve lower limb oxygen deficiency caused by severe diabetes. Ipoxy/OxyFex may be able to prevent necrosis (cell death) in both human and animal tissues and organ systems that are deprived of oxygen and are in need of metabolic support, as the drug works to pick up oxygen in the lungs and offload it to oxygen-deprived tissues.

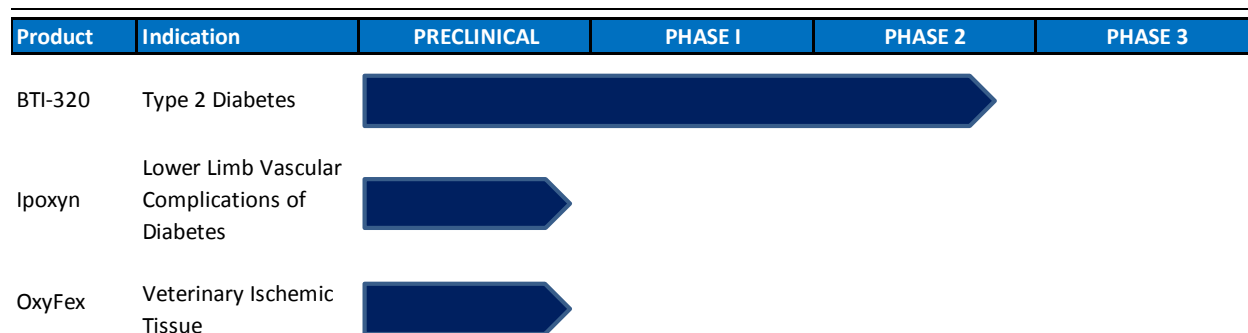
The Company’s development efforts are headed by Dr. David Platt, who is considered an authority in the CCC arena. Dr. Platt’s efforts are supplemented by input from a medical and scientific advisory board of highly experienced physicians, as described on pages 10-13 of the base Executive Informational Overview® (EIO). The EIO was published on March 26, 2014, and is available from [www.crystalra.com](http://www.crystalra.com).

Dr. Platt is an expert and pioneer in the use of galactomannan in drug design, with more than 10 patents to his name during his 30-year history of developing new technologies and building companies. As well, he is the co-editor of *Carbohydrate Drug Design* and is influential in the design of drugs using complex carbohydrates. Based on this expertise, Dr. Platt founded and has been CEO of three publicly traded companies—International Gene Group/SafeScience (now LaJolla Pharmaceutical [LJPC-NASDAQ]) in the cancer, kidney, and liver fibrosis space; Pro-Pharmaceuticals (now Galectin Therapeutics [GALT-NASDAQ]) in the liver and cancer space; and at present Boston Therapeutics in the diabetes and inflammatory disease arena.

## PRODUCT PIPELINE

Boston Therapeutics’ development efforts within the diabetes and oxygen delivery categories are outlined in Figure 1 (page 5) and in the accompanying section, and are described in greater detail on pages 14-32 of the EIO.

Figure 1  
PIPELINE



Source: Boston Therapeutics, Inc.

### BTI-320 for Diabetes

BTI-320 is a non-systemic, non-toxic, tablet in development as an adjunctive therapy for Type 2 diabetes and its complications. The compound—which is in Phase II development—works in the gastrointestinal tract to block the action of carbohydrate-hydrolyzing enzymes that break down carbohydrates into glucose. This reduces the amount of glucose available for absorption into the bloodstream. BTI-320’s molecular mechanism of action was presented in a late-breaking poster at the American Association of Clinical Endocrinologists’ (AAE) 23rd Annual Scientific and Clinical Congress in May 2014. The treatment was also overviewed at the AAE Congress for its viability for glycemic control.

The majority of anti-diabetes drugs on the market today—hypoglycemic drugs—force blood sugar levels down systemically by targeting organs, such as the pancreas and other cells within the body. This can increase the risk of side effects, as has been shown in recent Food and Drug Administration (FDA) findings. In contrast, BTI-320 offers a preemptive approach to blood sugar management by targeting enzymes in the mouth and small intestine to reduce the uptake of glucose during the digestion of carbohydrate foods—which may provide for an improved safety profile.

The active ingredient in BTI-320 is mannan. Mannans are a group of plant-derived complex carbohydrates, or polysaccharides, which consist mainly of polymers of the sugar mannose. Some of the plants from which mannans are derived include guar, locust bean, fenugreek, barley, and konjac. Published studies on mannans have shown that they possess significant biological activity—ranging from inhibiting cholesterol absorption, promoting wound healing, and inhibiting tumor growth. Studies have also shown that consuming mannan before a meal can reduce the rise in blood glucose subsequent to that meal. Therefore, supplementation with mannan may be beneficial in the management of diabetes by supporting healthy blood sugar levels.

The Company entered into a clinical trial at Dartmouth Medical Center in Lebanon, New Hampshire, for BTI-320 to measure post-prandial elevation of blood glucose. The goal was to leverage data from this study in the marketing of BTI-320. This Phase IIa trial, with results recently published in the peer-reviewed journal *Endocrine Practice*, showed that BTI-320 was well tolerated in patients taking various anti-diabetic agents, including metformin. In August 2014, a Phase IIb clinical study of BTI-320 completed patient enrollment of individuals with Type 2 diabetes who were currently being treated with metformin. At a trial location in New York, the patients are being given BTI-320 under double-blind, placebo-controlled conditions, and are then being monitored for continuous blood glucose levels and postprandial (after-meal) blood glucose levels. The main endpoints of the study are to evaluate the effect of BTI-320 versus placebo in the area under the curve (AUC) of glucose and on insulin levels in the blood for four hours following intake of a meal. Clinical results are expected in the fourth quarter 2014.

BTI-320’s safety profile has reduced risk due to its Generally Recognized as Safe (GRAS) classification.

*Anticipated IND Filing/Phase III Trial*

Boston Therapeutics aims to file an Investigational New Drug (IND) application with the FDA in 2015, in advance of a planned Phase III trial. Phase III is expected to be conducted in the U.S., Hong Kong, and China in collaboration with a U.S. diabetes clinic.

In order to prepare for the IND filing and future clinical studies, Boston Therapeutics entered into an agreement with a pharmaceutical manufacturing company, Patheon Inc., in May 2014. Under the agreement, Patheon is producing the pharmaceutical-grade BTI-320 tablets including all methods development, and analytical, stability, and other necessary testing under IND requirements. The first batch of BTI-320 was expected within six months.

Patheon Inc. is a pharmaceutical company (incorporated in Canada and with corporate offices in Durham, North Carolina), which provides contract development and manufacturing services of prescription and over-the-counter (OTC) pharmaceutical products for approximately 300 pharmaceutical and biotechnology companies. Its global manufacturing network includes approximately 6,000 employees providing services at 12 commercial contract manufacturing facilities, and nine development centers across North America and Europe.

**SugarDown® for Blood Sugar Management (Marketed Product)**

Boston Therapeutics' marketed product, SugarDown® (as shown in Figure 2), is an OTC, non-systemic, chewable dietary supplement taken prior to meals in functional claims supporting healthy blood sugar and in preliminary studies demonstrating to moderate post-meal blood glucose. The product works in the gastrointestinal tract to reduce the sharp spikes in blood sugar associated with eating carbohydrate foods.

Figure 2  
SUGARDOWN®



Source: Boston Therapeutics, Inc.

SugarDown® is currently sold over the Internet in the U.S. through the website [www.sugardown.com](http://www.sugardown.com) and by distribution partners in China, Hong Kong, Macau, and South Korea by its licensee, Advance Pharmaceutical Co. Ltd. In the first six months of 2014, Boston Therapeutics reported revenue under the agreement with Advance Pharmaceutical of \$62,366, up from \$20,688 in revenue under this agreement in the first six months of 2013.

In May 2014, Boston Therapeutics entered into an agreement with Benchworks SD, LLC. Benchworks, based in Maryland, is a full-service marketing and branding agency that has previously worked with customers including Pfizer Inc., Shire Pharmaceuticals, Noven Therapeutics, Coca-Cola, Aramark, CBRE, the islands of the Bahamas, the University of Maryland University College, and on a wide variety of other branding and product launch campaigns for medications, energy drinks, and so on. Boston Therapeutics' agreement with Benchworks is targeted at increasing brand awareness and sales of SugarDown® through a three-pronged approach:

- (1) increase awareness among people who may be at risk of developing diabetes and these patients' caregivers;
- (2) create a bond with healthcare educators and nutritionists who would recommend SugarDown® for their patients; and
- (3) strengthen the medical profile of SugarDown® by continuing to build on new data from additional clinical trial results and new scientific findings.



---

*Clinical Support for SugarDown®*

In January 2013, Boston Therapeutics announced the final results of a study conducted at the University of Sydney, showing the post-meal incremental area under the curve (iAUC) for glucose and insulin were significantly lower following consumption of SugarDown® tablets prior to a high carbohydrate meal of rice in a dose-dependent manner, resulting in, on average, a 25.5% reduction in the post-meal iAUC for glucose and a 20% reduction in post-meal insulin response for the 10 volunteers in the study. Importantly, no severe adverse effects were reported or observed throughout the study.

Phase IIb Study for SugarDown® in Type 2 Diabetes

In May 2014, Boston Therapeutics initiated a Phase IIb study to assess efficacy and safety of SugarDown® in Type 2 diabetes patients, which is already sold as a dietary supplement for moderating blood sugar levels. This study is enrolling 24 patients who are being treated with metformin alone, and assesses the impact of two different doses of SugarDown® (versus a placebo) taken after meals for five weeks. The primary endpoint is postprandial (or, “after eating”) serum glucose AUC; secondary endpoints are peak postprandial serum glucose, time to peak postprandial serum glucose, and peak blood serum excursion at two hours from baseline. This five-week confirmation study of SugarDown® will be randomized and double blinded. Results from the trial are expected to aid the branding and marketing efforts of Benchworks in positioning SugarDown® as a way to support healthy blood sugar levels. Boston Therapeutics has announced that it expects to receive results from its SugarDown® clinical studies during 2014.

Further details on the Phase IIb study, called SD-002, are available at the following website:  
[www.clinicaltrials.gov/ct2/show/NCT02135549?term=SD-002&rank=1](http://www.clinicaltrials.gov/ct2/show/NCT02135549?term=SD-002&rank=1).

**Ipxyn to Treat Ischemic Tissue and Prevent Necrosis**

Ipxyn is a carbohydrate-based intravenous solution in preclinical early stage development for hypoxic conditions—where there is a deficiency in the amount of oxygen reaching tissues—and to prevent necrosis or cell death in both human and animal tissues and organ systems when they are deprived of oxygen and in need of metabolic support. With a wide range of potential indications, Boston Therapeutics expects to initially target Ipxyn toward lower-limb ischemia stemming from severe diabetes, where this condition can lead to severe diabetic ulcers and ultimately lower limb amputation.

The Ipxyn 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. As well, Ipxyn has shown to be stable at room temperature, have a five-year shelf life, and requires no blood type matching. Lower limb ischemia is a life-threatening complication for patients with poorly controlled diabetes and affects roughly 10% of the diabetic population. The primary raw material for Ipxyn is extracted from controlled sourced bovine blood, which Boston Therapeutics states can be obtained from multiple sources at commodity prices under Good Manufacturing Practices (GMP).

OxyFex, a veterinary analog to Ipxyn, is also in development, which could be initially commercialized prior to Ipxyn. Following the launch of OxyFex, the Company plans to proceed with human trials on Ipxyn for hypoxic medical conditions. Since there is considerable commonality between the metabolic functions of humans and other mammals, the Company believes that it is appropriate for animal testing to become a starting point for many clinical development programs that can directly translate into clinical development programs for humans.

### *Current Treatments for Hypoxia or Anti-Necrosis (and Lower Limb Ischemia)*

Ipxyn seeks to address a market for hypoxia or anti-necrosis treatments—which may present a global market opportunity of \$30 billion, according to the Centers for Disease Control and Prevention (CDC). Today, there are no substitutes for human blood to deliver oxygen to the body. Despite their possible risks, standard therapy for reversing hypoxia involves blood infusions, administering RBCs, or breathing hyperbaric oxygen. Hyperbaric medicine or hyperbaric oxygen therapy (HBOT) is a medical term for using oxygen at a level higher than atmospheric pressure, though this treatment can only be done at a medical facility, with each session priced between \$200 to over \$1,000. Within the market for lower limb ischemia treatments, the most effective treatments have shown to be bypass surgery and angioplasty. In severe cases, however, where the lower limb arteries are severely damaged by disease, revascularization is likely not a possibility. In these situations, medical therapy such as anticoagulants, antiplatelet therapy, defibronogenating agents, rheologic drugs, and prostanoids are attempted, though these have largely demonstrated to be unsuccessful as they are not able to provide for significant long-term improvement.

### **Product Development Strategy**

Contingent on funding, Boston Therapeutics expects to begin Phase III trials in 2015 for BTI-320 and further development studies for Ipxyn following the introduction of OxyFex. While focused on developing novel formulations, Boston Therapeutics is also seeking to leverage development partnerships to apply its CCC drug design toward other indications. Ultimately, the Company seeks to enter into licensing, co-marketing, or co-development agreements for its products.

### **Notable Recent Additions to Executive Management and Advisory Boards**

Boston Therapeutics had seven full-time employees as of June 30, 2014. Over the past few months, Boston Therapeutics has strengthened its scientific expertise with the addition of a new chief scientist as well as expanded Scientific and Medical Advisory Boards. Brief biographies for the newest individuals to join the Company—Drs. Benjamin Rivnay, Zbigniew Witczak, Meng Tan, Philip Raskin, Charles M. Clark, Jr., and Jaime Davidson—are provided below. For a full list of the Company's executive management and Scientific and Medical Advisory Board members and their biographies, please consult Crystal Research Associates' base report on Boston Therapeutics, the Executive Informational Overview® (EIO) published March 26, 2014, and available from [www.crystalra.com](http://www.crystalra.com).

#### *Benjamin Rivnay, Ph.D., Chief Scientist*

Dr. Rivnay is an experienced director of technology and research activities within the biotechnology industry. Most recently, he was director of research and development at Formatech Inc., where he managed more than 50 projects on formulation development for a diverse group of drugs as well as studies for stability and material compatibility, initial engineering and process development activities, and preparation of non-cGMP product lots for toxicology studies and other research purposes. Prior to this, he was vice president of research and development and lab director at Repromedix Corporation, where he introduced more than 50 new test products for both male and female infertility. Earlier, he served as senior investigator and program leader at Procept Inc., where he initiated and led a new R&D program focusing on the development of anti-allergic drugs, and as senior scientist at Neurex Corporation. He holds a Ph.D. in biochemistry from The Weizmann Institute of Science and a B.Sc. in biology from Tel Aviv University.

#### *Zbigniew J. Witczak, Ph.D., Scientific Advisory Board*

Dr. Witczak is professor and chair of the Department of Pharmaceutical Sciences at Wilkes University in Wilkes-Barre, Pennsylvania, and has taught Principles of Bioorganic and Medicinal Chemistry at the Nesbitt School of Pharmacy at Wilkes University for the past 14 years. A member of the American Chemical Society, he is the recipient of numerous honors and awards, including Selected 2011 ACS Fellow of the American Chemical Society and Elected U.S. Representative to the International Carbohydrate Organization in 2006. He is the author or coauthor of more than 75 research articles in the area of carbohydrate chemistry. He received Ph.D. and M.S. degrees in organic chemistry from Medical University in Łódź, Poland.



*Meng H. Tan, M.D., Medical Advisory Board*

Dr. Tan is a professor of internal medicine (metabolism, endocrinology, and diabetes) at the University of Michigan. A past president of the Canadian Diabetes Association, senior medical director of the Diabetes Endocrine Platform Team and distinguished medical fellow of Eli Lilly and Company (LLY-NYSE), he is a member of the American Diabetes Association and fellow of the American College of Endocrinology. Dr. Tan received an M.D. from Dalhousie University.

*Philip Raskin, M.D., Medical Advisory Board*

Dr. Raskin is the Clifton and Betsy Chair in Biomedical Research and professor of medicine at the University of Texas Southwestern Medical Center in Dallas. He is also director of the diabetes clinic and former director of the University Diabetes Treatment Center at Parkland Memorial Hospital in Dallas. A member of the American Diabetes Association, he is the editor of the *Journal of Diabetes and Its Complications*. He received an M.D. from the University of Pittsburgh.

*Charles M. Clark, Jr., M.D., Medical Advisory Board*

Dr. Clark is professor emeritus of medicine at Indiana University Medical Center in Indianapolis. A past president of the American Diabetes Association, he has served as chairman of the National Diabetes Education Program Steering Committee and as editor of *Diabetes Care*. He has also served as chair of the Conference on the Worldwide Burden of Diabetes. He received an M.D. from Indiana University School of Medicine.

*Jaime A. Davidson, M.D., Medical Advisory Board*

Dr. Davidson is clinical professor of internal medicine in the Division of Endocrinology, Touchstone Diabetes Center at the University of Texas Southwestern Medical Center in Dallas. He serves as president of WorldWIDE, a non-profit diabetes education foundation, and as a member of the editorial board of *The Journal of Diabetes*. A member of the American Diabetes Association since 1974, he has also served as chair of the American Association of Clinical Endocrinologists/American College of Endocrinology Diabetes Consensus Guidelines. He received an M.D. from the Universidad Nacional Autonoma de Mexico in Mexico City. Dr. Davidson completed his post-graduate training in the U.S. with internship and residency training in Texas and his endocrinology fellowship at Indiana University School of Medicine.

## **Corporate Information**

On August 24, 2009, the Company was established as a Delaware corporation under the name Avanyx Therapeutics, Inc. On November 10, 2010, the Company, which until then focused on its injectable drug Ipxyn, entered into an Agreement and Plan of Merger with Boston Therapeutics, Inc., a privately-held New Hampshire Corporation (NH-Co.), adding the oral drug candidate BTI-320 (then called PAZ320) and SugarDown® to its product pipeline. The transaction provided for the merger of NH-Co. into Avanyx (with Avanyx Therapeutics being the surviving entity) and the issuance by the Company of four million shares of common stock to the stockholders of NH-Co. in exchange for 100% of the outstanding common stock of NH-Co. Avanyx subsequently changed its name to Boston Therapeutics, Inc.

## Key Points to Consider

- Boston Therapeutics, Inc. is focused on developing products that address the diabetes and inflammatory disease markets, employing novel complex carbohydrate chemistry (CCC) technology. The Company's portfolio includes two development-stage candidates—BTI-320 and Iproxyn (and veterinary analog OxyFex)—and a marketed over-the-counter (OTC) dietary supplement called SugarDown®. The Company is positioned to benefit from two simultaneous paths to market—OTC and pharmaceutical drug development.
- BTI-320 is a non-systemic tablet for the post-meal reduction of the elevation of blood glucose. The compound is designed to be taken before meals to inhibit the carbohydrate-hydrolyzing enzymes that release glucose from carbohydrates during digestion. BTI-320 has demonstrated a favorable safety profile with minimal side effects, in large part because it is a non-systemic method for treating diabetes. The Company is preparing documents for an IND submission with the FDA for a Phase III study. BTI-320 addresses an unmet medical need for people to manage their blood sugar, especially in those who are pre-diabetic and for people with Type 2 diabetes. Lower blood glucose is believed to slow the onset and progression of diabetes and its complications.
  - The compound's API holds Generally Recognized as Safe (GRAS) classification. The Company's strategy of combining proven compounds with novel delivery methods and pharmaceutical compositions seeks to reduce development time and costs and lower regulatory risks, while delivering valuable products in areas of unmet need to the marketplace.
  - A Phase IIa trial conducted at Dartmouth Medical Center in Lebanon, New Hampshire, showed that BTI-320 was well tolerated in patients taking various anti-diabetic agents, including metformin. Phase IIb is ongoing and has completed patient enrollment. Trial results are expected in late 2014.
- Boston Therapeutics' marketed product, SugarDown®, is an OTC, non-systemic, chewable dietary supplement taken prior to meals in order to reduce post-meal elevation in glucose. The product works in the gastrointestinal tract to reduce the spikes in blood sugar associated with eating high carbohydrate foods.
- Also in development is Iproxyn, a glycoprotein-based injectable therapeutic agent that may prove successful in reversing an inadequate supply of oxygen and support various metabolic functions in the body in a manner and with effects similar to those resulting from the infusion of RBCs—without the limitations of compatibility, availability, short shelf life, volume, and logistical challenges commonly associated with whole blood transfusions. The initial indication for Iproxyn could be lower-limb ischemia associated with diabetes.
  - Iproxyn is being targeted to both the human and animal market—where tissues and organ systems are deprived of oxygen and are in need of metabolic support.
- Boston Therapeutics' management is highly experienced, with its CEO, David Platt, Ph.D., a pioneer in designing therapeutic drugs made from carbohydrates for the past two decades. He is also the inventor or co-inventor on a number of patents and been significantly involved in the approval process for several drugs.
  - The Company is the third start-up founded by Dr. Platt—the first two were International Gene Group, whose core technology GCS-100 was acquired by Prospect Therapeutics, and is now known as LaJolla Pharmaceuticals, and Pro-Pharmaceuticals, which is now Galectin Therapeutics. Core technologies of both of these companies were either developed or co-developed by Dr. Platt.

- Boston Therapeutics' product candidates are well-differentiated formulations that address significant unmet medical needs. The Company is working to secure a robust intellectual property portfolio composed of patents, patent applications, and trademarks.
  - The technology and products are currently protected by two patent applications filed under the international Patent Cooperation Treaty (PCT) and their related national-stage applications, one provisional patent application in the U.S., and several trademarks.
  - Boston Therapeutics' patent portfolio covers three main areas: (1) mannans; (2) hemoglobin composition and methods of use; and (3) taste masking in chewable tablets.
- At June 30, 2014, the Company held cash and cash equivalents of over \$1.5 million. In August 2014, Boston Therapeutics filed a preliminary Form S-1 with the SEC for the raise of up to \$10 million.

## Risks and Disclosures

This Quarterly Update has been prepared by Boston Therapeutics, Inc. (“Boston Therapeutics” or “the Company”) with the assistance of Crystal Research Associates, LLC (“CRA”) based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this Update relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Boston Therapeutics’ statements on Forms 10-K, 10-Q, and 8-K, as well as other forms filed from time to time.

The content of this report with respect to Boston Therapeutics has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and U.S. Securities and Exchange Commission (SEC) filings. Boston Therapeutics is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Boston Therapeutics or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA’s compensation by the Company is a cash amount of thirty-eight thousand, nine hundred U.S. dollars for its services in creating the base Executive Informational Overview® (EIO) and for Updates. For more complete information about the risks involved in an investment in the Company, please see Boston Therapeutics’ most recently filed Annual Report on Form 10-K for the year ended December 31, 2013.

Investors should carefully consider risks and information about Boston Therapeutics’ business. Investors should not interpret the order in which considerations are presented in the Company’s filings as an indication of their relative importance. The risks and uncertainties overviewed in Boston Therapeutics’ Form 10-K or in Crystal Research Associates’ base EIO are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Boston Therapeutics or that it currently believes to be immaterial may also adversely affect its business. If any of such risks and uncertainties develops into an actual event, Boston Therapeutics’ business, financial condition, and results of operations could be materially adversely affected, and the trading price of the Company’s shares could decline.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. Additional information about Boston Therapeutics and its public filings, as well as copies of this report, can be obtained by calling (603) 935-9799.

Intentionally Blank.

Intentionally Blank.



Intentionally Blank.



# crystal research

a s s o c i a t e s

*Facts Without Fiction*

## QUARTERLY UPDATE: August 22, 2014

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

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

**Corporate Headquarters:**

880 Third Avenue, 6th Floor  
New York, NY 10022  
Office: (212) 851-6685  
Fax: (609) 395-9339

**Satellite Office Location:**

2500 Quantum Lakes Drive, Ste. 203  
Boynton Beach, FL 33426  
Office: (561) 853-2234  
Fax: (561) 853-2246