

February 7, 2017



# Boston Therapeutics Business Update

## Year End Review and a Look Forward to 2017

LAWRENCE, MA -- (Marketwired) -- 02/07/17 -- On February 1, 2017 Boston Therapeutics, Inc., headquartered in Lawrence MA, (OTCQB: BTHE) disclosed its restructured operations activity in a two part session covering the last five months as well as a look forward to anticipated milestones. As an innovator in designing compounds using complex carbohydrate chemistry, the company has initiated the deployment of some of its investigative formulations in a sequenced product pipeline. It is focused on developing, commercializing and partnering as well as exploring global merger opportunities to leverage therapeutic molecules and therapeutic protein combinations that address prediabetes, diabetes and inflammatory diseases, including: BTI320, the first non-systemic chewable therapeutic agent designed to reduce HbA1c indirectly through active reduction of the amount of free sugar that can be absorbed in the gut. This is a significant step for a potentially safe and effective non-hypoglycemia inducing material that could reduce the risks for many who are experiencing poor outcomes from diabetes and the associated metabolic disease related insults.

### ***Current State of Affairs***

The prevalence of pre-diabetes and impaired glucose tolerance is believed to becoming a global epidemic as evidenced by the rapidly increasing incidence of high blood glucose levels and obesity throughout the world. The hallmark of pre-diabetes -- chronically impaired blood glucose response -- is a significant risk factor for the development of type 2 diabetes mellitus (T2DM) as well as the manifestation of metabolic syndromes including obesity, hypertension, non-alcoholic fatty liver diseases, hypertriglyceridemia, cardiovascular diseases and stroke.

A growing body of evidence suggests that postprandial hyperglycemia and glycemic variability are independent risk factors for increasing the mortality and accelerating the development of T2DM. Dietary control to restore normal postprandial glycemic response (PPGR) is emerging to be critically important in the prevention of T2MD and related metabolic syndromes. To date, no effective dietary method can readily or accurately predict PPGR associated with food type. Where the current gold standard estimates PPGR through carbohydrate content or glycemic index as guided reference, glycemic variability often limits the applicability of the two methods in a real-life patient management situation. As such, personalized diets with glycemic variability taken into consideration require special focus for intervention to control PPGR and modify its subsequent metabolic consequences. New portable, wearable continuous glucose monitoring devices (Dexcom Inc., US, Medtronic, Ireland, etc.) open a new, important self-management technique for better healthcare management and for the accurate and clinically relevant effect that a

compound can have on postprandial blood sugar spikes. Boston Therapeutics is working with these advanced technologies, sensors, and wearable devices to employ mobile apps that have the potential to offer patient access to clinically significant data monitoring for real-time development of the BTI320 investigative drug materials. This complements existing data and will provide a more complete view of safety and significant efficacy for the management and even delay and risk reduction of these metabolic disease related illnesses. This effect will be supported by the hallmark reductions of HbA1c.

### ***Recent Clinical Confirmation***

The investigative material from Boston Therapeutics, BTI320, has been in development for the past several years and, with operational licensing partners in Asia, we have progressed what is believed to be a new and patented, effective investigative material for the benefit of safe blood glucose management. In a proof of concept trial (Protocol Code: SG01) conducted at the Chinese University of Hong Kong (CUHK), positive effect of BTI320 on postprandial hyperglycemia in a high-risk pre-diabetic Chinese population was demonstrated. An abbreviated description of this clinical trial innovation was presented at the seminar for "Frontier Technologies with Impact in Public Health" in the Chinese University of Hong Kong sponsored by the Hong Kong Jockey Club School of Public Health and Primary Care in September 2016. This group continues to be a key collaborator in this and future trials. Announcement of basic data sets was reported on clinicaltrials.gov (<https://clinicaltrials.gov/ct2/show/NCT02358668>) in January 2017. Data analyses and manuscripts are currently under embargo pending potential presentation at the America Diabetes Association meeting in June 2017.

### ***Key points of Discussion***

- ***Positive Phase II Data Supports the Effect and Safety of BTI320*** in a randomized, double-blind, placebo controlled clinical trial (NCT02358668, Clinicaltrials.gov). With > 95% overall compliance across study groups, the phase II proof of concept trial (Protocol Code: SG01) demonstrated that both low dose (4g) and high dose (8g) BTI320 are safe and effective in significantly reducing various continuous glucose monitor (CGMS) parameters when compared against placebo. The relevant glycemic variability, presented in preliminary analyses, as a positive confirmation of reducing blood sugar spikes, demonstrated no change in fructosamine (a measure of short half-life glycated plasma proteins) from the baseline to week 4 of the observation period. No anticipated change is expected due to sufficient glycemic control in this pre-diabetic population. Further confirmation of control, BTI320 can be reported to be effective in inhibiting and lowering postprandial glucose excursions and reflects greater reduction in many of the CGMS parameters when compared to placebo from baseline to week 16 of the study period: MBG (mean blood glucose); AUC (area under the curve) at 1, 2 and 3 hours; AUC 180 at 24 and 72 hours; MPMG (mean post meal glucose); MAGE (maximum amplitude glucose excursions) and HbA1c.
- ***Planned key supplementary analyses revealed a better understanding of diabetes management and care in the prevention of IGT and other pre-diabetic conditions.*** To account for the glycemic variability among individual subjects on a

day-to-day basis, supplementary CGMS analyses (with variability adjusted) were performed to appropriately reflect the drug effects of BTI320 on an individual level with no group data pooled. The validated supplementary analyses were carefully designed to explore the sugar spike reduction effect of low dose (4g) and high dose (8g) of BTI320 against placebo via CGMS parameters in a controlled setting. Since BTI320 was previously demonstrated to significantly reduce postprandial glucose and insulin response in a controlled glycemic loading study at the Sydney University Glycemic Index Research Services (SUGiRS) among a normal volunteer population (overweight but otherwise healthy subjects), it was hypothesized that both low and high dose of BTI320 were also effective in reducing some CGMS parameters among the high risk pre-diabetic Asian population. Full data to be presented in June 2017, manuscript in process.

### ***Planned Milestones***

In October 2016, the Company and Advance Pharmaceutical Company Limited (APCL) announced collaborative advancement in the clinical development of BTI320 and APCL will be receiving up to US\$400,000 from the Hong Kong Innovation and Technology Commission (ITC) for advance screening by proprietary Automated Retinal Image Analysis (ARIA). The device is a non-invasive screening tool that will be used in a randomized, controlled, cross over, dose study to compare the effect of BTI320 in subjects (n=120) at high risks for diabetes and stroke. The objective of the study will be evaluation on the effect of BTI320 at dose with control on (i) calculated 5-year probability of stroke, and (ii) glycated hemoglobin (HbA1c) and fructosamine in pre-diabetic subjects. The goal will be to obtain a proof of concept for inclusion of BTI320 as adjunctive therapy in the consideration of an at-risk aging population where the identification and early life style change can have a significant effect on the quality of life.

### ***Below is the summary of our 2017 operating plan.***

(1) ***IND Amendment processed and global expansion opportunities planned.*** BTI will initiate the accepted FDA IND clinical trial with the Joslin Diabetes Centre (Boston MA) and will increment new sites for a multicenter expansion that is supported by our Asian collaborator. BTI's new study specific Steering Committee and its contract research partners, have investigated and evaluated the completed clinical trials. All past and present clinical studies have been brought current with FDA with supportive comment. We are supplementing and will be completing new developments in the area of GRAS (generally regarded as safe), toxicology, as well as the mechanisms of action with our licensed alliance/partner: (Sugardown Company Limited (SCL), subsidiary of APCL) and others. These will support and update the opportunity to address a worldwide population as we advance the registrations and territories.

(2) ***Manufacturing operations have been re-qualified to establish vendor agreements, to extend the stability of the product, and to prepare for new formulations.*** The company and SCL have initiated and will continue stability confirmation and formulation planning to extend inventory life and to allow for use in clinical development as well as to qualify and secure the contract operations for the formulation of drug product. The company is also exploring off shore product options. For

manufacturing and registrations opportunities, China as well as other regions we are preparing to service the specific healthcare needs of the various global healthcare systems. (A formulation of the material is now registered in Korea as Sugar Balance and Singapore as Sugar Block). Establishing efficacy and customer traction in these and other regions are important steps in confirming reliability and reproducibility to ensure product integrity and to cross various populations with a specific benefit concerning local dietary intake.

**(3) Regulatory documentation for domestic and worldwide integration plus the extension and implementation of intellectual property and patents.** Collaboration opportunities with several Contract Research Organizations (CRO) in China is ongoing and currently progressing to exploit the best of our collaboration opportunity for cost sharing and resource planning for all registrations for Asia and the US/EU. New patents have issued and new positions and formulations are unfolding as we supplement patent filings with clinical and developmental discoveries from the recently completed as well as planned new trials.

### **SugarDown<sup>®</sup>**

The Company also developed and markets SugarDown<sup>®</sup>, a sugar blocker dietary food supplement designed to support glycemic health. More information is available at [www.bostonti.com](http://www.bostonti.com). SugarDown<sup>®</sup> in its present formulation is a natural sugar blocker dietary supplement product made entirely from a non-digestible sugar molecule that can help people maintain healthier weight levels and is the first chewable tablet of its kind. In a previous study, SugarDown<sup>®</sup> demonstrated significant reduction of glucose and insulin Area Under the Curve (AUC) when taken with Jasmine rice, a food with a glycemic index of about 90 compared to glucose, which is 100. Sugary soft drinks that also have high glycemic index, include sucrose and maltose which is also found in beer. More information can be found on [www.sugardown.com](http://www.sugardown.com).

### **About Boston Therapeutics, Inc.**

Boston Therapeutics, headquartered in Lawrence MA, (OTCQB: BTHE) is an innovator in designing compounds using complex carbohydrate chemistry. The company's product pipeline is focused on developing and commercializing therapeutic molecules that address diabetes and inflammatory diseases, including: BTI-320, a non-systemic chewable therapeutic compound designed to reduce HbA1c. More information can be found on [www.bostonti.com](http://www.bostonti.com).

### **Forward Looking Statement**

This press release includes forward-looking statements. These statements may be identified by words such as "feel," "believes," "expects," "estimates," "projects," "intends," "should," "is to be," or the negative of such terms, or other comparable terminology. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to risks and uncertainties, which could cause actual results to differ materially from the forward-looking statements contained herein. Factors that could cause actual results to differ materially include, but are not limited to: our limited

operations and need to expand in the near future; risks associated with obtaining regulatory approval of our products; the ability to protect our intellectual property; the potential lack of market acceptance of our products; potential competition; our inability to retain key members of our management team; our inability to raise additional capital to fund our operations and business plan; our ability to continue as a going concern; our liquidity and other risks and uncertainties and other factors discussed from time to time in our filings with the Securities and Exchange Commission ("SEC"), including our annual report on Form 10-K filed with the SEC. Boston Therapeutics expressly disclaims any obligation to publicly update any forward-looking statements contained herein, whether as a result of new information, future events or otherwise, except as required by law.

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