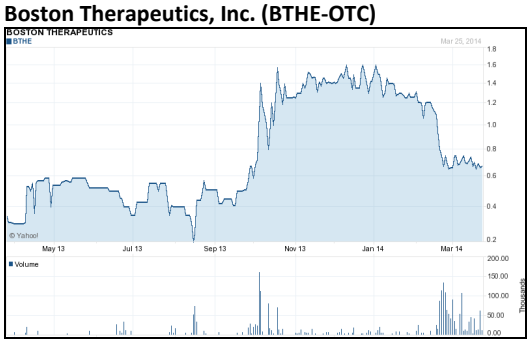
Boston Therapeutics, Inc.
1750 Elm Street, Suite 103
Manchester, NH 03104
Phone: (603) 935-9799
Fax: (603) 685-4784
www.bostonti.com

Ticker (Exchange)	BTHE (OTC)
Recent Price (03/25/2014)	$0.67
52-week Range	$0.15 - $1.67
Shares Outstanding	~37 million
Market Capitalization	~$25 million
Avg. 3-month Volume	22,872
Insider Ownership +>5%	67%
Institutional Ownership	—
EPS (Qtr. ended 12/31/2013)	($0.18)
Employees	8

Boston Therapeutics, Inc. (BTHE-OTC)



BOSTON THERAPEUTICS' PRODUCT PIPELINE

Product	Indication	PRECLINICAL	PHASE I	PHASE 2	PHASE 3
BTI320	Type 2 Diabetes				
Ipoxyn™	Lower Limb Vascular Complications of Diabetes				
OxyFex™	Veterinary Ischemic Tissue				

Company Description

Boston Therapeutics, Inc. (or "the Company") develops products to address 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 lead pharmaceutical candidate, BTI320 (formerly PAZ320), is a Phase II/III non-systemic, non-toxic, carbohydrate-based chewable 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 is Ipoxyn™ (and a veterinary analog of Ipoxyn™, 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 Ipoxyn™ 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 a Phase IIa trial, BTI320 showed a 40% reduction in elevation of post-meal blood sugar with no serious adverse events. Enrollment in Phase IIb is underway, with the Company preparing for an IND filing with the FDA for a Phase III study.
- Over 382 million people are living with diabetes, which is projected to be 592 million by 2035. By 2018, the global market for diabetes drugs is forecast to be $58 billion, up from ~$35 billion today.
- The Company's 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 in two Asian markets.
- Boston Therapeutics expects to file a registration for OxyFex™ and could begin marketing the compound for veterinary applications within 12 months of funding in a variety of locations worldwide.
- The Company holds intellectual property to protect its carbohydrate drug technology. Management is experienced in regulatory and clinical development, having made multiple submissions and approvals to the FDA. Founder Dr. David Platt is a world-renowned scientist and has developed or co-developed core technologies for three public companies.
- In 2013, the Company raised $5.6 million in support of clinical development. At December 31, 2013, its cash position was roughly $3.4 million and current liabilities were approximately $340,000.

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Executive Overview

Boston Therapeutics, Inc. ("Boston Therapeutics" or "the Company") is a pharmaceutical company addressing the diabetes and inflammatory disease markets. Uniquely positioned, 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, BTI320 (formerly PAZ320), is a non-systemic, non-toxic, plant-based chewable 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, Ipoxyn™ (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). Ipoxyn™ is being initially evaluated to relieve lower limb oxygen deficiency caused by severe diabetes. Ipoxyn™/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 individuals who are considered authorities in the CCC arena. These efforts are supplemented by input from a medical and scientific advisory board of highly experienced physicians, as described on pages 10-13. Boston Therapeutics' Founder and CEO, Dr. David Platt (biography on page 10), 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 and the accompanying section, and are described in greater detail within the Core Story on pages 14-32.

Figure 1

PIPELINE

Product	Indication	PRECLINICAL	PHASE I	PHASE 2	PHASE 3
BTI320	Type 2 Diabetes				
Ipoxyn™	Lower Limb Vascular Complications of Diabetes				
OxyFex™	Veterinary Ischemic Tissue				

Source: Boston Therapeutics, Inc.

BTI320 for Diabetes

BTI320 is a non-systemic, non-toxic, chewable tablet in development as an adjunctive therapy for Type 2 diabetes and its complications. The compound—which is currently in Phase II trials—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. 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, BTI320 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 BTI320 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 BTI320 to measure post-prandial elevation of blood glucose. The goal was to leverage data from this study in the marketing of BTI320. This Phase IIa trial, with results recently published in the peer-reviewed journal *Endocrine Practice*, showed that BTI320 was well tolerated in patients taking various anti-diabetic agents, including metformin.

BTI320's safety profile has reduced risk due to its **Generally Recognized as Safe (GRAS)** classification, and as well, has a **505(b)(2)** accelerated development pathway for FDA approval. This route permits companies to obtain FDA approval of New Drug Applications (NDAs) by relying, in part, on the FDA's findings for a previously approved drug. The benefits are many as this method may provide for a more expeditious way of achieving approval for product candidates by employing third-party data in support of a company's own clinical studies.

SugarDown® for Blood Sugar Management (Marketed Product)

Boston Therapeutics' marketed product, SugarDown®, 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. SugarDown® is currently sold over the Internet in the U.S. and by distribution partners in Hong Kong and South Korea by its licensee, Advance Pharmaceutical Co. Ltd. The product works in the gastrointestinal tract to reduce the sharp spikes in blood sugar associated with eating carbohydrate foods.

Ipoxyn™ to Treat Ischemic Tissue and Prevent Necrosis

Ipoxyn™ 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 Ipoxyn™ toward lower-limb ischemia stemming from severe diabetes, where this condition can lead to severe diabetic ulcers and ultimately lower limb amputation.

The 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. As well, Ipoxyn™ 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 Ipoxyn™ is extracted from controlled sourced bovine blood, which Boston Therapeutics states can be obtained from multiple sources at commodity prices under Good Manufacturing Practices (GMPs).

OxyFex™, a veterinary analog to Ipoxyn™, is also in development, which could be initially commercialized prior to Ipoxyn™. Following the launch of OxyFex™, the Company plans to proceed with human trials on Ipoxyn™ 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)

Ipoxyn™ 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 BTI320 and further development studies for Ipoxyn™ 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.

Manufacturing

Boston Therapeutics currently manufactures SugarDown® and BTI320 in the U.S. at a GMP-compliant facility. The Company expects to have access to a pilot-scale manufacturing facility with adequate capacity to produce Ipoxyn™/OxyFex™ for clinical trials and market introduction following European Medicines Evaluation Agency (EMEA)/FDA approval.

Corporate History

Boston Therapeutics currently has eight full-time employees. 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 Ipoxyn™, 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 BTI320 (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.

Growth Strategy

Carbohydrate molecules, which are essential to the transmission and recognition of cellular information, have been shown to play an important role in major diseases, including cancer, cardiovascular disease, Alzheimer's disease, inflammatory disease, and viral infections. However, due to their structural complexity, they have not received the degree of scientific attention as **nucleic acids** and **proteins**. Boston Therapeutics believes that there is a largely untapped market for carbohydrate compounds. Accordingly, the Company seeks to become a leading entity in developing novel compounds based on complex carbohydrate chemistry (CCC), with its efforts targeted toward treating diabetes and inflammatory disease.

Today, with over 33% of the U.S. population being either diabetic or pre-diabetic, current trends suggest that by 2050, one in three adults will be diabetic. As the seventh leading cause of death in the U.S., the American Diabetes Association estimates that the total cost of diagnosed diabetes in the U.S. is approximately $245 billion (including $176 billion in direct medical costs and $69 billion in reduced productivity). Current treatments carry their share of side effects, which can limit usage. The Company's other therapeutic targets hypoxia (a deficiency in the amount of oxygen reaching tissues) and necrosis (cell death), which can occur in individuals with stroke, heart disease, trauma, **anemia**, kidney failure, diabetic foot, and surgery, with no approved drug to treat or prevent these conditions. The worldwide market for anti-hypoxia or anti-necrosis technology is estimated at roughly $30 billion.

Following adequate funding, Boston Therapeutics expects to begin Phase III trials for BTI320 and further development studies for Ipoxyn™ within 12 months. The Company has stated that it intends to develop its most advanced clinical-stage drug candidates through approval (for BTI320, up to and including a Phase III human clinical trial designed to provide data on the drug's efficacy). Upon achieving successful results, Boston Therapeutics may elect to commercialize BTI320 alone or with a strategic partner in the U.S.; outside of the U.S. the Company may choose to out-license the rights to develop and commercialize the product. For Ipoxyn™, Boston Therapeutics may seek to enter strategic partnerships whereby the strategic partner(s) may co-fund clinical trials of the drug that are necessary for regulatory approvals and subsequent commercial sale in and outside of the U.S.

Licensing, Co-Marketing, or Co-Development Agreements

While the Company is focused on developing novel formulations, it is also seeking to leverage development partnerships to apply its CCC design toward other therapeutic indications. The Company entered into an exclusive licensing agreement with Advance Pharmaceutical Company, Ltd. (APC) to develop and market its SugarDown® product in China, Hong Kong, and Macau, as well as other Asian countries. Boston Therapeutics expects to enter into other licensing, co-marketing, or co-development agreements, benefitting from the expertise of marketing. The Company is constructing a scientific/medical advisory board composed of experienced physicians and key opinion leaders who have taken part in relevant clinical studies to assist the clinical trial process. Upon approval, Boston Therapeutics expects to market BTI320 to patients currently taking metformin—the most widely prescribed diabetes drug and a compound with 50 million prescriptions written in the U.S. each year.

Capitalize on Management Expertise

The Company expects to continue to leverage the extensive expertise of its founder and CEO, Dr. Platt, a Ph.D. chemical engineer with approximately 30 years of experience in the development of therapeutic drugs and a holder of many patents. Dr. Platt has been involved in the FDA approval process for several drugs, with this expertise vital to the Company as Boston Therapeutics develops its drugs through the clinical trial and approval process. The goal is to leverage the industry experience, expertise in CCC, and clinical development experience to identify, develop, and commercialize product candidates with solid market potential in areas of unmet medical needs—specifically targeting diabetes and inflammatory diseases.

Milestones

Completed Milestones

Boston Therapeutics has accomplished a number of significant milestones over the past 12 months, including those highlighted below, on its path toward achieving approval of its development-stage product candidates.

- *Phase IIa clinical trial results for BTI320.* Results showed a significant 40% reduction in the elevation of post-meal blood sugars with no serious adverse events.
- *Phase IIb initiated for BTI320.* The Company continues to build upon the positive results for BTI320 obtained in the Phase IIa safety and efficacy trial. A Phase IIb trial was initiated in France to assess the efficacy and safety of BTI320 in Type 2 diabetes patients as adjunctive therapy in combination with metformin. Boston Therapeutics is preparing for an additional Phase IIb in the U.S. and a Phase III multi-national trial, which could lead to BTI320 becoming an important adjunctive therapy—in combination with metformin—in treating individuals with Type 2 diabetes.
- *Initiated research study at the University of Minnesota to provide molecular-level data on BTI320 and its mechanism of action.* This study is intended to better characterize BTI320 and assess interactions of BTI320 with various carbohydrate-hydrolyzing enzymes.
- *Phase IIa clinical trial results published for BTI320 in the July/August 2013 issue of peer-reviewed journal: Endocrine Practice.* These results were published by the principal investigators, evaluating the safety and efficacy of BTI320 (demonstrating a 40% reduction in elevation of post-meal blood glucose) with no serious adverse events in patients.
- *Preparations began for an **Investigational New Drug (IND)** submission to U.S. FDA for Phase III trial in the U.S., Europe, Hong Kong, and China.* This Phase III trial is to evaluate the effects of BTI320 on post-meal glucose levels and **HbA1c** in patients with Type 2 diabetes as adjunctive therapy in combination with metformin.
- *New director appointments.* S. Colin Neill as audit committee chairman and director (biography on pages 12-13) and Conroy Chi-Heng Cheng as director (biography on page 13).
- *New management appointments*. Engaged Edward Shea as vice president of business development (biography on page 11), Tina Gagnon as director of finance (biography on page 11), Yael Bobruff as director of clinical affairs (biography on page 11), and Anthony Squeglia as chief financial officer (biography on page 11).
- *Appointed Larry K. Ellingson, Former Chair of the American Diabetes Association, as Chair of the Scientific Advisory Board* (biography on page 12).
- *Strengthened balance sheet with the closing of approximately $5.3 million in total gross proceeds from private placement of common stock and warrants to existing and new accredited investors*. Proceeds earmarked to fund ongoing BTI320 clinical trials.

Upcoming Potential Milestones

Figure 2 (page 8) outlines potential upcoming milestones being targeted by Boston Therapeutics over the next 12-18 months, noting that the Company seeks to speed up development of its two lead candidates via the FDA's 505(b)(2) regulatory pathway. This route permits companies to obtain FDA approval of new drug applications (NDAs) by relying, in part, on the FDA's findings for a previously approved drug. The benefits are many, as this method may provide for a more expeditious way of achieving approval for its product candidates by employing third-party data in support of a company's own clinical studies. In particular, a new research study at the University of Minnesota is underway, which could provide greater information as to how well BTI320's mechanism of action works non-systemically in the gastrointestinal tract to block the uptake of glucose into the bloodstream. As well, having recently raised approximately $5.6 million in gross proceeds in private and public placements, the Company continues to create awareness for its technology via conferences, the media, and through the financial and investment community.

Figure 2

POTENTIAL MILESTONES

Product	2014	2015	2016
BTI320	– File IND – Initiate Phase III pivotal study	– Finalize Phase III clinical study	– New Drug Application (NDA)
Ipoxyn™	– Initiate preclinical experiments – Short-term toxicity studies – Pre-IND meeting with the FDA	– IND application	– First in human study indication

Source: Boston Therapeutics, Inc.

Intellectual Property

Boston Therapeutics relies on patents, trademarks, trade secrets, technological know-how, and other proprietary rights, which are essential to the success of its business. The Company's technology and products are protected by an intellectual property portfolio comprising two patent applications filed under the international Patent Cooperation Treaty (PCT) and their related national-stage applications, one provisional patent application, 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. Throughout the development process and commercial scale-up of the Company's products, Boston Therapeutics anticipates further intellectual property could be realized from the creation of the chemistry, manufacturing, and controls (CMC) for each of its products.

Mannans

Boston Therapeutics holds a PCT patent application covering the composition of its chemically purified, soluble mannans from legumes seeds, and the use of these mannans in palatable dietary supplements. This patent application is vital for the Company's marketed SugarDown® product and its BTI320 product candidate in development. With regard to SugarDown®, the Company has also filed a provisional patent with the U.S. Patent and Trademark Office (USPTO) and has received a registered trademark. The provisional application is directed at compositions and methods for taste masking, which is beneficial in chewable pharmaceutical formulations.

Hemoglobin Composition and Methods of Use

As it relates to its hemoglobin technology, the Company has made significant discoveries, capitalizing on some 25 years of worldwide development expertise to create a new patent portfolio and secure proprietary positions for its technology in managing hypoxic conditions. Specifically, Ipoxyn™ is the subject of a hemoglobin compositions and methods of use PCT patent application that covers the composition of the Company's hemoglobin oxygen transport agent, consisting primarily of carbohydrate-shielded hemoglobin or hybrid hemoglobin molecules that deliver oxygen. The application also covers the use of this technology in treating hypoxia and related conditions. The Company expects to further build this patent portfolio and increase market exclusivity as clinical development progresses.

Taste Masking

In the U.S., Boston Therapeutics has filed a provisional patent application targeted toward protecting the Company's use of polymers to coat the active agents in its chewable tablets (e.g., SugarDown®). The application covers the preparation of coating pharmaceutically active agents with polymers or ion exchange resins in a manner that masks the taste but also preserves the rapid disintegration of the tablets.

Company Leadership

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. The executive management team has more than 100 years of combined experience. Biographies of these individuals, listed in Figure 3, are provided below.

Figure 3
MANAGEMENT

David Platt, Ph.D.	Chairman, Chief Executive Officer, and Director
Kenneth A. Tassey, Jr.	President and Director
Anthony Squeglia	Chief Financial Officer
Edward Shea	Vice President of Business Development
Tina M. Gagnon	Consulting Director of Finance
Yael T. Bobruff, Ph.D.	Clinical Affairs Director
Hana Chen-Walden, M.D.	Chief Medical Director (Consultant)
Peter Sheehan, M.D.	Advisor, Medical Director
Larry K. Ellingson	Chairman, Scientific Advisory Board
David Liu, Ph.D.	Scientific Advisor

Source: Boston Therapeutics, Inc.

Management

David Platt, Ph.D., Chairman, Chief Executive Officer, and Director

Dr. Platt served as president of Boston Therapeutics from the Company's inception in August 2009 through November 2010. From 2001 to February 2009, Dr. Platt was chief executive officer and chairman of the Board of Directors of Pro-Pharmaceuticals, Inc. (now Galectin Therapeutics [GALT-NASDAQ]), which he co-founded and was co-developer of the core technology. From 1995 to 2000, Dr. Platt was chief executive officer and chairman of the Board of Directors of SafeScience Inc., a NASDAQ-listed company he founded. From 1992 to 1995, Dr. Platt was the chief executive officer, chairman of the board, and a founder of International Gene Group, Inc., the predecessor company to SafeScience. He 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. Dr. Platt has published peer-reviewed articles and holds many patents, primarily in the field of carbohydrate chemistry.

Kenneth A. Tassey, Jr., President and Director

Mr. Tassey has served as president of Boston Therapeutics since November 2010. Prior to that, Mr. Tassey co-founded Boston Therapeutics 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. Tassey was president of TKCI, a consulting firm for commercial finance projects. Prior to TKCI, from 2005 to 2007, Mr. Tassey served as president of Liberty Shore LLC, as a consultant to businesses and to commercial and residential lenders. Mr. Tassey has a background in business management and operations.

Anthony Squeglia, Chief Financial Officer

From 2007 to 2012, Mr. Squeglia served as chief financial officer of Pro-Pharmaceuticals and Galectin Therapeutics. From 2003 to 2007, he was vice president of investor relations for Pro-Pharmaceuticals and was instrumental in the Company's listing on AMEX as well as in its fundraising efforts. From 2001 to 2003, Mr. Squeglia was a partner in JFS Advisors, a management consulting firm that delivered strategic services to entrepreneurial businesses, such as for fundraising, business planning, positioning, branding, marketing, and sales channel development. Previously, Mr. Squeglia helped 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 MBA from Pepperdine University and a BBA from The Wharton School, University of Pennsylvania.

Edward Shea, Vice President of Business Development

Mr. Shea is vice president of business development. He brings 25 years of bio-pharmaceutical experience in commercial development, marketing, and sales, most recently serving as senior eastern area sales director, ViroPharma, Inc. Mr. Shea's diverse experience includes more than 15 years of business development, marketing, and sales leadership positions with GlaxoSmithKine plc (GSK-NYSE) and Salix Pharmaceuticals (SLXP-NASDAQ), and business development experience with two start-up biopharmaceutical companies, ViroPharma and Critical Therapeutics. He holds a B.S. in business/marketing and an MBA from Salve Regina University in Newport, Rhode Island.

Tina M. Gagnon, Consulting Director of Finance

Ms. Gagnon has more than 20 years of experience in finance. Most recently, she served as corporate controller at Micronetics, Inc. (NOIZ-NASDAQ), where she oversaw a staff responsible for accounts receivable, accounts payable, inventory management, and other activities. Prior to this, she was controller at Amherst Technologies, LLC; assistant controller of Fruit of the Loom's Sports & Licensing Division; and senior corporate auditor at Standex International Corp. She holds a B.S. in accountancy from Bentley College.

Yael T. Bobruff, Ph.D., Clinical Affairs Director

Dr. Bobruff was most recently a postdoctoral researcher in the Department of Systems Biology at Harvard University Medical School in Boston, where she studied the genetic processes and mechanisms contributing to the evolution of host-pathogen interactions. She earned a B.Sc. in biology from the Hebrew University of Jerusalem, an M.Sc. in civil and environmental engineering, and a Ph.D. in biological science from Stanford University.

Hana Chen-Walden, M.D., Chief Medical Director (Consultant)

Dr. Chen-Walden is an endocrinologist and has specialized in regulatory affairs in the pharmaceutical industry in the U.S and Europe. She has 30 years of regulatory experience with the EMEA and in individual European countries. Since 2004, Dr. Chen-Walden consulted for European Clinical and Regulatory Consultancy in medical monitoring, quality assurance, and regulatory input for clinical studies in the fields of oncology, cardiology, diabetes, neurology, respiratory diseases, and medical devices. From 2000 to 2003, Dr. Chen-Walden was director of international regulatory affairs at Covalent Group Ltd. From 1997 to 2000, she was medical, drug safety, and regulatory director at CRC, a clinical **contract research organization (CRO)** in France. Dr. Chen Walden received a doctorate of medicine from University of Tel Aviv, Israel. She has practiced medicine in Germany and France.

Peter Sheehan, M.D., Advisor, Medical Director

Dr. Sheehan, an internationally respected specialist in the field of diabetes, is focused in the areas of peripheral artery disease, diabetic neuropathy, and wound healing. He has served as the American Diabetes Association (ADA) Foot Council Chairman, on the national Board of Directors, and currently as chairman of the Cardiometabolic Risk Initiative. Dr. Sheehan was on the Board of Directors of the Wound Healing Society and served as president of the Wound Healing Foundation. He is also a member of the Steering Committee of the P.A.D. Coalition (peripheral artery disease). He is a graduate of the SUNY-Downstate School of Medicine, where he also completed a residency

in Internal Medicine. Dr. Sheehan continued his training at the Yale University School of Medicine in New Haven and completed a fellowship in endocrinology and metabolism.

Larry K. Ellingson, Chairman, Scientific Advisory Board

In February 2014, Boston Therapeutics appointed Larry Ellingson as chairman of its Scientific Advisory Board. He is a former chairman of the Board of the American Diabetes Association, and has more than four decades of experience in drug development with an emphasis on diabetes and related diseases. Mr. Ellingson is the principal of Global Diabetes Consulting, which works with several companies as well as the North Dakota State University College of Pharmacy. He was executive director, diabetes care at Eli Lilly & Co (LLY-NYSE). He is also a former chair of the Board of Protemix Ltd., a biotechnology company focused on proteomics and the development of molecules for diabetes and related diseases. He holds an Executive MBA from Babson College and a B.S. in pharmacy from North Dakota State University.

David Liu, Ph.D., Scientific Advisor

Dr. Liu currently serves as vice president, research and development at HDM Systems Corp., managing the development of power electronic devices for battery-based systems used in transportation and green energy storage applications. In his previous work as a research scientist in the Biomedical Research Department at St. Elizabeth's Medical Center, Tufts Medical School, Dr. Liu contributed to the fundamental understanding of the red blood cell (RBC) membrane architecture, the molecular pathophysiology of various hereditary hemolytic anemia and identification of critical protein domains of RBC surface receptor for malaria invasion. He has published over 60 research papers on these subjects in a variety of prominent journals. He subsequently served as chairman of the board of International Power Devices, Inc. (IPD), a producer of high-density DC/DC power supply devices used by telecommunication and data communication companies, such as Cisco and Nortel Networks. Since 1992, Dr. Liu has been an associate professor of medicine, Tufts University School of Medicine, Boston, Massachusetts. Dr. Liu received a Ph.D. in biochemistry from Carnegie-Mellon University.

Board of Directors

David Platt, Ph.D., Chairman, Chief Executive Officer, and Director

Biography on page 10.

Kenneth A. Tassey, Jr., President and Director

Biography on page 10.

S. Colin Neill, Audit Committee Chairman and Director

Mr. Neill became president of Pharmos Corporation in January 2008, and has served as CFO, secretary, and treasurer of Pharmos since October 2006. Prior to becoming president, he also served as senior vice president from October 2006 to January 2008. From September 2003 to October 2006, Mr. Neill served as CFO, treasurer and secretary of Axonyx Inc., a biopharmaceutical company that developed products and technologies to treat Alzheimer's disease and other central nervous system disorders, where he played an integral role in the merger between Axonyx and TorreyPines Therapeutics Inc., a privately-held biopharmaceutical company. Mr. Neill served as senior vice president, CFO, secretary and treasurer of ClinTrials Research Inc., a $100 million publicly-traded global CRO in the drug development business, from 1998 to its successful sale in 2001. Following that sale from April 2001 to September 2003, Mr. Neill served as an independent consultant, assisting small start-up and development-stage companies in raising capital. Earlier experience was gained as vice president finance and CFO of BTR Inc., a $3.5 billion U.S. subsidiary of BTR plc, a British diversified manufacturing company, and vice president financial services of the BOC Group Inc., a $2.5 billion British-owned industrial gas company with substantial operations in the healthcare field. Mr. Neill served four years with American Express Travel Related Services, first as chief internal auditor for worldwide operations and then as head of business planning and financial analysis.

Mr. Neill began his career in public accounting with Arthur Andersen LLP in Ireland and later with Price Waterhouse LLP as a senior manager in New York City. He also served with Price Waterhouse for two years in Paris, France. Mr. Neill graduated from Trinity College, Dublin with a first class honors degree in business/economics and holds a Master's degree in accounting and finance from the London School of Economics. He is a Certified Public Accountant in New York State and a Chartered Accountant in Ireland. Mr. Neill served on the board of Galectin Therapeutics (formerly Pro Pharmaceuticals) from May 2007 to October 2011 and from April 2004 to June 2008 on the board of OXIS International, Inc.

Dale H. Conaway, D.V.M., Director

Dr. Conaway, a director since September 2009, is the chief veterinary medical officer for the Office of Research Oversight, an office within the Veterans Health Administration under the U.S. Department of Veterans Affairs. From 2001 to 2006, he was the deputy regional director (Southern Region). From 1998 to 2001, Dr. Conaway served as manager of the Equine Drug Testing and Animal Disease Surveillance Laboratories for the Michigan Department of Agriculture. From 1994 to 1998, he was regulatory affairs manager for the Michigan Department of Public Health Vaccine Production Division. Dr. Conaway received a DVM degree from Tuskegee Institute and an M.S. degree in pathology from the College of Veterinary Medicine at Michigan State University.

Henry J. Esber, Ph.D., Director

Dr. Esber has been a director of the Company since December 2011 and has been a principal in Esber D&D consulting since 2005. From 2003 to 2005, he was a senior consultant, business development at Charles River Labs, Discovery and Development Services. From 2005 to 2006, Dr. Esber was a consultant and from 2006, he was senior vice president and chief business officer for Bio-Quant, which he had co-founded. Dr. Esber was also the co-founder of BioSignature Diagnostics, Inc. and Advanced Drug Delivery, Inc. From December 2009 to January 2013, Dr. Esber was a director of Apricus Biosciences, Inc. (APRI-NASDAQ). From April 2006 to February 2009, Dr. Esber was a director of Pro-Pharmaceuticals. He serves on the Scientific Advisory Boards of several biotechnology companies and is the author of more than 130 technical publications. Dr. Esber has more than 35 years of experience in the areas of oncology/tumor immunology and immunotherapy as well as strong knowledge in the field of toxicology and regulatory affairs. Dr. Esber received a B.S. in biology/pre-med from the College of William and Mary, an M.S. in public health and parasitology from the University of North Carolina, and a Ph.D. in immunology/microbiology from West Virginia University Medical Center. Dr. Esber was previously a director of the Company from September 2009 through December 2010.

Dr. Rom E. Eliaz, Ph.D., MBA, Director

Since September 2009, Dr. Eliaz has been a CEO of Nasvax, an Israel-based biotech company and president and CEO of JJ Pharma Inc. since September 2009. He has also been CEO and managing director, Elrom Ventures Corp. since May 2007. From January 2007 to October 2007, Dr. Eliaz was a senior director of development at Intradigm Corp. From March 2004 to December 2006, he was a director of development at Pfizer Inc. (Rinat Neuroscience).

Conroy Chi-Heng Cheng, Director

Mr. Conroy Chi-Heng Cheng serves as the chief executive officer and executive director of Net Plus Company Limited. He has been an executive director of New World Development Co. Ltd. since June 2010. He serves as a director of Chow Tai Fook Enterprises Limited. He served as an independent non-executive director of Hong Kong Energy Holdings Limited (alternate name JIC Technology Co. Ltd. & China Renewable Energy Investment Limited) from July 2002 to May 2007. Mr. Cheng holds a B.A. in economics from the University of Western Ontario, Ontario, Canada.

Core Story

THE SCIENCE

Complex Carbohydrate Chemistry (CCC) Platform

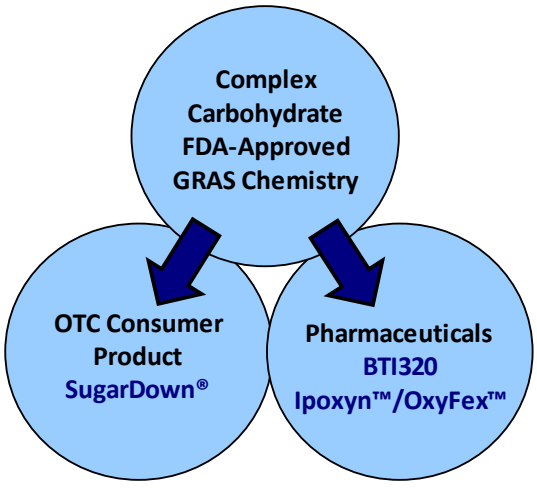
As a class of molecules, carbohydrates have a vast array of shapes, orientations, and compositions, and have demonstrated a fundamental role not only in normal cell functions but also in major disease pathologies, including cancer, cardiovascular disease, and inflammatory diseases. It is this role, which has led to a growing interest in using carbohydrates for drug design. Boston Therapeutics is employing complex carbohydrate chemistry to develop a range of therapeutics, including pure carbohydrates and protein-linked carbohydrates or **glycoproteins**.

Complex carbohydrates consist of a chemical structure that is made up of three or more sugars, which are typically connected together to form a chain. These sugars are mostly rich in fiber, vitamins, and minerals. Because of their complexity, complex carbohydrates take longer to digest and do not raise the sugar levels in the blood as quickly as **simple carbohydrates** (which are simple sugars with a chemical structure that is composed of one or two sugars). Complex carbohydrates act as fuel for the body and are key contributors to the body's energy production. They are normally found in whole-meal bread, cereals, spinach, yams, broccoli, beans, zucchini, lentils, skimmed milk, whole grains, and many other leguminous plants and vegetables, with nutritional values most often higher than those of simple carbohydrates. While complex carbohydrates contain certain elements of simple ones, their chemical structures are very different and they can be distinguished by their nutritional properties.

Scientific efforts based on the use of carbohydrates have historically been limited in comparison to nucleic acids and proteins because of the carbohydrates' structural complexity. Boston Therapeutics believes that the gap in development efforts within this category may present a unique opportunity for the Company to capitalize on its expertise in carbohydrate engineering in order to bring to market FDA-approved, GRAS (Generally Recognized As Safe) therapeutic molecules within areas of unmet medical needs, such as in diabetes and inflammatory conditions. The Company is currently developing two pharmaceutical compounds (BTI320 and Ipoxyn™ [and a veterinary compound (OxyFex™]) as well as marketing an OTC supplement product equivalent to BTI320—as depicted in Figure 4.

Figure 4

APPLIED COMPLEX CARBOHYDRATE CHEMISTRY (CCC) PLATFORM



Source: Boston Therapeutics, Inc.

CEO Dr. David Platt (biography on page 10) has been a pioneer behind the development of the Company's technology in applied carbohydrate chemistry, with his scientific collaborators over the last two decades written in two books—*Carbohydrate Drug Design* (2006) and *Galectins* (2008). Capitalizing on this knowledge base, Boston Therapeutics is developing and engineering a pipeline of complex carbohydrate-based therapeutics to address unmet medical needs in both a safe and effective manner, and in both oral and injectable delivery formulations.

PRODUCT DEVELOPMENT PIPELINE

The Company intends to develop its most advanced clinical-stage Phase II drug candidate—BTI320 (formerly PAZ320) for diabetes—up to and including through Phase III human clinical trials (providing data on the drug's efficacy). Upon achieving success in these efforts, the Company intends to commercialize the compound either internally or with a partner in the U.S. Outside of the U.S., Boston Therapeutics may seek to out-license development and commercialization rights for BTI320. For preclinical stage candidate, Ipoxyn™, an anti-necrosis drug, the Company may enter into a strategic partnership with a partner to co-fund human clinical trials necessary for regulatory approvals in both domestic and international markets. Figure 5 provides a product development timeline.

Figure 5
PIPELINE

Product	Indication	Description	PRECLINICAL	PHASE I	PHASE 2	PHASE 3
BTI320	Type 2 Diabetes	Chewable tablet taken prior to meals to manage post-meal sugar spike				
Ipoxyn™	Lower Limb Vascular Complications of Diabetes	Injectable anti-necrosis drug				
OxyFex™	Veterinary Ischemic Tissue	Injectable anti-necrosis drug				

Source: Boston Therapeutics, Inc.

DIABETES MELLITUS

Known simply as diabetes, **diabetes mellitus** is a group of three metabolic diseases—Type 1, Type 2, and gestational diabetes (described in the accompanying section on pages 16-20)—and occurs when an individual has abnormally high levels of glucose in the circulating blood caused by either a failure of the body's pancreas to produce insulin and/or an inability to respond sufficiently to circulating insulin.

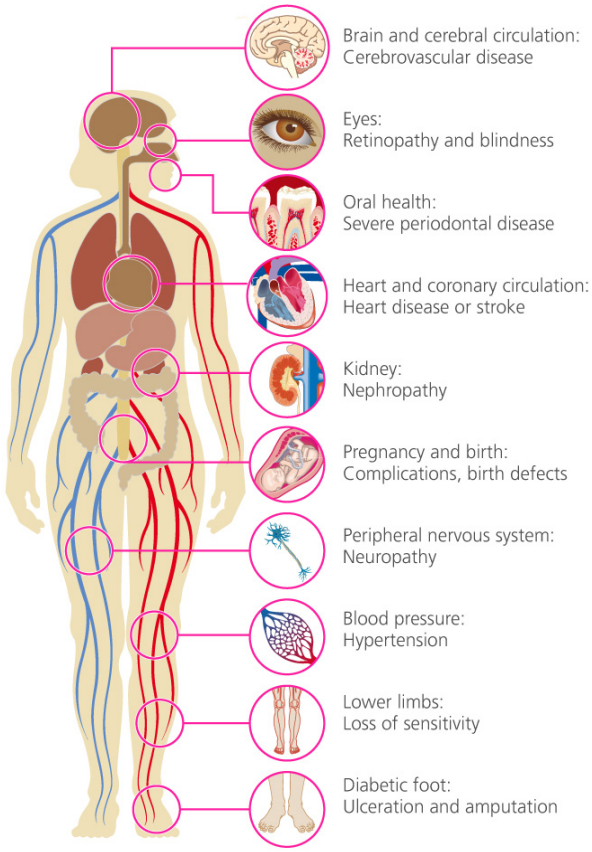
Diabetes is considered an auto-immune disease since the body's immune system attacks and destroys insulin-producing **beta cells** in the pancreas. When not adequately controlled, diabetes can lead to a number of complications including stroke, blindness, amputation, kidney failure, and heart attack, among others (depicted in Figure 6 [page 16]), which can ultimately be fatal—calling attention to the importance of managing and treating this metabolic disease—which represents the seventh leading cause of death among the American population.

Prediabetes is a condition in which an individual has blood sugar levels higher than normal, but not high enough to be diagnosed with diabetes. At these levels, this individual is at higher risk for developing Type 2 diabetes and other serious health problems, including heart disease and stroke. Without lifestyle changes to improve health, roughly 15% to 30% of people with prediabetes will develop Type 2 diabetes within five years.

Figure 6

DIABETES COMPLICATIONS

Diabetes is the leading cause of kidney failure, blindness, and non-traumatic amputation in adults.



Source: Healthline.com

Types of Diabetes

The three different types of diabetes are described below, with greater emphasis for the purpose of this report on Type 2, the most common type and the type for which Boston Therapeutics' development efforts are largely focused.

- Type 1 diabetes results from the body's failure to produce insulin and can only be treated with insulin injections or insulin analogs. This type of diabetes, which typically begins in childhood, affects only about 5% to 10% of individuals with the disease.

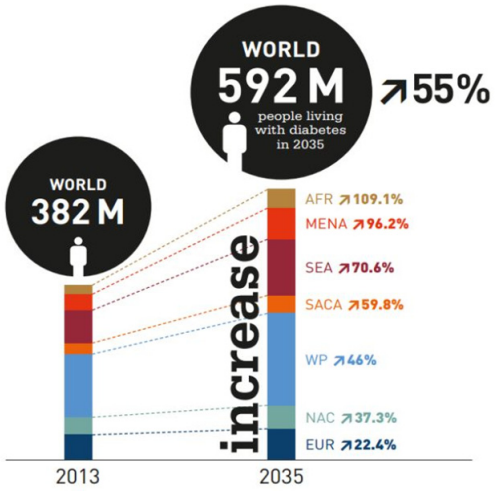
- Type 2 diabetes results from insulin resistance by the body's cells (a condition in which the cells in the body ignore or have become desensitized to insulin), deficient insulin production by the pancreas, or a combination of both. Type 2 diabetes is quite different from Type 1 diabetes in that Type 2 is more closely linked to an individual's lifestyle choices (versus genetics as with Type 1). Type 2 diabetes is serious, costly, and necessitates treatment from the point of diagnosis for the remainder of an individual's life—specifically in managing its potential complications.

- Gestational diabetes is determined when pregnant women (who never had diabetes before) have high blood glucose level during pregnancy. This type of diabetes may precede development of Type 2 diabetes and affects roughly 4% of all pregnant women.

Individuals with Type 1 and Type 2 diabetes typically manage their blood glucose levels on a meal-to-meal basis, as high levels of glucose in the bloodstream for an extended period of time can lead to complications caused by reduced oxygen supply and nerve tissue damage to eyes, kidney, brain, heart, and limbs. With the objective of maintaining a daily blood glucose level as recommended by a physician, standard treatments for diabetes include exercise and diet and typically oral hypoglycemic drugs, such as metformin (among other treatments, as described on pages 18-20) for Type 2 diabetics and insulin injection regimens for Type 1 diabetics.

Figure 7

NUMBER OF INDIVIDUALS LIVING WITH DIABETES WORLDWIDE (BY COUNTRY)



Source: IDF Diabetes Atlas 6th Edition, IDF (2013).

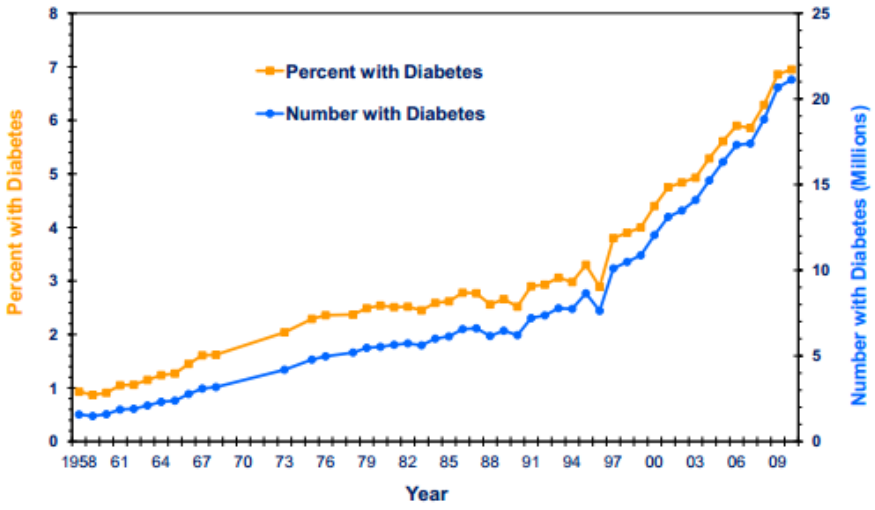
Market Data

In 2013, according the International Diabetes Federation (IDF), 382 million people were living with diabetes—a figure that the IDF believes could increase to 592 million by 2035 (as shown in Figure 7). In the U.S., the Centers for Disease Control and Prevention (CDC) estimated that there were 25.8 million Americans, or 8.3% of the U.S. population, living with diabetes in 2011 and 79 million who were prediabetic.

The rate of individuals affected by Type 2 diabetes is increasing in every country, including in economically developed countries where higher rates of obesity are linked to high-calorie diets combined with low exercise levels. For example, Figure 8 illustrates the drastic growth of the diabetic population in the U.S. Among the population of individuals over age 65, roughly 26.9% or 10.9 million people had diabetes in 2010, and about 215,000 individuals under the age of 20 had diabetes. The prevalence of Type 2 diabetes increases with age and is most common in individuals over 40. That said, however, diabetes is becoming increasingly more common in adolescence, with childhood rates growing.

Figure 8

NUMBER AND PERCENTAGE OF U.S. POPULATION WITH DIAGNOSED DIABETES (1958-2010)



Source: CDC's Division of Diabetes Translation, National Diabetes Surveillance System (http://www.cdc.gov/diabetes/statistics).

The total estimated cost of diagnosed diabetes in 2012 was roughly $245 billion, which encompassed $176 billion in direct medical costs and $69 billion in reduced productivity. The main components of medical expenditures for diabetic individuals include hospital inpatient care (43% of the total medical cost), prescription medications to treat the complications of diabetes (18%), antidiabetic agents and diabetes supplies (12%), physician office visits (9%), and nursing/residential facility stays (8%). In particular, individuals with diagnosed diabetes incur average medical expenditures of about $13,700 per year, which includes roughly $7,900 attributed to diabetes (Source: American Diabetes Association).

According to Standard & Poor's, the diabetes drug market is estimated at $35 billion and is on pace to exceed $58 billion by 2018. GBI Research (a publisher of in-depth strategic intelligence reports in a broad range of professional industries) forecasts the market, specifically for Type 2 diabetes, to grow from $20.4 billion in 2012 to $38.8 billion in 2019, with a compound annual growth rate (CAGR) of 10.2%. This growth is expected to stem from the anticipated approval of products in relatively novel treatment classes—such as **GLP-1 agonists**, **DPP-4 inhibitors**, and **SGLT-2 inhibitors**, as introduced below and on pages 19-20.

Key facts and figures on the diabetes market are summarized in Figure 9.

Figure 9

DIABETES FACTS SUMMARY

- 25.8 million people with diabetes (8.3% of U.S. population)
  - 460% increase since 1980
- 79 million people considered pre-diabetic
- 1 of 3 U.S. adults will have diabetes by 2050 if current trends continue
- Leading cause of:
  - kidney failure
  - non-traumatic lower-limb amputations
  - new cases of blindness
- Major cause of heart disease and stroke
- $245 billion in direct and indirect cost to U.S. economy

Source: CDC Division of Diabetes Translation, National Diabetes Surveillance System and 2011 CDC Diabetes Fact Sheet.

Type 2 Diabetes Treatments

Figure 10

DIFFERENT DIABETES TREATMENTS

- Sulfonylureas
- Biguanides
- Meglitinides
- Thiazolidinediones
- DPP-4 inhibitors
- SGLT2 Inhibitors
- Alpha-glucosidase inhibitors
- Bile Acid Sequestrants

Source: American Diabetes Association.

The Type 2 diabetes treatment market encompasses a wide array of compounds—with a variety of drugs competing with one another for different segments of the market. Specifically, there are different types, or classes, of drugs that work in distinct ways to lower blood glucose (blood sugar) levels. These different classes of treatments, as summarized in Figure 10, are further described in the accompanying section (Source: American Diabetes Association).

- ***Sulfonylureas***. Sulfonylureas stimulate the beta cells of the pancreas to release more insulin. Having been in use since the 1950s, the only first-generation sulfonylurea still in use today is Chlorpropamide (Diabinese). Compared to the first generation, the second-generation sulfonylureas use smaller doses, with three drugs available within this category: glipizide (Glucotrol and Glucotrol XL), glyburide (Micronase, Glynase, and Diabeta), and glimepiride (Amaryl). These drugs are typically taken one to two times a day and prior to meals. All sulfonylurea drugs have similar effects on blood glucose levels though are unique in their side effects, dosing schedule, and drug interactions.

- ***Biguanides.*** Metformin (Glucophage), a biguanide, lowers blood glucose levels primarily by decreasing the amount of glucose produced by the liver. Metformin also helps to lower blood glucose levels by making muscle tissue more sensitive to insulin so glucose can be absorbed. The commonly prescribed dosage is twice daily, with a potential side effect of diarrhea (though this improves when the drug is taken with food).

- ***Meglitinides.*** Repaglinide (Prandin) and nateglinide (Starlix) are meglitinides—drugs that stimulate the beta cells to release insulin and are taken before each of three meals.

- ***Thiazolidinediones.*** Rosiglitazone (Avandia) and pioglitazone (Actos) are in a group of drugs called thiazolidinediones, which help insulin perform better in the muscle and fat and also reduce glucose production in the liver. Troglitazone (Rezulin) (as the first drug approved in this group) was removed from the market due to serious liver problems in a small number of people. To date, rosiglitazone and pioglitazone have not shown the same problems but patients taking these drugs are still closely monitored as a precaution for liver complications. Both drugs appear to increase the risk for heart failure in some individuals, and there is debate as to whether rosiglitazone may contribute to an increased risk for heart attacks.

- ***DPP-4 Inhibitors.*** Dipeptidyl peptidase-4 (DPP-4) inhibitors, a new class of medications, help improve A1C without causing **hypoglycemia**. Sitagliptin (Januvia), saxagliptin (Onglyza), linagliptin (Tradjenta), alogliptin (Nesina) are the DPP-4 inhibitors currently on the market in the U.S. These drugs work by preventing the breakdown of a naturally occurring compound in the body, GLP-1. GLP-1 reduces blood glucose levels in the body, but is broken down very quickly—thus it does not work well when injected alone as a drug. By interfering in the process that breaks down GLP-1, DPP-4 inhibitors allow it to remain active in the body longer, lowering blood glucose levels only when they are elevated. DPP-4 inhibitors do not tend to cause weight gain and tend to have a neutral or positive effect on cholesterol levels.

- ***SGLT-2 Inhibitors.*** As a new class of medication, sodium-glucose transporter 2 (SGLT-2) works in the kidney to reabsorb glucose and block this action, causing excess glucose to be eliminated in the urine. Glucose in the bloodstream passes through the kidneys, where it can either be excreted or reabsorbed. Canagliflozin (Invokana) is the first SGLT-2 inhibitor approved by the FDA to treat Type 2 diabetes. Since it increases glucose levels in the urine, urinary tract and yeast infections can result.

- ***Alpha-glucosidase inhibitors.*** Alpha-glucosidase inhibitors include acarbose (Precose®) and meglitol (Glyset). These drugs help the body to lower blood glucose levels by blocking the breakdown of starches, such as bread, potatoes, and pasta in the intestine. As well, they slow the breakdown of some sugars, such as table sugar, and slow the rise in blood glucose levels following meals. Side effects may include diarrhea and gas.

    - Of note is that Precose®, an oral tablet administered to Type 2 diabetics and, in some countries people with prediabetes, works to lower a patient's blood sugar by preventing the breakdown of starches into sugars. Having been available for Type 2 diabetes since 1990, generic acarbose is now sold by numerous companies around the world. The acarbose compound is known as an alpha-glucosidase inhibitor, which slows the digestion of carbohydrates in the body and in turn helps control blood sugar levels. It can be administered on its own or as a combination therapy with other types of oral diabetes medicines and is usually taken three times a day with meals but dosages can vary. Greater details on Precose®, as it relates to BTI320 being developed by Boston Therapeutics, is provided on page 34, under Potential Competition from Bayer HealthCare Pharmaceuticals Inc.

- ***Bile Acid Sequestrants (BAS).*** The bile acid sequestrant (BAS) colesevelam (Welchol) is a cholesterol-lowering medication that correspondingly reduces blood glucose levels in diabetes patients. BASs also help remove cholesterol from the body, predominantly LDL cholesterol, which is often elevated in people with diabetes. The medications reduce LDL cholesterol by binding with bile acids in the digestive system; the body then uses cholesterol to replace the bile acids, which lowers cholesterol levels. Because BASs are not absorbed into the bloodstream, they are usually safe for use by patients who may not be able to use other medications because of liver problems. Side effects may include gas and constipation.

- ***Oral combination therapy.*** Since the above outlined drugs act in different ways to lower blood glucose levels, they may be used together. For instance, a biguanide and a sulfonylurea may be used together. In fact, many combinations can be used. While using more than one drug can be more costly and also raise side effect risks, combining oral medications can improve blood glucose control when not achieving the desired side effects with a single treatment.

First-Line Therapy

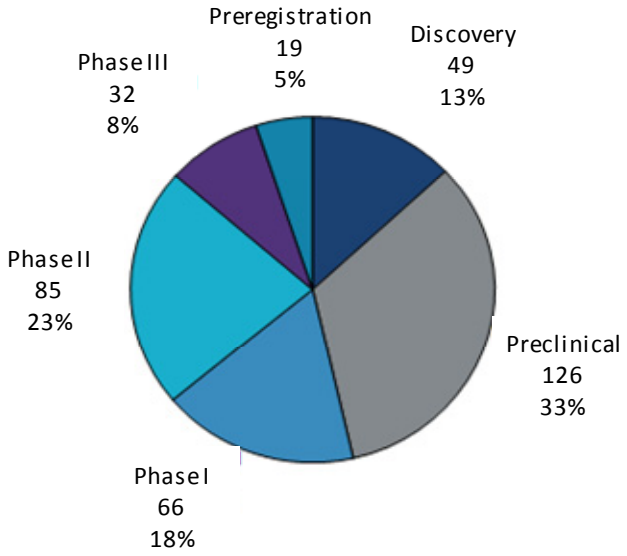
With the aforementioned outline of treatment options, typical first-line therapy for Type 2 diabetes is metformin (a biguanide, as described on page 19), which is available in a generic form. For many patients in which metformin is not able to effectively control the disease, other drugs or must be added for use in combination. Within an established second-line therapy is the use of sulfonylureas (as described on page 18), a class of drugs which has also been 'genericized,' for use in combination with metformin.

Development Efforts

In the pipeline for Type 2 diabetes treatments, there are roughly 400 products—spread fairly evenly across the different development stages (as shown in Figure 11). As well, there are 11 products in the registration process for marketing approval, with the majority of these being novel formulations or combinations of existing products. With such a solid pipeline of candidates, it is likely that the category could continue to experience long-term growth; though alongside this growth, there will likely be increased competition among participating drugs in the marketplace (see Potential Competition, pages 33-37).

Figure 11

TYPE 2 DIABETES: GLOBAL PIPELINE BY STAGE OF DEVELOPMENT (2013)



Source: GBI Research.

BTI320 (To Reduce Post-Meal Blood Glucose)

Boston Therapeutics is developing BTI320 (**Alpha-Glucosidase [Maltase] Inhibitor**) as a non-systemic chewable drug tablet intended to reduce postprandial or post-meal elevation of blood glucose (a **PPG Regulator**). BTI320 is intended to be administered prior to meals to inhibit carbohydrate-hydrolyzing enzymes in the gastrointestinal tract, which release glucose from complex carbohydrates foods during digestion. This, in turn, reduces the availability of glucose for absorption into the bloodstream. Importantly, BTI320 is not intended to lower blood sugar, but rather to reduce or keep post-meal blood sugar from spiking. The candidate has completed Phase IIa and is enrolling patients in two Phase IIb trials.

Mannan in Managing Diabetes

BTI320 is part of a group of plant-derived complex carbohydrates, or polysaccharides, which are composed primarily of polymers of the sugar mannose. Plants from which mannans are derived include guar, locust bean, fenugreek, barley, and konjac. Studies published have shown that mannans carry significant biological activity—ranging from inhibiting cholesterol absorption to promoting wound healing and inhibiting tumor growth. As well, studies have further supported that consuming mannan prior to a meal can lower the rise in blood glucose subsequent to that meal—where supplementing with mannan may be a beneficial in managing diabetes by means of supporting healthy levels of blood sugar in the body.

How It Works

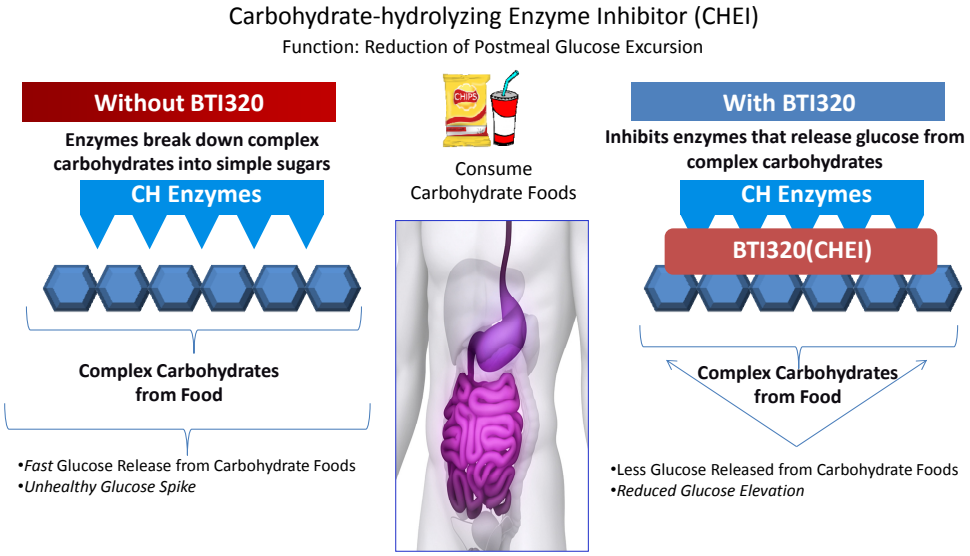
Derived from glucomannan (which has been shown to lower postprandial glucose), BTI320 acts by blocking key carbohydrate-hydrolyzing enzymes, such as amylase, maltase, lactase, and sucrose, in the gastrointestinal tract. Initially, as shown in Figure 12, BTI320 binds to long-chain starch polysaccharides in food and to the digestive enzymes that cleave these large sugars into glucose. Next, the compound temporarily coats the lumen of the small intestine, slowing glucose absorption. Lastly, BTI320 prompts satiety, which facilitates portion control (a secondary benefit). Working in conjunction, each mechanism of action works to lower the rate of glucose absorption from the small intestine to the blood and may assist diabetes patients with better control throughout the day.

Clinical Trials

The Company completed a Phase II trial for BTI320 and is initiating/enrolling two Phase IIb trials. A summary of current and planned trials is provided in Figure 13 (page 22), with further details in the accompanying sections.

Figure 12

ACTION OF BTI320 IN THE BODY



Source: Boston Therapeutics, Inc.

Figure 13

BTI320: CURRENT AND PLANNED TRIALS

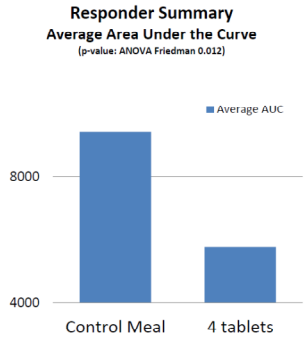
Trial Type	Status	Patient Population	Goals
Phase II Study Dartmouth-Hitchcock Medical Center, U.S.	**Completed** Data published in *Endocrine Practice* Q3 2013	• 21 people with Type 2 diabetes • Currently using oral agents or insulin	• Efficacy and safety • In combination with oral anti-diabetic medications and insulin
Phase IIb Lisieux, France **Phase IIb** U.S.	**Enrolling** Initiating	• 24 people with Type 2 diabetes currently using metformin • 24 people with Type 2 diabetes with metformin	• Efficacy and safety
Phase III U.S., Europe, Hong Kong, Korea, and China	**Planned** Collaboration with U.S. diabetes clinic		• Evaluation of the effects of BTI320 on glucose HbA1c, AUC in patients currently taking metformin
Mechanism of Action Validation University of Minnesota	Initiated		• To study and validate BTI320 mechanism of inhibition of carbohydrate-hydrolyzing enzymes

Source: Boston Therapeutics, Inc.

Phase II Study: Dartmouth Medical Center in Lebanon, New Hampshire

Figure 14

BTI320: PHASE II TRIAL RESULTS



NOTE: Trial Conducted at Dartmouth Medical Center.

Source: Boston Therapeutics, Inc.

Boston Therapeutics announced in October 2011 that it had initiated a clinical trial at Dartmouth-Hitchcock Medical Center in New Hampshire to evaluate the safety and efficacy of BTI320 when added to oral agents or insulin regimen in patients with Type 2 diabetes. In July 2012, the Company announced that it had completed patient enrollment in this trial, evaluating BTI320 in 24 patients between the ages of 18 and 75 with Type 2 diabetes and a **body mass index (BMI)** of 25-40 kg/m2 and with HbA1c of less than or equal to 9%. HbA1c is a lab test that shows the average level of blood sugar (glucose) over the previous three months.

In February 2013, it was announced that the study demonstrated that 45% of patients responded with an average 40% reduction of post-meal blood glucose versus baseline in a dose-dependent manner (Figure 14). As well, results demonstrated that BTI320 did not correlate with duration of diabetes, with the compound effective regardless of coexisting diabetes medications. Furthermore, there was no severe hypoglycemia, and only mild gastrointestinal side effects. Another effect among patients was satiety—where patients felt full following treatment.

Overall, no serious adverse events were reported in Type 2 diabetic patients from the data analysis of the open-label dose escalation crossover trial. The abstract for the clinical study is published in the July/August 2013 issue of *Endocrine Practice* available at the link below:
http://www.endocrinepractice.org/content/048w8465455576l6/?p=6f600b1c6b5241b885590cffd85d34eb&pi=9.

Phase IIb Study: Centre Hospitalier Robert Bisson, Lisieux, France

In November 2013, the Company announced that it had commenced enrollment for patients in a Phase IIb clinical study for BTI320. In total, 24 patients with Type 2 diabetes who are currently receiving treatment with metformin are to be administered BTI320 under double-blind, placebo-controlled conditions, noting that metformin is the most widely prescribed drug for diabetes and often the first drug prescribed to newly diagnosed diabetes patients. For these patients, blood glucose will be monitored using **continuous glucose monitors (CGM)** and following a test meal, their postprandial (post-meal) blood glucose levels measured. The primary endpoint of the study is to evaluate the effect of BTI320 versus placebo in the **area under the curve (AUC)** of glucose and on insulin levels in the blood for four hours post meal intake. This study is being conducted at Centre Hospitalier Robert Bisson, Lisieux, France.

Mechanism of Action Study: University of Minnesota

In October 2013, Boston Therapeutics announced that it was sponsoring a research study—called "NMR Studies of BTI320 with Sugar Hydrolyzing Enzymes"—with the University of Minnesota (UMN) on BTI320, with a goal to provide molecular-level information on BTI320 and its mechanism of action. Specifically, the study aims to better characterize BTI320 galactomannan, and assess interactions of the drug with various sugar-hydrolyzing enzymes, e.g., glucosidase and maltase. The study may further provide insight into **allosteric** properties of BTI320 with enzymes, measuring the effect of the drug on enzyme-mediated sugar hydrolysis, and comparing it with other diabetes drugs. The study is to be conducted by Kevin H. Mayo, Ph.D., a professor in the Department of Biochemistry, Molecular Biology and Biophysics at UMN Minneapolis, with Dr. Mayo's UMN laboratory using **nuclear magnetic resonance (NMR) spectroscopy** for many years to investigate interactions of various carbohydrates and proteins.

Commercial Potential

BTI320 could hold commercial potential in a large and growing market for effective diabetes treatments as the compound has demonstrated to be pharmacologically differentiated from commercially available postprandial (post-meal) glucose (PPG) drugs, such as Byetta®, Bydureon™, Victoza®, Lispro, Lantus®, and Invokana™. Boston Therapeutics believes the compound is safe and effective in individuals with diabetes as well as prediabetes in managing daily levels of blood glucose. Many patients with diabetes experience less than optimal relief when taking currently approved therapies alone or in combination with one another. As well, other types of PPGs are only effective in the early stages of impaired glucose tolerance. BTI320 has the potential to be approved in combination with metformin, the most prescribed diabetes drug with 50 million prescriptions annually, which could present a material milestone for the Company.

SugarDown® (Marketed OTC Product)

Figure 15
SUGARDOWN®

Source: Boston Therapeutics, Inc.

Boston Therapeutics currently markets an OTC version of BTI320, called SugarDown® (Figure 15)—a chewable dietary supplement with a complex carbohydrate composition. SugarDown® is composed of a patented, modified mannan polysaccharide from plant cell walls. Mannans have been used for many years in the food industry and are deemed Generally Recognized as Safe (GRAS) by the U.S. Food and Drug Administration.

SugarDown® is designed to support healthy blood glucose levels and has been shown in preliminary studies to reduce the post-meal sugar spike associated with eating high glycemic index (GI) foods or carbohydrate foods and beverages. The GI provides a measure of how quickly blood sugar levels (i.e., glucose levels in the blood) rise after eating specific types of food, as effects from different foods on blood sugar levels can vary significantly. For example, a low-GI food releases glucose more slowly and steadily, which leads to more suitable postprandial (after meal) blood glucose readings, whereas a high-GI food causes a more rapid rise in blood glucose levels, as would be suitable for energy recovery post-exercise or for a hypoglycemic individual. SugarDown® may be taken (either one to two tablets) immediately and up to 30 minutes before eating foods or drinking liquids that contain carbohydrates.

The Company believes that SugarDown® is a safe and effective dietary supplement for assisting people who are considered at risk of developing diabetes and people living with diabetes in managing daily blood glucose levels. Specifically, it may provide individuals with a non-systemic tool to reduce post-meal elevation of blood glucose. As well, an added benefit to the chewable tablet is that it can support a weight management program by encouraging a sense of satiety or fullness before a meal, and maintaining beneficial intestinal flora and regularity. SugarDown® is manufactured in the U.S. at a Good Manufacturing Practices (GMP)-compliant facility.

Study Results

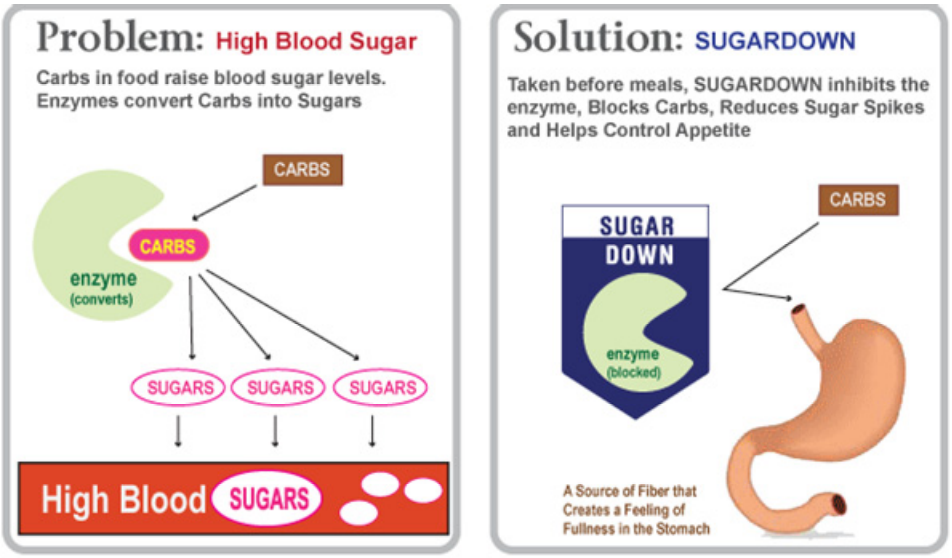
Published studies have shown that mannans possess significant biological activity—ranging from inhibition of cholesterol absorption to promoting wound healing and inhibiting tumor growth. Studies have also shown that consuming mannan before a meal can lessen the rise in blood glucose after the meal. Thus, supplementation with mannan may be beneficial in managing diabetes by supporting healthy blood sugar levels.

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 a reduction of up to 56% in post-meal elevation of blood glucose compared with the rice consumed alone. There was, 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.

How It Works

When consuming foods with carbohydrates, enzymes in the mouth and intestinal tract break down the carbohydrate into smaller components—one of which is glucose. Glucose is necessary by the body for energy and is absorbed through the intestine into the bloodstream. Too much sugar in the blood is not healthy and can result from eating "bad" carbohydrates. Boston Therapeutics' SugarDown®, when taken prior to meals containing carbohydrates, has shown to inhibit enzymes that break down complex carbohydrates into glucose, which reduces the amount of glucose that is available for absorption, thus moderating the after-meal glucose (blood sugar) spike. It is recommended to take one to two tablets prior to a meal or snack, for a daily dose of three to six tablets. Importantly, SugarDown® works in the GI tract to promote healthy blood sugar management and in a preliminary study it reduced the glycemic effect of carbohydrate foods before they are absorbed as glucose. A depiction of how SugarDown® works is provided in Figure 16.

Figure 16
HOW SUGARDOWN® WORKS



Source: Boston Therapeutics, Inc.

Requirements for a Dietary Supplement

A dietary supplement is defined in the Dietary Supplement Health and Education Act of 1994 (DSHEA) as a product intended to supplement the diet, containing one or more dietary ingredients (i.e. vitamins, minerals, herbs, or other botanicals, amino acids, and other substances), is taken orally as a pill, capsule, tablet, or liquid, and is labeled on the front panel of the supplement as such.

Dietary supplements do not require regulatory clearance (such as FDA approval) though they may not claim an ability to diagnose, cure, mitigate, treat, or prevent a condition or disease—these claims may only be made by regulatory approved pharmaceuticals. Claims that manufacturers may make for their products are limited to health claims, function claims, and nutrition content claims. Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reduced risk of disease and health-relation condition. Nutrient content claims describe the relative amount of a nutrient or dietary substance contained in a product. A structure/function claim defines how a product may affect organs or systems within the body, though it may not make a mention of a particular disease. While such claims do not require FDA approval, the manufacturer must provide the text of the claim to the FDA and the manufacturer is responsible for the accuracy of these claims (which are not FDA approved). As well, if a dietary supplement label includes a claim, it must, additionally include a disclaimer that the FDA has not evaluated the claim and that the product is not intended to diagnose, treat, cure or prevent any disease. Should a label be untruthful or misleading, the FDA can order a product be taken off the market.

Status

Boston Therapeutics filed a structure and function claim application with the FDA in June 2010 with respect to SugarDown®, which describes the proposed mechanism of action in reducing post-meal elevation of glucose in the blood. As well, the Company has submitted 30 structural and functional claims to the FDA. The Company seeks to leverage results from SugarDown® trials by securing clearance as a medical food to be prescribed in conjunction with metformin. A medical food can be only for patients under medical supervision (which is active and ongoing). Medical food labels are more stringent than those of dietary supplements and they must contain a statement of identity, the common or usual product name, an accurate statement of the net quantity of contents, the name and address of the manufacturer, packer, or distributor, and a full ingredient list (in descending order of predominance). All statements and information required by or under authority of the Federal Food, Drug, and Cosmetic Act (FFDCA) on a label must be prominent, visible, and in English.

The product, which may target both the prediabetes and diabetes markets, is currently available for distribution in Asia and Europe, and in the U.S. through the website www.sugardown.com. The Company also announced in December 2011 that it had secured its first purchase order for distribution of the product in Italy. The goal is to upgrade SugarDown® to a prescription product, BTI320, and build upon physicians' acceptance from the initial marketing programs.

CONDITIONS REQUIRING OXYGEN DELIVERY

Hypoxia is a condition where the tissues in the body are not oxygenated adequately, generally stemming from an insufficient concentration of oxygen in the blood. Oxygen deprivation can have severe adverse effects on various cells within the body that need to perform important biological processes. Symptoms that result from oxygen deprivation due to the compensatory mechanisms adopted by the body include increases in heart rate, as well as myocardial contractility, and cardiac output. As more blood is pumped by the heart in order to increase the output of circulating oxygenated blood, a decrease in the amount of blood supplied to the peripheral tissues may occur, resulting in a bluish discoloration or **cyanosis** in these areas.

Hypoxia can be classified as *local* if it affects a specific area of the body and *generalized* if it involves the whole body. It is "anoxia" when a complete deprivation of oxygen supply occurs in the body. Hypoxia may be caused by different conditions, such as anemia, where the amount of functional hemoglobin is decreased, affecting the oxygen-carrying ability of the blood. It may also be caused by conditions such as heart failure, cardiac arrest, or heart attack—when the circulation of blood is slowed down and consequently insufficient amounts of oxygen are delivered within the body.

In addition to individuals with medical conditions, healthy people may also develop hypoxia. Situations where this may occur include travel to high altitudes, where an individual may develop **altitude sickness** and cannot get enough oxygen from the air at high altitudes. As well, individuals who are deep sea divers are also at risk of hypoxia if their breathing gases have been incorrectly prepared or if rusty cylinders in their gas tanks have extracted oxygen.

Whatever the cause, hypoxic conditions are harmful to maintaining normal functionality in all living tissues within the body. For mammals in particular, red blood cells (RBCs) deliver oxygen throughout the body using hemoglobin—a protein that carries and releases oxygen to the body's tissues. In typical conditions, roughly 98% of oxygen is delivered by hemoglobin in the RBCs, with less than 2% dissolved in the plasma (the fluid part of the blood). As the heart pumps blood, RBCs pick up oxygen in the lungs and transport it throughout the body. Blood travels through increasingly smaller blood vessels to the capillaries—some so narrow that RBCs can only pass through them in single file. The majority of oxygen release occurs within the capillaries, with oxygen-depleted RBCs returning to the lungs to be replenished. Sufficient blood flow, blood pressure, and RBC counts are essential to this process. Oxygen deprivation, or hypoxia, for only several minutes, can result in cell damage, organ dysfunction, and when occurring for extended periods of time, death.

Origins of Inadequate Tissue Oxygenation

The origins of inadequate tissue oxygenation can largely be classified into the three categories listed below.

- ***Cardiopulmonary failure*** (impaired function of the heart or lungs). This condition is possibly caused by the inability of the heart to pump sufficient quantities of blood to meet the needs of the tissues or the failure of the lungs to oxygenate blood adequately.

- *Anemia* (insufficient RBCs in circulation). Chronic disorders affecting RBCs' functionality or production, such as chemotherapy and radiation for treatment of cancer, or blood-borne diseases, such as bone marrow diseases, may be the cause of anemia. Additional causes may stem from acute blood loss resulting from accidental injury or surgery.

- *Ischemia* (inadequate RBC flow for tissue oxygenation). Likely caused by obstructed or constricted blood vessels, ischemia can lead to stroke, heart attack, or other organ or tissue dysfunction. Following ischemia is necrosis, the result of severe and acute injury.

Ischemia and Necrosis

Necrosis, which is the result of severe and acute injury following ischemia (Figure 17), is involved in many pathological conditions, including heart attacks, brain injuries and stroke, neurodegenerative diseases like Alzheimer's, dementia, Lou Gehrig's disease (ALS), septic shock, liver cirrhosis, chronic hepatitis, pancreatitis, muscle necrosis, diabetes mellitus, acute or critical limb ischemia, gangrene, chronic pressure ulcers, and many others.

Figure 17
NECROSIS AND ISCHEMIA

Necrosis	Localized death of living tissue
Ischemia	Deficient supply of blood to body part, leading to necrosis

Source: Boston Therapeutics, Inc.

Treatment for necrosis is based upon its origin, and typically involves two distinct processes. Most often, the underlying cause of the necrosis must be treated prior to dealing with the dead tissue. The standard therapy for necrosis is typically debridement, where the dead tissue is removed either surgically or non-surgically. Dependent on the degree of the necrosis, this may range from removing small patches of skin, to completely removing organs or limbs. Another option is the chemical removal of necrotic tissue, in which enzymatic debriding agents are used to target the various components of dead tissue.

Caused by a severe obstruction of peripheral circulation, limb ischemia is a chronic condition which leads to severe pain in the extremities. Stemming from the constriction of blood vessels, RBCs are not able to freely flow specifically through the capillaries, which leads to the deprivation of oxygen or ischemia. Complications can include gangrenous sores and wounds, typically in the legs and feet, which do not heal. If left untreated, these lesions can lead to amputation of the affected limb. A life-threatening complication for patients with poorly-controlled diabetes, lower limb ischemia affects roughly 10% of the diabetic population.

While efforts have been underway for decades to provide oxygenation to ischemic tissue, none of these developments have proven fully successful—with treatments including blood-derived elements, **synthetic perfluorocarbons**, or RBC modifiers.

Ipoxyn™ (To Treat Ischemic Tissue and Prevent Necrosis)

Boston Therapeutics' complex carbohydrate chemistry (CCC) technology is being employed to develop an injectable, intravenous drug to prevent necrosis and to treat ischemic conditions that may lead to necrosis. The Company is approaching ischemic tissue treatment and necrosis prevention from a unique vantage with its preclinical stage candidate, Ipoxyn™ (which is a **new chemical entity [NCE]** versus a biological blood substitute). A glycoprotein-based injectable therapeutic agent, Ipoxyn™ may prove successful in being able to reverse 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—all factors commonly associated with transfusions of whole blood.

Ipoxyn™ consists of a stabilized glycol-protein composition containing oxygen-rechargeable iron, targeting tissues and organ systems deprived of oxygen and in need of metabolic support. Other intravenous fluids commonly used in emergency trauma to restore blood volume, such as **Ringer's lactate** or saline, are not designed to and do not effectively carry oxygen. Boston Therapeutics has plans to introduce Ipoxyn™ in clinical trials for hypoxic medical conditions as a compound to greatly improve survival of patients, targeting multiple indications in which hypoxia is a cause. With a wide array of potential targets, the initial intent is to address the oxygen deprivation in the peripheral vascular system that leads to lower-limb ischemia stemming from diabetes, with this being a factor underlying more than half of the 150,000 lower limb amputations performed in the U.S. every year

In addition to hypoxic medical conditions, there is an unmet clinical need for treatments of various acute ischemic conditions, where hypoxia can develop from a local restriction of constrained blood vessels, or poor and compromised flow. This can lead to insufficient supply of oxygen by otherwise well-oxygenated and distributed RBCs. Ipoxyn™, because it is extremely small in its molecular size (roughly 1/5,000th the size of a red blood cell), is able to perfuse constricted, ischemic capillaries, which are inaccessible to RBCs. This small molecular size is critical when treating individuals with vascular complications as RBCs may be enlarged and lower limb vasculature may be compromised in these patients. Ipoxyn™ may be able to transport and dispense oxygen widely without clot formation and flow stoppage risk.

Key Specifics of Compound

Ipoxyn™ is an iron carrier glycoprotein, with two distinct side chains, designated as alpha and beta. Each side chain has a molecular weight of roughly 32,000 Daltons, which is sometimes referred to as a dimmer. When folded, two of the dimmers become the globular protein. The glycoprotein, which is well conserved throughout nature, supports oxygen transport throughout mammals' bodies. Ipoxyn™'s ability to distribute and effect normal tissue oxygen levels at plasma levels of less than 0.5 grams per deciliter and, in conjunction, support normal tissue metabolic function appear to eliminate the toxic effects of higher dose regimens from earlier formulations that may be less homogeneous. As well, the regimen of uniform infusion has resulted in no demonstrated toxic effect levels from administration at three times the therapeutic benefit. Key specifics of the compound are summarized in Figure 18.

Figure 18

IPOXYN™: KEY SPECIFICS OF COMPOUND

- Carbohydrate-based intravenous solutions to potentially prevent necrosis (cell death)
- Treats ischemia (lack of oxygen supply to living cells)
- New Chemical Entity (NCE), not biologic agent—thus strong regulatory position versus biologic competitors
- May prevent amputation associated with lower limb ischemia or diabetic foot
- Contains oxygen rechargeable iron, which picks up oxygen in lungs
- 5,000 times smaller than red blood cells (RBCs)
- Does not require blood type matching

Source: Boston Therapeutics, Inc.

The Company maintains that it has unrestricted access (subject to adequate funding) to both adequate raw materials at commodity pricing and processing facilities to produce sufficient quantities of Ipoxyn™ under Good Manufacturing Practices (GMP) to complete preclinical pharmacokinetic, safety, and efficacy studies supporting an Investigational New Drug (IND) filing in the U.S. and Europe. The primary raw material for Ipoxyn™ is extracted from controlled sourced bovine blood. The controlled source of the protein extract is ultra-purified and sterile-filtered prior to rigorous processing, where multiple steps ensure purity, potency, stability as well as chemical treatment for reduction or elimination of any possible infectivity. A complete GMP procedure is expected to be established for Ipoxyn™. As with any new drug candidate application, Ipoxyn™ will require a Phase I/II and III clinical trials, with the goal to license the compound with a pharmaceutical/biotechnology company prior to the end of Phase I/II.

Development Status

The Company has not conducted any clinical trials to confirm the efficacy of, or filed any applications with the FDA with respect to Ipoxyn™, though is in the process of developing the compound for preclinical studies in order to conduct clinical trials and file applications with the FDA where relevant. Preclinical animal study results for Ipoxyn™ were presented at the XIII International Symposium on Blood Substitutes and Oxygen Therapeutics in July 2011. With sufficient funding, the Company intends to file an IND with the FDA in 2015 with a goal of gaining access to a pilot-scale manufacturing facility with adequate capacity to produce Ipoxyn™ for clinical trials and market introduction following European Medicines Evaluation Agency (EMEA) approval.

Potential Market Strategy

Ipoxyn™ is being targeted as a safe and effective intervention for reversing acute hypoxia. As well, the compound could alleviate acute deficiency of oxygen and avert further life-threatening complications and muscle and tissue death, which can result from a sustained deficiency of oxygen (such as in lower limb ischemic patients). Based on preliminary good laboratory practices (GLP) testing of a material bio-similar to Ipoxyn™, where it was found that such bio-similar formulation had no material toxicity on a small group of animals, Boston Therapeutics believes the compound is safe and efficacious. Should clinical trials support this belief, Ipoxyn™ could become a significant new management tool. As well, there could be a market for veterinary applications, where Boston Therapeutics expects to make a registration filing for this market as soon as it is able to complete preclinical safety and efficacy studies. Clinical safety and efficacy studies under GMPs have not yet been initiated by the Company.

Boston Therapeutics intends to engage a medical advisory board consisting of leading physicians who have participated in relevant clinical studies and who are leaders in the field as well as other physician-specialists who can assist the Company in developing additional indications. As well, the Company may seek to enter into licensing or co-marketing agreements for some or all parts of the world, such as it did with Advance Pharmaceuticals to market SugarDown® for Asian markets, to capitalize on the marketing expertise of one or more expert pharmaceutical companies. In the veterinary market, the Company may engage wholesale distributors on national or regional levels.

Market Size

Figure 19
INDICATIONS WHERE NECROSIS OCCURS

- Stroke
- Heart disease
- Trauma
- Anemia
- Kidney failure
- Diabetic foot
- Surgery

Source: Boston Therapeutics, Inc.

According to the CDC, the global addressable market opportunity for necrosis is approximately $30 billion. Indications for which necrosis occurs are listed in Figure 19, noting that stroke is the leading cause of death in the U.S., with 800,000 individuals dying each year due to cardiovascular disease and stroke. Boston Therapeutics expects to initially pursue the compound to relieve lower limb oxygen insufficiency caused by diabetes.

Other Applications

Ipoxyn™ may also have application in animals, such as livestock and companion animals (e.g., dogs, cats, horses, birds, and reptiles), as well as other animals in aquaria, zoos, ocean aria, and other facilities that house animals, as described below. For that reason, the Company is developing Ipoxyn™ in a veterinary application called OxyFex™.

OxyFex™ (Veterinary Analog to Ipoxyn™)

OxyFex™ is the Company's veterinary duplicate to Ipoxyn™. Within the veterinary market, there is currently an unmet need for blood replacement and oxygen delivery products for damaged or ischemic tissue caused by trauma, surgery, anemia, and other disease conditions. With only limited blood banking available for animals, OxyFex™ may serve as the only available oxygen delivery mechanism for animals suffering ischemia or traumatic and surgical blood loss events. The Company expects to file a registration for OxyFex™ and could begin marketing the compound for veterinary applications within 12 months with adequate funding in a variety of locations around the world. Of note is that a biosimilar product to OxyFex™, called Oxyglobin, was approved in 1998 by the U.S. FDA Center for Veterinary Medicine and in 1999 by the European Commission for the treatment of canine anemia regardless of its cause. Oxyglobin is currently unavailable in the U.S. but is stated on OPK Biotech's website to be available for canine use in the EU.

Market Size

It is estimated that there are roughly 15,000 small animal veterinary practices in the U.S., 4,000 mixed animal practices that treat small and large animals in the U.S., and 22,000 small animal practices in Europe. The average veterinary practice treats only a small percentage of canine anemia cases with RBC transfusion, with the remaining animals receiving either cage rest or treatment such as fluid administration, iron supplements, nutritional supplements, or inspired oxygen.

Potential Marketing Strategy

Boston Therapeutics is targeting veterinary treatment of canine anemia as its first market for seeking early regulatory approval in the European Union. Since there is considerable commonality between the metabolic functions of humans and other mammals, 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. Third-party testing has already been conducted by a company that developed a bio-similar product to Ipoxyn™. In this case, testing included repeated intravenous infusions of the product in dogs, which was reported in literature and regulatory filings, and where the testing did not result in the animal subjects' reported mortality/morbidity. Data with regard to anemic dogs infused with the bio-similar product showed increased plasma hemoglobin levels, which led to an increase of the oxygen carrying capacity of treated animals. Importantly, while Boston Therapeutics has completed certain animal studies that it believes were successful, pre-clinical results in animal studies are not necessarily predictive of outcomes in human clinical trials.

Competitive Landscape: Biopure Products

In 1998, the FDA Center for Veterinary Medicine approved a bio-similar product to OxyFex™, which was Biopure Corporation's Oxyglobin (with the European Commission approving Oxyglobin in 1999)—in both cases to treat canine anemia, regardless of the cause. Biopure was a biopharmaceutical company specialized in oxygen therapeutics for use in both human and veterinary applications. Oxyglobin was intended to transport oxygen to the body's tissues, employing hemoglobin-based oxygen carrying (HBOC) molecules in solution to increase oxygen transfer to the tissues. The competing companies with Biopure were Allied Pharmaceutical, Northfield Laboratories, Baxter International, and Hemosol of Toronto.

Biopure had developed two products: Hemopure® (HBOC-1) [hemoglobin glutamer-250 (bovine)] for human use and Oxyglobin (HBOC-301) [hemoglobin glutamer-200 (bovine)] for veterinary use, as described on page 32.

Hemopure®

Biopure's Hemopure's average oxygen content was maximized due to the reduced size of the stabilized HBOC molecules compared to RBCs. Due to the reduced size of the HBOC in Hemopure®, oxygen could be transported to restricted areas where normal RBCs failed to reach. Hemopure® was only indicated for temporary oxygen replenishment through the oxygen bridge, with an average half-life of 19 hours and with long-term oxygen support requiring RBC blood transfusion.

Hemopure®, however, was not able to gain approval in the U.S. or UK because of safety and reliability concerns by the European Commission and the FDA, respectively. In July 2009, Biopure announced it had filed for bankruptcy protection under Chapter 11, Title 11, United States Code and in September 2009 entered into an agreement with OPK Biotech LLC for the sale of substantially all of its assets. OPK Biotech states on its website that Hemopure® is available in South Africa for adult, human patients to treat surgical anemia.

Boston Therapeutics' believes its products may prove to be superior to Hemopure® by comparison on cardio-toxicity parameters and hold a different oxygenation profile as well as have longer stability and shelf life at room temperature. A summary of the potential key competitive advantages of Ipoxyn™ (OxyFex™) is provided in Figure 20 (page 32).

Figure 20

IPOXYN™/OXYFEX™: POTENTIAL COMPETITIVE ADVANTAGES

- No current drug available to prevent or treat necrosis
- Ischemia is currently treated by high-pressure (hyperbaric) chamber
- All oxygen therapeutic drugs have failed FDA trials
- Stable and does not scavenge nitric oxide
- Stable at room temperature

Source: Boston Therapeutics, Inc.

Oxyglobin® [hemoglobin glutamer-200 (bovine)]

Although approved for dogs only and currently only available in Europe, Oxyglobin [hemoglobin glutamer-200 (bovine)] or HBOC-301 is the first and only oxygen therapeutic to receive marketing clearance from the U.S. FDA and the European Commission (EMEA) for veterinary use based on data from more than 800 case studies nationwide. The compound is both an oxygen-carrying fluid therapy and an alternative to RBC transfusion (e.g., massive blood loss, immune-mediated hemolytic anemia, etc.). Differing from Hemopure® in molecule size of the stabilized HBOC, Oxyglobin is approved for oxygen fluid therapy (administered intravenously). The stabilized HBOC flows through the blood plasma in the body where oxygen transport occurs.

Boston Therapeutics' Compound Versus Biopure's

A key finding from Boston Therapeutics with regard to its compound, Ipoxyn™, is the polysaccharide manipulation on the protein chain molecule, which can be rendered low in toxicity with enhanced carbohydrate chemistry. As well, it can be manufactured inexpensively. This finding allows for the development with the full advantage of two decades of thorough clinical and preclinical development based on biological similarity to Oxyglobin. Furthermore, Oxyglobin did not suffer the toxicity record as demonstrated by Hemopure®. An FDA meeting in late 2008 reinforced this regulatory strategy, making Ipoxyn™ a new chemical entity (NCE) with no toxicity background associated with the chemical structure of the compound and cleared the path for a regular application for an IND for limb ischemia indication.

Potential Competition

Boston Therapeutics, Inc. is focused on developing novel products targeting the diabetes and inflammatory disease markets. The Company's portfolio includes two development-stage candidates—BTI320 and Ipoxyn™ (and veterinary analog OxyFex™)—and a marketed over-the-counter (OTC) dietary supplement for diabetes, called SugarDown®. The Company's carbohydrate-based compounds may be able to better manage blood glucose in diabetics and more effectively manage conditions requiring oxygen delivery, such as ischemia and its resulting condition of necrosis, as the drug works to pick up oxygen in the lungs and deliver it to oxygen-deprived tissues. Boston Therapeutics' novel compounds employ complex carbohydrate chemistry (CCC) technology, which due to its innate structural complexity, has not been given the same consideration as nucleic acids and proteins. That said, competition within the two therapeutic categories being addressed by Boston Therapeutics is strong, as described in the accompanying section.

PREDIABETES AND TYPE 2 DIABETES

The diabetes treatment market is a highly competitive market, with almost every major drug manufacturer looking to serve the 382 million-plus people currently living with or at risk for developing Type 2 diabetes in the world. As of late 2013, there were 15 Type 2 diabetes drugs in Phase III or later clinical development (Source: Frost & Sullivan's *Competition Intensifies as Pharma Companies Race to Launch Type 2 Diabetes Drugs*, August 20, 2013). As a result of a global focus on new and improved diabetes and prediabetes treatments, Frost & Sullivan analysts further stated an expectation of a "steady stream of new product launches over the next six years," where competitive new entrants would demonstrate superior safety and disease control characteristics. Similarly, Barclays' analysts have forecast a half-dozen new diabetes product approvals over the next two years, prompting companies with existing therapies to ramp up sales and marketing efforts in an attempt to shore up their competitive position and build brand loyalty (Source: Bloomberg's *Novo's Sales Assault on U.S. Diabetes Market Sets Rivalry*, September 10, 2013).

However, despite the intense marketing competition, many of the drugs in the pipeline are very similar to current products: for example, employing a longer-acting or faster-onset of an approved medication. Thus, there is considerable opportunity for new therapies with a unique mode of action that can achieve favorable disease management and be administered in a more convenient manner. To this end, analysts forecast that key products in the prediabetes and diabetes arena going forward will be "pills that combine two or more of the different types of drugs" (Source: Bloomberg, September 10, 2013).

It is worth noting that there are a number of ways to approach diabetes care, from traditional insulin administration to mealtime-only medicines to newer approaches like Boston Therapeutics', which is designed to work even at the prediabetes (pre-insulin) stage in order to slow the onset of Type 2 diabetes and which may help delay a patient's need for insulin altogether.

As new technologies come to market, such as Boston Therapeutics' innovative approach to managing blood glucose levels during digestion, they may ultimately seek to take market share from the global healthcare companies investing in their own new diabetes products. Alternatively, Boston Therapeutics like other small but skilled pharmaceutical/biotechnology companies may directly benefit from the increasing competition and investments by larger companies into the diabetes care space. As such, companies holding novel diabetes technologies may be prime acquisition or joint venture targets over the next several years.

The summaries on pages 34-35 are not intended to be an exhaustive collection of potential competitors to Boston Therapeutics in the diabetes space; however, they are believed to be representative of the type of competition the Company may encounter as it seeks to further commercialize its products/technologies.

Bayer HealthCare Pharmaceuticals Inc.

The U.S. arm of global pharmaceutical company Bayer AG (BAYRY-OTC), Bayer HealthCare Pharmaceuticals, is active in women's health, diagnostic imaging, hematology, neurology, cancer, and many other specialty therapeutic areas. The company's product portfolio has included Precose® (acarbose), which is an oral tablet administered to Type 2 diabetics and, in some countries people with prediabetes, which works to lower a patient's blood sugar by preventing the breakdown of starches into sugars. Having been available for Type 2 diabetes since 1990, generic acarbose is now sold by numerous companies around the world. Globally, it is marketed by Bayer in more than 95 countries (outside of the U.S.) under brand names Glucobay®, Prandase®, or Glucor®. The acarbose compound is known as an alpha-glucosidase inhibitor, which slows the digestion of carbohydrates in the body and in turn helps control blood sugar levels. It can be administered on its own or as a combination therapy with other types of oral diabetes medicines and is usually taken three times a day with meals but dosages can vary. Research has found that the most common side effects for acarbose are gastrointestinal symptoms, such as abdominal pain, diarrhea, and flatulence, which occurred at an incidence of 19%, 31%, and 74%, respectively, in clinical trials versus corresponding incidences of 9%, 12%, and 29% in placebo-treated patients (Source: Bayer's prescribing information for Precose®, 2011).

Novo Nordisk A/S (NVO-NYSE)

Headquartered in Denmark, Novo Nordisk is a global healthcare company focused primarily on products for diabetes care, haemophilia care, growth hormone therapies, and hormone replacement therapies. The company's diabetes products specifically include Tresiba® (insulin degludec) in the EU and Japan, Victoza® (liraglutide injection), Levemir® (insulin detemir), NovoMix® (biphasic insulin aspart), NovoRapid® or NovoLog® (insulin aspart), and a large variety of insulin pens and devices as well as 14 diabetes (Type 1 and Type 2) compounds in various stages of development from Phase I to final regulatory review. While thus far Novo Nordisk has appeared largely focused on injectable products (even the company's NovoLog® mealtime insulin, which is taken 5 to 10 minutes before eating, is an injection), the company recently announced that it planned to invest up to $3.7 billion by 2020 in developing diabetes tablets that can replace traditional insulin injections. The company has reported having six diabetes pills under development, which include both oral insulin and an oral GLP-1 agonist (Source: Reuters' *Novo Nordisk to invest up to $3.7 billion on diabetes pills*, October 7, 2013).

Merck & Co., Inc. (MRK-NYSE)

Merck & Co. ("Merck" in the U.S. and Canada and Merck Sharp & Dohme Corp. or "MSD" elsewhere) focuses on pharmaceuticals, consumer products, vaccines, and animal health. The company is headquartered in New Jersey but operates globally to develop and market products for diseases like Alzheimer's, diabetes, and cancer. Its lead diabetes franchise entails Januvia® (sitagliptin) and Janumet® (sitagliptin/metformin), which are dipeptidyl peptidase-4 (DPP-4) inhibitors launched in 2006/2007. Januvia® is a daily pill prescribed to help lower blood sugar levels in Type 2 diabetes adult patients, and Janumet® is a twice-daily pill taken with meals. Despite concerns that taking these DPP-4 inhibitors can increase a patient's risk of developing pancreatitis, global sales of Januvia® and Janumet® were approximately $5.7 billion in FY 2012 (Source: *Forbes*, July 23, 2013). As a result of a recent increase in competition, Merck in 2013 emphasized greater marketing of Januvia®, which included increased spending on physician education and entering into co-promotion agreements with other companies. In addition, the company is advancing two additional Type 2 diabetes drugs—both oral—through its pipeline: (1) ertugliflozin (MK-8835), an oral sodium glucose cotransporter (SGLT-2) inhibitor in Phase II clinical trials; and (2) omarigliptin (MK-3102), an oral, once-weekly DPP-4 inhibitor in Phase III trials.

The Phase II candidate, ertugliflozin, is being developed in combination with Pfizer Inc. (PFE-NYSE). It follows the FDA's first approval of an SGLT-2 product, Johnson & Johnson's (JNJ-NYSE) Invokana® (canagliflozin) tablets, which were approved in the U.S. in March 2013. Merck and Pfizer's ertugliflozin SGLT-2 product candidate functions by excreting glucose in urine in order to help stabilize sugar levels.

AstraZeneca PLC (AZN-NYSE)

AstraZeneca is a global biopharmaceutical company focused primarily on cancer, cardiovascular/metabolic diseases like diabetes, and respiratory/inflammation/autoimmune conditions. In the past, the company jointly developed and co-promoted its diabetes medicines with Bristol-Myers Squibb Co. (BMY-NYSE), which includes prominent Type 2 diabetes medications Onglyza® (saxagliptin), a DPP-4 inhibitor that stimulates the pancreas into increasing insulin production while reducing the liver's sugar output, and Bydureon® (exenatide) and Byetta® (exenatide injection), both of which are injectable GLP-1 agonists. In December 2013, Bristol-Myers and AstraZeneca entered into an agreement whereby AstraZeneca is acquiring full ownership of the companies' joint diabetes business in consideration of $2.7 billion paid to Bristol-Myers at closing and up to $1.4 billion in regulatory, launch, and sales-related payments and future royalty payments until 2025. AstraZeneca thus holds the rights to the following products: Onglyza®, Kombiglyze™ XR (saxagliptin and metformin HCl extended release), Komboglyze™ (saxagliptin and metformin HCl), Byetta®, Bydureon®, metreleptin, Symlin® (pramlintide acetate), and dapagliflozin (marketed as Forxiga® outside the U.S. and Farxiga™ inside the U.S.).

Forxiga®/Farxiga™ was approved by the EU in 2012 and by the FDA in January 2014. It belongs to the new class of SGLT-2 inhibitors currently being launched or advanced through regulatory reviews by several companies. Farxiga™ is an oral medicine taken once a day to improve glycemic control in adults with Type 2 diabetes. In addition, AstraZeneca's combination medicine called Xigduo™, which combines Forxiga®/Farxiga™ with metformin hydrochloride in a twice-daily tablet, was approved in Europe in January 2014.

OXYGEN DELIVERY PRODUCTS AND TECHNOLOGY

As Boston Therapeutics continues to develop Ipoxyn™ for necrosis and other ischemic/hypoxic conditions, including oxygen deprivation in the peripheral vascular system that leads to lower-limb ischemia stemming from diabetes, the Company may encounter competition from traditional therapies, such as blood infusions, administering red blood cells (RBCs), and hyperbaric oxygen. Studies and testing of Ipoxyn™, however, seeks to demonstrate that this new method of delivering oxygen can offer multiple improvements over conventional approaches, including being more readily available with a longer shelf-life than RBC products, being safe for all blood types without requiring testing for compatibility, and being appropriate for use both inside and outside of the hospital (thus expanding its utility to critical care, emergency environments—where time is of the essence). A summary of these potential competitive advantages is provided in Figure 21.

Figure 21

ANTICIPATED COMPETITIVE ADVANTAGES OF IPOXYN™

Availability	Readily available with a two year shelf-life versus a two-week shelf life for RBCs, and being easier to perfuse
Stability	Can be stored at room temperature for months while maintaining full capacity for oxygen delivery and release and logistical convenience
Sterile	Free of infectious agents and unnecessary elements when produced with GMP manufacturing
Compatibility	Safe for all blood types in a wide range of conditions and does not require pre-infusion typing or testing for compatibility
Critical Care	Can be safely applied to treat or prevent ischemic conditions in emergency cases of shock, trauma, heart attack, stroke, etc. due to a readily available infusion package for emergency medical teams to use on site
Molecular Structure	Small molecular size versus RBCs, thus IPOXYN™ may have better flow characteristics and circumvents constricted vessels that restrict flow of RBCs
Oxygenation	High solubility gives IPOXYN™ high capacity and faster exchange of oxygen in tissues, as well as facilitates the release of oxygen from RBCs, leading to greater overall efficiency

Source: Boston Therapeutics, Inc.

In addition to traditional therapies, Boston Therapeutics' Ipoxyn™ may compete with other pharmaceutical approaches to oxygen delivery and investigational hemoglobin solutions currently in development, as well as medical devices and therapies in the cardiovascular arena. Within the market for lower limb ischemia treatments, the most effective treatments have shown to be bypass surgery and angioplasty, though in severe cases, where the lower limb arteries are severely damaged by disease, revascularization is likely not an 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 generally unsuccessful as they are not able to provide for significant long term improvement.

It is noteworthy that the Company is also developing OxyFex™, a veterinary version of its oxygen delivery mechanism designed to treat animals suffering with ischemia or traumatic and surgical blood loss. As in humans, a blood transfusion is a possible treatment for animals with hypoxia, though there are also some clinical approaches, such as OPK Biotech's Oxyglobin®, as described on page 37.

The following is not a comprehensive list therapies and companies targeting the area of oxygen delivery products, either marketed or in development, but is intended to be representative of the type of competition Boston Therapeutics could encounter as it furthers development in this field.

Technologies

Hyperbaric Oxygen Therapy (HBOT)

Hyperbaric oxygen has been found to be effective at treating a number of conditions, from decompression sickness after scuba diving to skin and bone infections that may cause necrosis (tissue death). The Mayo Clinic lists the following indications as suitable for HBOT: bubbles of air in the blood vessels (arterial gas embolism), decompression sickness, carbon monoxide poisoning, non-healing wounds, crushing injuries, gangrene, skin or bone infections that cause tissue death, radiation injuries, burns, skin grafts or skin flaps at risk of tissue death, and severe anemia. The process for HBOT entails breathing in pure oxygen in a pressurized room where the air pressure is higher than the normal atmospheric pressure. As such, it requires specialized chambers that are not available at every medical or trauma center. Patients may have to search to find a hospital equipped with hyperbaric oxygen. Some outpatient centers or private facilities may also have small HBOT units. The intent is that breathing oxygen at a higher than normal air pressure allows the lungs to take in up to three times more oxygen than usual—increasing the level of oxygen circulating in the bloodstream and promoting healing. It may take anywhere from 3 to 30 HBOT sessions to treat a patient, depending on the condition.

Erythropoietin (EPO) Products

Another method to increase oxygenation in the blood is to administer erythropoietin (EPO). EPO is a protein produced naturally in the kidneys. It is generally released in the body in response to decreased levels of oxygen in body tissue. The role of EPO is to stimulate the erythropoietic system in the bone marrow to produce more RBCs. Many pharmaceutical companies offer EPO-based injection and infusion products that trigger the patient's body to begin producing more of their own RBCs (as opposed to receiving an infusion of RBCs directly). However, EPO is subject to limitations. Because it has a short half-life in the body, it requires frequent repeat injections, and is largely used to treat either chronic anemia or in anticipation of blood loss during surgery. Though there are variations of EPO and EPO-stimulating agents today that are faster acting or longer lasting, it is still not considered an ideal solution for temporary use or in emergency situations of acute blood loss. Using EPO as a way to increase the body's red blood cell (RBC) mass and thus increase the oxygen in blood has also given rise to allegations of "blood doping" in sports.

Companies

Oxygen Biotherapeutics, Inc. (OXBT-NASDAQ)

Specialty pharmaceutical company Oxygen Biotherapeutics (formerly Synthetic Blood International, Inc.) is working to develop oxygen-based therapies. The company's primary product candidate is Oxycyte®, a perfluorocarbon (PFC) therapeutic oxygen carrier in Phase II clinical trials. Administered directly into the veins, Oxycyte® is intended to help deliver oxygen to specific oxygen-deprived tissues within the body. The company believes this product could be targeted for use in traumatic brain injury, decompression sickness, skin care, wound treatment, and acute ischemic conditions. Oxycyte® is currently in Phase IIb trials for traumatic brain injury in Switzerland and Israel. Studies of a topical cream version of Oxycyte® have been completed in India. In addition, the U.S. Navy is investigating an emulsion of the product in ongoing preclinical research for its potential in decompression illness. Oxygen Biotherapeutics believes the Navy's preclinical safety studies could be concluded in mid-2014. The company completed its own Phase I and IIa studies for Oxycyte® in the U.S. but Phase IIb was put on clinical hold by the FDA due to questions raised by the regulatory agency (Source: Oxygen Biotherapeutics).

FibroGen, Inc.

San Francisco-based FibroGen has focused on research and development of therapeutics for fibrosis (pathological scarring) and related fields since 1995. In addition to its emphasis on fibrosis, FibroGen is emerging as a drug discovery company studying prolyl hydroxylases, which have a role in regulating the activity of hypoxia-inducible factor (HIF). When activated, HIF coordinates cellular and physiological responses that protect against tissue damage and cell death and that restore oxygen balance. The company develops small molecules targeted toward harnessing and directing the protective effects of HIF physiology in order to treat various medical conditions. One such example is using HIF-stabilizing therapeutics (called FG-4592 and FG-2216) to treat anemia of chronic kidney disease by using hypoxic signaling to upregulate EPO in the body. Both of these are in Phase II/III development. In July 2013, FibroGen entered into a strategic collaboration with AstraZeneca for development and commercialization of FG-4592, whereby AstraZeneca committed to pay FibroGen upfront and subsequent non-contingent payments of $350 million, potential future milestone payments of up to $465 million, potential future sales-related milestone payments, and tiered royalty payments on future sales in the low 20% range.

Similarly, the company is also developing cytoprotective HIF-based products to treat trauma associated with tissue damage or injury. FibroGen reports that it has preclinical evidence to support the potential of HIF stabilization therapy in acute ischemic conditions, including myocardial infarction, acute renal failure, and stroke. Ongoing drug discovery efforts continue to evaluate the use of this technology at providing chronic cytoprotection, such as in neurodegenerative disease, or in sickle cell, revascularization for peripheral vascular disease, treatment of sepsis, metabolic shifts to burn fats, pulmonary dysplasia, and other indications.

OPK Biotech LLC

Cambridge, Massachusetts-based OPK Biotech is a company focused on creating and distributing products designed to carry oxygen to the body's tissues. Its technology emphasizes infusing chemically stabilized hemoglobin molecules (versus RBCs) into the bloodstream. Hemoglobin both carries oxygen and facilitates the release of oxygen from the blood's existing RBCs—two functions that increase the delivery of oxygen to the tissues. OPK's efforts in oxygen delivery have led to the commercialization of Oxyglobin® (The Oxygen Carrying Fluid™) for veterinary use in canine anemia. OPK Biotech states on its website that Oxyglobin® is the only treatment to offer immediate relief from the clinical signs of anemia in dogs (other than a blood transfusion); though, it does have side effects. Common side effects of Oxyglobin® are discolored skin, mucous membranes, and urine; circulatory overload; and vomiting. This product is stable at room temperature for three years after manufacture and is compatible with all blood types and does not require blood typing. In addition to its veterinary product, OPK Biotech states on its website that it markets Hemopure® in South Africa for adult, human patients to treat surgical anemia. Hemopure® (which, like Oxyglobin®, is also a bovine hemoglobin product) is not approved in the U.S., but has been used in South Africa since 2001.

Key Points

- 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—BTI320 (formerly PAZ320) and Ipoxyn™ (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.
    - BTI320 is a non-systemic, chewable 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. BTI320 has demonstrated a favorable safety profile with minimal side effects, in large part because it is a non-systemic method for treating diabetes. Enrollment in Phase IIb trial is underway and enrollment in a Phase llb in the U.S. is expected shortly. The Company is preparing documents for an IND submission with the FDA for a Phase III study. BTI320 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, and a 505(b)(2) accelerated development pathway for FDA approval. The Company's strategy of combining proven drug candidates with novel delivery methods and pharmaceutical compositions is intended to reduce clinical development time and costs and lower regulatory risks, while delivering valuable products in areas of high unmet need to the marketplace.
    - Boston Therapeutics entered into a clinical trial at Dartmouth Medical Center in Lebanon, New Hampshire, for BTI320 to measure post-prandial elevation of blood glucose. The goal was to leverage data from this study in the marketing of BTI320. This Phase IIa trial, for which results were recently published in the peer-reviewed journal *Endocrine Practice*, showed that BTI320 was well tolerated in patients taking various anti-diabetic agents, including metformin.
- 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 sharp spikes in blood sugar associated with eating high carbohydrate foods.
- The Company is also developing Ipoxyn™, a glycoprotein-based injectable therapeutic agent, which 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 Ipoxyn™ could be lower-limb ischemia associated with diabetes.
    - Ipoxyn™ 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.
- As of December 31, 2013, Boston Therapeutics had cash of nearly $3.4 million and current liabilities of approximately $340,000. During 2013, the Company raised $5.6 million in support of its product portfolio's near-term clinical requirements. The Company plans to seek additional capital through private placements and public offerings of its common stock.

Historical Financial Results

Figures 22, 23, and 24 summarize Boston Therapeutics, Inc.'s key historical financial statements: the Condensed Consolidated Statements of Operations, Balance Sheets, and Statements of Cash Flows, as presented in the Company's Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 14, 2014.

Figure 22
STATEMENTS OF OPERATIONS

	For the Years Ended December 31, 2013 and 2012	
	December 31, 2013	**December 31, 2012**
Revenue	$ 323,412	$ 42,254
Cost of goods sold	278,205	56,859
Gross margin (deficit)	45,207	(14,605)
Operating expenses:		
Research and development	542,492	178,938
Sales and marketing	329,218	232,411
General and administrative	3,753,742	1,036,566
Total operating expenses	4,625,452	1,447,915
Operating loss	(4,580,245)	(1,462,520)
Interest expense	(19,692)	(18,384)
Other Income	1,505	—
Foreign currency loss	(3,071)	(3,211)
Net loss	$ (4,601,503)	$ (1,484,115)
Net loss per share- basic and diluted	$ (0.18)	$ (0.09)
Weighted average shares outstanding basic and diluted	25,370,626	16,873,903

Source: Boston Therapeutics, Inc.

Figure 23
BALANCE SHEETS

	December 31, 2013	December 31, 2012
ASSETS		
Cash and cash equivalents	$ 3,387,428	$ 552,315
Accounts receivable	99,786	17,351
Prepaid expenses and other current assets	153,681	9,073
Inventory	110,625	16,809
Total current assets	3,751,520	595,548
Property and equipment, net	15,176	7,075
Intangible assets	696,429	760,714
Goodwill	69,782	69,782
Other assets	2,125	2,125
Total assets	$ 4,535,032	$ 1,435,244
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 170,977	$ 294,187
Accrued expenses and other current liabilities	720,965	146,774
Total current liabilities	891,942	440,961
Notes payable - related parties	297,820	297,820
Total liabilities	1,189,762	738,781
COMMITMENTS AND CONTINGENCIES		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common stock, $0.001 par value, 200,000,000 and 100,000,000 shares authorized, 37,362,160 and 18,745,706 shares issued and outstanding at December 31, 2013 and 2012, respectively	37,362	18,746
Additional paid-in capital	10,606,810	3,375,116
Accumulated deficit	(7,298,902)	(2,697,399)
Total stockholders' equity	3,345,270	696,463
Total liabilities and stockholders' equity	$ 4,535,032	$ 1,435,244

Source: Boston Therapeutics, Inc.

Figure 24
STATEMENTS OF CASH FLOWS

	December 31, 2013	December 31, 2012
Cash flows from operating activities:		
Net loss	$ (4,601,503)	$ (1,484,115)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	67,103	64,968
Stock-based compensation	1,554,913	480,108
Issuance of common stock and common stock warrants for consulting services	509,967	128,775
Changes in operating assets and liabilities:		
Accounts receivable	(82,435)	(17,351)
Inventory	(93,816)	6,787
Prepaid expenses and other current assets	(144,608)	(5,867)
Accounts payable	(123,210)	(47,686)
Accrued expenses	574,191	21,458
Net cash used in operating activities	(2,339,398)	(852,923)
Cash flows from investing activities:		
Purchase of property and equipment	(10,919)	(7,757)
Net cash used in investing activities	(10,919)	(7,757)
Cash flows from financing activities:		
Proceeds from notes payable - related parties	—	40,000
Proceeds from issuance of common stock and common stock warrants (net of issuance costs)	5,185,430	1,147,000
Net cash provided by financing activities	5,185,430	1,187,000
Net increase in cash and cash equivalents	2,835,113	326,320
Cash and cash equivalents, beginning of period	552,315	225,995
Cash and cash equivalents, end of period	$ 3,387,428	$ 552,315
Supplemental disclosure of cash flow information		
Cash paid during the period for:		
Interest	$ —	$ —
Income taxes	$ —	$ —

Source: Boston Therapeutics, Inc.

Risks and Disclosures

This Executive Informational Overview® (EIO) 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 EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in 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 this report 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 this or other filings as an indication of their relative importance. The risks and uncertainties overviewed in Boston Therapeutics' Form 10-K 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.

RISKS RELATED TO THE COMPANY'S BUSINESS

If Boston Therapeutics does not receive additional funding, it will have to curtail or cease operations.

Boston Therapeutics has incurred losses totaling $7.3 million since inception through December 31, 2013. As of December 31, 2013, Boston Therapeutics had approximately $3.4 million cash on hand. The opinion of the Company's independent registered public accountants on the Company's audited financial statements as of and for the year ended December 31, 2013, contains an explanatory paragraph regarding substantial doubt about the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent upon raising capital from financing transactions. Boston Therapeutics raised approximately $5.6 million in gross proceeds in private and public placements during the year ended December 31, 2013. To stay in business, Boston Therapeutics will need to raise additional capital through public or private sales of the Company's securities, debt financing, or short-term bank loans, or a combination of the foregoing.

Revenues generated from the Company's operations are not presently sufficient to sustain its operations and Boston Therapeutics may not generate sufficient sales or other revenue from SugarDown® alone to fund operations. Boston Therapeutics will need additional capital to fully implement its business, operating, and development plans. However, additional funding from an alternate source or sources may not be available to the Company on favorable terms, if at all. To the extent that money is raised through the sale of the Company's securities, the issuance of those securities could result in dilution to existing security holders. If Boston Therapeutics raises money through debt financing or bank loans, it may be required to secure the financing with some or all of its business assets, which could be sold or retained by the creditor should Boston Therapeutics default in its payment obligations. If Boston Therapeutics fails to raise sufficient funds, it would have to curtail or cease operations.

Management has developed what it believes is a viable plan to continue as a going concern. The plan relies upon the Company's ability to obtain additional sources of capital and financing. If the amount of capital Boston Therapeutics is able to raise from financing activities, together with the Company's revenues from operations, is not sufficient to satisfy its capital needs, even to the extent that Boston Therapeutics reduces operations accordingly, Boston Therapeutics may be required to cease operations.

Boston Therapeutics is a company with a limited operating history, which makes it difficult to evaluate the Company's current business and future prospects.

Boston Therapeutics is a company with limited operating history, and the Company's operations are subject to all of the risks inherent in establishing a new business enterprise. The likelihood of the Company's success must be considered in light of the problems, expenses, difficulties, complications, and delays frequently encountered in connection with the formation of a new business, the development of new technologies, or those subject to clinical testing, and the competitive and regulatory environment in which Boston Therapeutics will operate. Boston Therapeutics has made initial sales of the Company's SugarDown® product as a dietary supplement and, while Boston Therapeutics expects to continue selling or licensing that product, Boston Therapeutics has no other products currently available for sale, and none are expected to be commercially available for at least 18 months, if at all. Boston Therapeutics may never obtain U.S. Food and Drug Administration (FDA) approval of the Company's products in development and, even if Boston Therapeutics does so and is also able to commercialize the Company's products, it may never generate revenue sufficient to become profitable. The Company's failure to generate revenue and profit would likely cause its securities to decrease in value and/or become worthless.

Additional financing required to implement the Company's business plan may not be available on favorable terms or at all, and Boston Therapeutics may have to accept financing terms that would adversely affect the Company's shareholders.

Boston Therapeutics will need to continue to conduct significant research, development, testing, and regulatory compliance activities for Ipoxyn™ and to a lesser degree on BTI320 that, together with projected general and administrative expenses, Boston Therapeutics expects will result in operating losses for the foreseeable future. Boston Therapeutics may not generate sales or other revenue from SugarDown® alone to fund operations and will remain dependent on outside sources of financing until that time and Boston Therapeutics will need to raise funds from additional financing. Boston Therapeutics has no commitments for any financing at this time, and any financing commitments may result in dilution to the Company's existing stockholders. Boston Therapeutics may have difficulty obtaining additional funding, and may have to accept terms that would adversely affect the Company's stockholders. For example, the terms of any future financings may impose restrictions on the Company's right to declare dividends or on the manner in which Boston Therapeutics conducts the Company's business. Additionally, Boston Therapeutics may raise funding by issuing convertible notes, which if converted into shares of the Company's common stock, would dilute the Company's then shareholders' interests. Lending institutions or private investors may impose restrictions on a future decision by the Company to make capital expenditures, acquisitions, or significant asset sales. If Boston Therapeutics is unable to raise additional funds, it may be forced to curtail or even abandon its business plan.

The Company's ability to grow and compete in the future will be adversely affected if adequate capital is not available.

The ability of the Company's business to grow and compete depends on the availability of adequate capital, which in turn depends in large part on the Company's cash flow from operations and the availability of equity and debt financing. The Company's cash flow from operations may not be sufficient or Boston Therapeutics may not be able to obtain equity or debt financing on acceptable terms or at all to implement the Company's growth strategy. As a result, adequate capital may not be available to finance the Company's current growth plans, take advantage of business opportunities, or respond to competitive pressures, any of which could harm the Company's business.

The Company's products are based on novel, unproven technologies.

The Company's drug candidates in development are based on novel, unproven technologies using proprietary carbohydrate compounds in combination with FDA-approved drugs currently used in the treatment of diabetes, ischemia, anemia, trauma, and other diseases. Carbohydrates are difficult to synthesize, and Boston Therapeutics may not be able to synthesize carbohydrates that would be usable as delivery vehicles for the anti-hypoxia drugs the Company is working with or other therapeutics it intends to develop. Although Boston Therapeutics has completed certain animal studies that it believes were successful, preclinical results in animal studies are not necessarily predictive of outcomes in human clinical trials. Clinical trials are costly, time-consuming, and may not be successful. They involve the testing of potential therapeutic agents, or effective treatments, in humans, typically in three phases, to determine the safety and efficacy of the products necessary for an approved drug. Many products in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if the Company's products progress successfully through initial human testing, they may fail in later stages of development. Boston Therapeutics may engage others to conduct the Company's clinical trials, including clinical research organizations and, possibly, government-sponsored agencies. These trials may not start or be completed as Boston Therapeutics forecasts, or may not achieve desired results.

Boston Therapeutics may be unable to commercialize its products.

Even if the Company's current and anticipated products achieve positive results in clinical trials, Boston Therapeutics may be unable to commercialize them. Potential products may fail to receive necessary regulatory approvals, and such products, along with products that do not require regulatory approval, may be difficult to manufacture on a large scale, be uneconomical to produce, fail to achieve market acceptance, or be precluded from commercialization by proprietary rights of third parties. The Company's inability to commercialize its products would substantially impair the viability of the business.

The Company's reliance on a limited number of customers for a significant portion of its revenues could materially and adversely affect results of operations and liquidity.

During the year ended December 31, 2013, the Company's top customer accounted for 97% of total revenue. While Boston Therapeutics expects this concentration to go down as its business expands, if the concentration remains and Boston Therapeutics is not able to secure further business from this customer or is unable to replace the business provided by this customer, it may have a material adverse effect on the Company's business, result of operations, financial condition, or liquidity.

Boston Therapeutics is dependent upon two of its officers for management and direction and the loss of these persons could adversely affect the Company's operations and results.

Boston Therapeutics is dependent upon both Dr. Platt and Mr. Tassey for implementation of the Company's proposed expansion strategy and execution of the Company's business plan. The loss of Dr. Platt or Mr. Tassey could have a material adverse effect upon its results of operations and financial position. Boston Therapeutics does maintain "key person" life insurance policies for Dr. Platt and Mr. Tassey.

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

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

Boston Therapeutics will depend on third parties to manufacture and market its products and to design trial protocols, arrange for and monitor the clinical trials, and collect and analyze data.

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

In addition, Boston Therapeutics has limited experience in marketing, sales, or distribution, and recently hired an experienced business development executive to commercialize the Company's pharmaceutical products. Boston Therapeutics currently has an agreement with Advance Pharmaceutical Co. Ltd. to develop markets in Hong Kong, South Korea, China, and Macau for SugarDown®. If Boston Therapeutics develops additional commercial products, it will need to rely on licensees, collaborators, joint venture partners, or independent distributors to market and sell those products and may need to rely on additional third parties to market the Company's products.

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

Boston Therapeutics is exposed to product liability, preclinical, and clinical liability risks, which could place a substantial financial burden upon it, should Boston Therapeutics be sued.

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

Boston Therapeutics currently maintains product liability insurance for SugarDown®. There is no guarantee that such insurance will provide adequate coverage against the Company's potential liabilities. Since Boston Therapeutics does not currently have any FDA-approved products or other formulations, it does not currently have any other product liability insurance covering commercialized products. Boston Therapeutics may not be able to obtain or maintain adequate product liability insurance, when needed, on acceptable terms, if at all, or such insurance may not provide adequate coverage against the Company's potential liabilities. Furthermore, the Company's current and potential partners with which Boston Therapeutics has collaborative agreements or the Company's future licensees may not be willing to indemnify the Company against these types of liabilities and may not themselves be sufficiently insured or have sufficient liquidity to satisfy any product liability claims. Claims or losses in excess of any product liability insurance coverage that may be obtained by the Company could have a material adverse effect on business, financial condition, and results of operations.

In addition, Boston Therapeutics may be unable to obtain or to maintain clinical trial or directors and officer's liability insurance on acceptable terms, if at all. Any inability to obtain and/or maintain insurance coverage on acceptable terms could prevent or limit the commercialization of any products Boston Therapeutics develops.

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

The continuing efforts of government and insurance companies, health maintenance organizations, and other payers of healthcare costs to contain or reduce costs of healthcare may affect the Company's future revenues and profitability, and the future revenues and profitability of the Company's potential customers, suppliers, and collaborative partners and the availability of capital. For example, in certain international markets, pricing or profitability of prescription pharmaceuticals is subject to government control. In the U.S., given recent federal and state government initiatives directed at lowering the total cost of healthcare, the U.S. Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription pharmaceuticals, and on the reform of the Medicare and Medicaid systems. While Boston Therapeutics cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm the Company's business, financial condition, and results of operations.

The Company's ability to commercialize its proposed products will depend, in part, on the extent to which appropriate reimbursement levels for the cost of the Company's proposed formulations and products and related treatments are obtained by governmental authorities, private health insurers, and other organizations, such as HMOs. Third-party payers are increasingly challenging the prices charged for medical drugs and services. Also, the trend toward managed healthcare in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of healthcare services and drugs, as well as legislative proposals to reform healthcare or reduce government insurance programs, may all result in lower prices for or rejection of the Company's products.

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

Boston Therapeutics expects that it will be required to enter into agreements with commercial partners to engage in sales, marketing, and distribution efforts around the Company's products in development. Boston Therapeutics may be unable to establish or maintain third-party relationships on a commercially reasonable basis, if at all. In addition, these third parties may have similar or more established relationships with the Company's competitors. If Boston Therapeutics does not enter into relationships with third parties for the sales and marketing of the Company's proposed products, Boston Therapeutics will need to develop the Company's own sales and marketing capabilities.

Boston Therapeutics may be unable to engage qualified distributors. Even if engaged, these distributors may fail to satisfy financial or contractual obligations to Boston Therapeutics; fail to adequately market the Company's products; cease operations with little or no notice to Boston Therapeutics; or offer, design, manufacture, or promote competing formulations or products.

If Boston Therapeutics fails to develop sales, marketing, and distribution channels, it could experience delays in generating sales and incur increased costs, which would harm the Company's financial results.

Boston Therapeutics will be subject to risks if it seeks to develop its own sales force.

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

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

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

RISKS RELATED TO THE COMPANY'S INDUSTRY

Boston Therapeutics will need regulatory approvals to commercialize the Company's products as drugs.

If Boston Therapeutics chooses to offer BTI320, Ipoxyn™, or any other product as a drug, the Company is required to obtain approval from the FDA to sell the products in the U.S. and from foreign regulatory authorities to sell the products in other countries. The FDA's review and approval process is lengthy, costly, and uncertain. Extensive preclinical and clinical data and supporting information must be submitted to the FDA for each indication for each product candidate to secure FDA approval. Before receiving FDA clearance to market the Company's proposed products, Boston Therapeutics will have to demonstrate that the Company's products are safe and effective on the patient population and for the diseases that are to be treated. Clinical trials, manufacturing, and marketing of drugs are subject to the rigorous testing and approval process of the FDA and equivalent foreign regulatory authorities. The Federal Food, Drug and Cosmetic Act and other federal, state, and foreign statutes and regulations govern and influence the testing, manufacture, labeling, advertising, distribution, and promotion of drugs and medical devices. As a result, regulatory approvals can take a number of years or longer to accomplish and require the expenditure of substantial financial, managerial, and other resources. The FDA could reject an application or require Boston Therapeutics to conduct additional clinical or other studies as part of the regulatory review process. Delays in obtaining or failure to obtain FDA approvals would prevent or delay the commercialization of the Company's product candidates, which would prevent, defer, or decrease the Company's receipt of revenues. In addition, if Boston Therapeutics receives initial regulatory approval, the Company's product candidates will be subject to extensive and rigorous ongoing domestic and foreign government regulation.

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

Data already obtained, or in the future obtained, from preclinical studies and clinical trials do not necessarily predict the results that will be obtained from later preclinical studies and clinical trials. Moreover, preclinical and clinical data is susceptible to varying interpretations, which could delay, limit, or prevent regulatory approval. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and effectiveness of a proposed formulation or product under development could delay or prevent regulatory clearance of the

potential drug, resulting in delays to commercialization, and could materially harm the Company's business. The Company's clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for the Company's drugs, and thus the Company's proposed drugs may not be approved for marketing.

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

Development and protection of Boston Therapeutics' intellectual property are critical to the business. All of the Company's intellectual property has been invented and/or developed or co-developed by the Company's CEO, Dr. Platt. If Boston Therapeutics does not adequately protect its intellectual property, competitors may be able to practice the Company's technologies. The Company's success depends, in part, on its ability to obtain patent protection for its products or processes in the U.S. and other countries, protect trade secrets, and prevent others from infringing on its proprietary rights.

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

Some or all of the Company's patent applications may not issue as patents or the claims of any issued patents may not afford meaningful protection for the Company's technologies or products. In addition, patents issued to Boston Therapeutics or the Company's licensors may be challenged and subsequently narrowed, invalidated, or circumvented. Patent litigation is widespread in the biotechnology industry and could harm the Company's business. Litigation might be necessary to protect the Company's patent position or to determine the scope and validity of third-party proprietary rights, and Boston Therapeutics may not have the required resources to pursue such litigation or to protect the Company's patent rights.

Although Boston Therapeutics will require the Company's scientific and technical employees and consultants to enter into broad assignment of inventions agreements, and all of the Company's employees, consultants, and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored. Currently, Boston Therapeutics does not have any scientific or technical employees. Boston Therapeutics has consultants and a network of uniquely experienced researchers, clinicians, and drug developers, some of whom have signed or been asked to sign agreements.

Products Boston Therapeutics develops could be subject to infringement claims asserted by others.

Boston Therapeutics cannot assure that products based on its patents or intellectual property that it licenses from others will not be challenged by a third party claiming infringement of proprietary rights. If Boston Therapeutics is not able to successfully defend the Company's patents or licensed rights, Boston Therapeutics may have to pay substantial damages, possibly including treble damages, for past infringement.

Boston Therapeutics faces intense competition in the biotechnology and pharmaceutical industries.

The biotechnology and pharmaceutical industries are intensely competitive. Boston Therapeutics faces direct competition from U.S. and foreign companies focusing on pharmaceutical products, which are rapidly evolving. The Company's competitors include major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of these competitors have greater financial and other resources, larger research and development staffs, and more effective marketing and manufacturing organizations, than Boston Therapeutics. In addition, academic and government institutions are increasingly likely to enter into exclusive licensing agreements with commercial enterprises, including the Company's competitors, to market commercial products based on technology developed at such institutions. The Company's competitors may succeed in developing or licensing technologies and products that are more effective

or less costly than its, or succeed in obtaining FDA or other regulatory approvals for product candidates before Boston Therapeutics. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors' financial, marketing, manufacturing, and other resources.

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

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

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

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

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

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

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

RISKS RELATING TO THE COMPANY'S COMMON STOCK

Stock prices for pharmaceutical and biotechnology companies are volatile.

The market price for securities of pharmaceutical and biotechnology companies historically has been highly volatile, and the market from time-to-time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. Fluctuations in the trading price or liquidity of the Company's common stock may adversely affect, among other things, the interest in the Company's stock by purchasers on the open market and the Company's ability to raise capital.

Boston Therapeutics has a limited market for its common stock, which makes the Company's securities very speculative.

Trading activity in the Company's common stock is limited. As a result, an investor may find it difficult to dispose of, or to obtain accurate quotations of the price of the Company's common stock. There can be no assurance that a more active market for the Company's common stock will develop, or if one should develop, there is no assurance that it will be sustained. This could severely limit the liquidity of the Company's common stock, and would likely have a material adverse effect on the market price of the Company's common stock and on the Boston Therapeutics' ability to raise additional capital.

Investors may face significant restrictions on the resale of the Company's common stock due to federal regulation of penny stocks.

The Company's common stock is currently quoted on the OTC under the symbol BTHE. The Company's common stock is subject to the requirements of Rule 15(g)-9, promulgated under the Securities Exchange Act as long as the price of the Company's common stock is below $5.00 per share. Under such rule, broker-dealers who recommend low-priced securities to persons other than established customers and accredited investors must satisfy special sales practice requirements, including a requirement that they make an individualized written suitability determination for the purchaser and receive the purchaser's consent prior to the transaction. The Securities Enforcement Remedies and Penny Stock Reform Act of 1990 also requires additional disclosure in connection with any trades involving a stock defined as a penny stock. Generally, the Commission defines a penny stock as any equity security not traded on a national exchange or quoted on NASDAQ that has a market price of less than $5.00 per share. The required penny stock disclosures include the delivery, prior to any transaction, of a disclosure schedule explaining the penny stock market and the risks associated with it. Such requirements could severely limit the market liquidity of the securities and the ability of purchasers to sell their securities in the secondary market.

Boston Therapeutics has not paid any cash dividends in the past and has no plans to issue cash dividends in the future, which could cause the value of the Company's common stock to have a lower value than other similar companies, which do pay cash dividends.

Boston Therapeutics has not paid any cash dividends on the Company's common stock to date and does not anticipate any cash dividends being paid to holders of the Company's common stock in the foreseeable future. While the Company's dividend policy will be based on the operating results and capital needs of the business, it is anticipated that any earnings will be retained to finance the Company's future expansion. As Boston Therapeutics has no plans to issue cash dividends in the future, the Company's common stock could be less desirable to other investors and as a result, the value of the Company's common stock may decline, or fail to reach the valuations of other similarly situated companies who have historically paid cash dividends in the past.

The Company's stock price may be volatile.

The market for the Company's common stock is subject to wide fluctuations in response to several factors, including, but not limited to the following:

- actual or anticipated variations in the Company's results of operations;
- the Company's ability or inability to generate new revenues;
- increased competition;
- conditions and trends in the pharmaceutical industry and/or the market for the Company's pharmaceutical products in general; and
- changes in regulatory policies.

Further, the Company's common stock is traded on the OTC.BB, as is the Company's intention, the Company's stock price may be impacted by factors that are unrelated or disproportionate to operating performance. These market fluctuations, as well as general economic, political, and market conditions, such as recessions, interest rates, or international currency fluctuations may adversely affect the market price of the common stock.

Future sales of the Company's securities, or the perception in the markets that these sales may occur, could depress the Company's stock price.

As of December 31, 2013, Boston Therapeutics had issued and outstanding (i) 37,362,160 shares of common stock, (ii) warrants issued to the investors in the Company's 2013 private placement collectively exercisable for 8,829,484 shares of common stock (the "Investor Warrants"), (iii) warrants issued to the placement agent for the Company's 2013 private placement exercisable for 1,808,849 shares of common stock (the "Placement Agent Warrants"), (iv) other warrants exercisable for 1,336,666 shares of common stock, and (v) outstanding stock options exercisable for 5,741,400 shares of common stock. These securities will be eligible for public sale only if registered under the Securities Act or if the stockholder qualifies for an exemption from registration under Rule 144 or other applicable exemption. Boston Therapeutics believes that the Company's stockholders are currently entitled to sell the Company's shares pursuant to Rule 144 to the extent they satisfy the conditions thereunder. An aggregate of 17,659,007 shares of outstanding common stock and 8,829,484 shares of common stock issuable upon exercise of outstanding Investor Warrants are registered for resale. The market price of the Company's capital stock could drop significantly if the holders of the shares being registered hereunder sell them or are perceived by the market as intending to sell them. Moreover, to the extent that additional shares of the Company's outstanding stock are registered, or otherwise become eligible for resale, and are sold, or the holders of such shares are perceived as intended to sell them, this could further depress the market price of the Company's common stock. These factors could also make it more difficult for Boston Therapeutics to raise capital or make acquisitions through the issuance of additional shares of the Company's common stock or other equity securities.

Boston Therapeutics has established "blank check" preferred stock, which can be designated by the Company's Board of Directors without shareholder approval.

The Company has authorized 5,000,000 shares of preferred stock. The shares of preferred stock of the Company may be issued from time to time in one or more series, each of which shall have a distinctive designation or title as shall be determined by the Board of Directors of the Company prior to the issuance of any shares thereof. The preferred stock shall have such voting powers, full or limited, or no voting powers, and such preferences and relative, participating, optional or other special rights and such qualifications, limitations, or restrictions thereof as adopted by the Board of Directors. Because the Board of Directors is able to designate the powers and preferences of the preferred stock without the vote of a majority of the Company's shareholders, shareholders of the Company will have no control over what designations and preferences the Company's preferred stock will have. If preferred stock is designated and issued, then depending upon the designation and preferences, the holders of the preferred stock may exercise voting control over the Company. As a result of this, the Company's shareholders will have no control over the designations and preferences of the preferred stock and as a result the operations of the Company.

The Company's management and four significant shareholders collectively own a substantial majority of the Company's common stock.

Collectively, the Company's officers, directors, and four significant shareholders own or exercise voting and investment control of approximately 67% of the Company's outstanding common stock. As a result, investors may be prevented from affecting matters involving the Company, including the following:

- the composition of the Company's Board of Directors and, through it, any determination with respect to the Company's business direction and policies, including the appointment and removal of officers;

- any determinations with respect to mergers or other business combinations;

- the Company's acquisition or disposition of assets; and
- the Company's corporate financing activities.

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

Certain provisions of Delaware law make it more difficult for a third party to acquire the Company and make a takeover more difficult to complete, even if such a transaction were in the stockholders' interest.

The Delaware General Corporation Law contains provisions that may have the effect of making it more difficult or delaying attempts by others to obtain control of the Company, even when these attempts may be in the best interests of the Company's stockholders. Boston Therapeutics is also subject to the anti-takeover provisions of the Delaware General Corporation Law, which prohibit the Company from engaging in a "business combination" with an "interested stockholder" unless the business combination is approved in a prescribed manner and prohibits the voting of shares held by persons acquiring certain numbers of shares without obtaining requisite approval. The statutes have the effect of making it more difficult to effect a change in control of a Delaware company.

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

Effective internal controls are necessary for Boston Therapeutics to provide reliable financial reports and effectively prevent fraud. Section 404 of the Sarbanes-Oxley Act of 2002 requires the Company to evaluate and report on its internal controls over financial reporting and, depending on its future growth, may require the Company's independent registered public accounting firm to annually attest to the Company's evaluation, as well as issue their own opinion on the Company's internal controls over financial reporting. The process of implementing and maintaining proper internal controls and complying with Section 404 is costly and time consuming. Boston Therapeutics cannot be certain that the measures it will undertake will ensure that it will maintain adequate controls over its financial processes and reporting in the future. Furthermore, if Boston Therapeutics is able to rapidly grow the business, the internal controls that it will need may become more complex, and significantly more resources will be required to ensure the Company's internal controls remain effective. Failure to implement required controls, or difficulties encountered in their implementation, could harm the Company's operating results or cause it to fail to meet reporting obligations. If the Company's auditors or Boston Therapeutics discover a material weakness in the Company's internal controls, the disclosure of that fact, even if the weakness is quickly remedied, could diminish investors' confidence in the Company's financial statements and harm the Company's stock price. In addition, non-compliance with Section 404 could subject the Company to a variety of administrative sanctions, including the suspension of trading, ineligibility for future listing on one of the NASDAQ Stock Markets or national securities exchanges, and the inability of registered broker-dealers to make a market in the Company's common stock, which may reduce the Company's stock price.

During the Company's assessment of the effectiveness of internal control over financial reporting as of December 31, 2012, management identified a material weakness in the Company's internal control over financial reporting due to the fact that Boston Therapeutics did not have a process established to ensure adequate levels of review of accounting and financial reporting matters, which resulted in the Company's closing process not identifying all required adjustments in a timely fashion. Remediations were enacted during the year end December 31, 2013, and management has concluded that the Company's internal controls over financial reporting as of December 31, 2013, are effective.

Glossary

505(b)(2) application—An FDA new drug application (NDA) approval pathway that provides a potentially streamlined path for sponsors who have developed improvements, modifications, or repositioning of existing drugs or chemical entities that have previously received FDA approval.

Allosteric—Relating or involving the alteration of the activity of an enzyme or protein through the molecular binding of an effector or regulatory substance at a specific site.

Alpha-Glucosidase [Maltase] Inhibitor—A type of oral anti-diabetic drug used for diabetes mellitus Type 2 that works by preventing the digestion of carbohydrates (such as starch and table sugar).

Alpha-Glucosidase—A type of enzyme that breaks down starch and disaccharides into glucose. Maltase, a similar enzyme that cleaves maltose (malt sugar), is nearly a functionally equivalent.

Altitude Sickness—Illness caused by ascent to a high altitude and the resulting shortage of oxygen, characterized mainly by hyperventilation, nausea, exhaustion, and cerebral edema.

Anemia—A condition marked by a deficiency of red blood cells (RBCs) or of hemoglobin in the blood. Anemia could result in shortness of breath, dizziness, or headaches, and in severe cases heart, brain, and organ damage or even death.

Area Under the Curve (AUC)—In the field of pharmacokinetics, the AUC is the area under the curve in a plot of concentration of drug in plasma against time. The AUC represents the total amount of drug absorbed by the body, irrespective of the rate of absorption.

Beta Cells—A type of cell in the pancreas. Within the pancreas, the beta cells are located in areas called the islets of Langerhans where they constitute the predominant type of cell. The beta cells make and release insulin, a hormone that controls the level of glucose (sugar) in the blood. Degeneration of the beta cells is the main cause of Type 1 (insulin-dependent) diabetes mellitus.

Biguanides—A class of medication used to treat Type 2 diabetes. Biguanides lower blood sugar in two ways: they reduce the amount of sugar produced by the liver and they can also increase the amount of sugar absorbed by muscle cells and decrease insulin resistance.

Bile Acid Sequestrants—A group of resins that bind to bile acids in the intestine and prevent them from being reabsorbed into the blood, causing the liver to produce more bile. Since the body needs cholesterol to make bile, the creation of bile reduces the amount of LDL cholesterol circulating in the blood.

Body Mass Index (BMI)—A weight-to-height ratio, calculated by dividing one's weight in kilograms by the square of one's height in meters and used as an indicator of obesity and underweight.

Cardiopulmonary Failure—The cessation of normal circulation of the blood due to failure of the heart to contract effectively; also known as cardiac arrest. A cardiac arrest is different from (but may be caused by) a heart attack, where blood flow to the muscle of the heart is impaired.

Complex Carbohydrate—A carbohydrate, as sucrose or starch, which consists of two or more monosaccharide units, i.e., a large molecule composed of long chains of sugar molecules.

Continuous Glucose Monitors (CGM)—An FDA-approved device that uses a tiny sensor inserted under the skin to check glucose and blood sugar levels in tissue fluid. The sensor stays in place for several days to a week. Glucose monitoring helps people with diabetes manage the disease and avoid its associated problems.

Contract Research Organization (CRO)—An organization that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis.

Cyanosis—A bluish discoloration of the skin resulting from poor circulation or inadequate oxygenation of the blood.

Diabetes Mellitus—A group of metabolic diseases characterized by high blood sugar (glucose) levels, which result from defects in insulin secretion by the pancreas and/or because cells do not respond to the insulin that is produced. Also known as simply diabetes, is the most common form of diabetes.

DPP-4 Inhibitors—A class of oral hypoglycemics that block DPP-4. They can be used to treat diabetes mellitus Type 2. DPP-4 is a protein that plays a major role in glucose metabolism.

Galactomannan—Polysaccharides often used in food products to increase the viscosity of the water phase. In the clinical area, galactomannan is a component of the cell wall of the mold Aspergillus, and its detection in blood is used to diagnose invasive aspergillosis infections in humans.

Generally Recognized as Safe (GRAS)—Designation by the FDA that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual food additive tolerance requirements.

GLP-1 Agonists—GLP-1 (Glucagon-like peptide-1) agonists are a class of drugs for the treatment of Type 2 diabetes. One of their advantages over older insulin secretagogues is that they have a lower risk of causing hypoglycemia. Known also as incretin mimetics.

Glycoproteins—A protein that has sugar molecules attached to it.

HbA1c—HbA1c is a test that measures the amount of glycosylated hemoglobin in an individual's blood. The test gives a good estimation of how well diabetes is being managed over time.

Hemoglobin—A protein produced within the bones that enables RBCs to transport oxygen throughout the body. Hemoglobin, when in contact with oxygen, also gives RBCs their color.

Hypoglycemia—Low blood sugar (glucose).

Hypoglycemic Drugs—Drugs used to treat diabetes mellitus by lowering glucose levels in the blood.

Hypoxic/Hypoxia—A condition in which the body or a region of the body is deprived of adequate oxygen supply. Hypoxia may be classified as either generalized, affecting the whole body, or local, affecting a region of the body. Also known as hypoxiation.

Inflammatory Bowel Disease (IBD)—A group of chronic intestinal disorders characterized by inflammation of the large intestine.

Investigational New Drug (IND)—Refers to the FDA program by which a pharmaceutical company obtains permission to ship an experimental drug across state lines (usually to clinical investigators) before a marketing application for the drug has been approved. The FDA reviews the IND for safety to assure that research subjects will not be subjected to unreasonable risk.

Ischemia—A decrease in the blood supply to a bodily organ, tissue, or part caused by constriction or obstruction of the blood vessels.

Mannan—Any of a group of polysaccharides, found in the ivory nut, carob bean, and the like, that yield mannose upon hydrolysis.

Meglitinides—A class of medications used to treat Type 2 diabetes that bind to the cell membrane of pancreatic beta cells, increasing insulin production and reducing blood sugar levels. Meglitinides work quickly and do not stay in the body long, so they need to be taken at or just before each meal. Their mechanism of action is similar to *sulfonylureas.*

Necrosis—A form of cell injury that results in the premature death of cells in living tissue by autolysis. Necrosis is caused by factors external to the cell or tissue, such as infection, toxins, or trauma. In contrast, apoptosis is a naturally occurring programmed and targeted cause of cellular death. While apoptosis often provides beneficial effects to the organism, necrosis is almost always detrimental and can be fatal.

New Chemical Entity (NCE)—A patented pharmaceutical compound that may be produced only by the patent holder or any company authorized for its production or usage.

Nuclear Magnetic Resonance (NMR) Spectroscopy—NMR entails the absorption of electromagnetic radiation of a specific frequency by an atomic nucleus that is placed in a strong magnetic field. This research technique exploits the magnetic properties of certain atomic nuclei and can provide detailed information about the structure, dynamics, reaction state, and chemical environment of molecules, as well as measure rates of metabolism.

Nucleic Acids—Any of a group of complex compounds found in all living cells and viruses. Nucleic acids in the form of DNA and RNA control cellular function and heredity.

Oral Combination Therapy—The practice of combining different classes of oral agents to treat a condition, relying on their complementary mechanisms of action to generate better therapeutic outcomes from those obtained with maximal doses of any single drug.

Polysaccharides—Any of a class of carbohydrate molecules composed of long chains of monosaccharide units bound together by glycosidic bonds. Examples include storage polysaccharides, such as starch and glycogen, and structural polysaccharides, such as cellulose and chitin.

PPG (Postprandial Glucose) Regulator—A class of antidiabetic drugs that focus on the control of blood glucose level postprandial (after meals). Postprandial hyperglycemia appears to be the rate-limiting factor for achieving optimal glycemic control in patients with Type 2 diabetes.

Prediabetes—The state in which some but not all of the diagnostic criteria for diabetes are met. It is often described as the “gray area” between normal blood sugar and diabetic levels.

Proteins—Large molecules composed of one or more chains of amino acids in a specific order. Proteins are required for the structure, function, and regulation of the body’s cells, tissues, and organs. Each protein has unique functions.

Ringer’s Lactate—A sterile aqueous solution that is similar to Ringer’s solution but contains sodium lactate in addition to calcium chloride, sodium chloride, and potassium chloride.

SGLT-2 Inhibitors—A class of drugs for the treatment of Type 2 diabetes. SGLT-2 is a glucose transport protein and the major cotransporter involved in glucose reabsorption in the kidney. Therefore, inhibition of SGLT-2 leads to a reduction in blood glucose levels.

Simple Carbohydrates—Carbohydrates with a chemical structure that has one or two sugars. Simple carbohydrates are broken down quickly by the body to be used as energy and are found naturally in foods such as fruits and milk products. They are also found in processed and refined sugars, such as candy, table sugar, syrups, and soft drinks.

Sulfonylureas—A class of anti-diabetic drugs that are used in the management of diabetes mellitus Type 2. They act by increasing insulin release from the beta cells in the pancreas.

Synthetic Perfluorocarbons—Any of various hydrocarbon derivatives in which all hydrogen atoms have been replaced with fluorine and that include blood substitutes used in emulsified form. Perfluorocarbon emulsions (PFCE) are one of the major classes of synthetic oxygen therapeutics currently on the market. They are composed of liquid perfluorocarbon emulsified in water and salt.

Thiazolidinediones—A class of medications used in the treatment of diabetes mellitus Type 2. Also known as glitazones, they were introduced in the late 1990s.

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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