

Apr 18, 2018 5pm EST Boston Therapeutics Inc Business Update Conference Call
--

Transcript

CORPORATE PARTICIPANTS

Carl W Rausch, Chief Executive Officer
Lori V Upham, Chief Operating Officer
International replay number: 1-412-317-6671
Replay ID: 2971422

Lori V Upham, COO

Good Afternoon and thank you everyone for being here. My name is Loraine Upham and I am the Chief Operating Officer of Boston Therapeutics and I will be the moderator for today's call. Questions and Answers will follow short presentations by our CEO, Carl Rausch and myself.

First please allow me to share our safe harbor announcement.

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.

Now that we have that out of the way, we are happy to be here today to share the exciting changes that have been taking place at the Company. As you may have read in recent press releases, Boston Therapeutics recently acquired a small, privately held company called CureDM and it is my pleasure to join Boston Therapeutics from CureDM as Chief Operating Officer. In addition, we recently announced our intent to acquire Medical Technology Associates, another privately held company with strategically synergistic assets that we believe will help us continue to build value for the Company assuming we are successful in signing definitive agreements and moving to a closing. To best describe the potential impact of this acquisition and the proposed value that it represents, please let me introduce our CEO, Carl Rausch. Carl?

Carl W Rausch, Chief Executive Officer

Thank you for the introduction, and if I may, I would like to just give a support of the Boston Therapeutics profile and the great opportunity that the addition of Medical Technology Associates can bring to the Boston Therapeutics path of growth in the area of metabolism and metabolic support. Boston has been in the area of metabolism control since its inception. That is the control of sugar.

The body functions on sugar breakdown and on oxygen distribution to the cells. Too much or too little of each and the body function breaks down and DIES.

When Boston Therapeutics started, I was a consultant to the Company on a part time basis and the area of development I advised on, got them started in system development of the synergy of carbohydrate and oxygen carrying protein interactions for safe infusion. Boston Therapeutics let the program lapse due to the polysaccharide development programs.

I was asked to take over the CEO position in 2016. We have grown Boston Therapeutics in the Asia region and looked for rekindling the connection. In 2018 the common investors in the two entities have reached a tentative understanding and we expanded the US presence.

Medical Technology Associates II (MTAII) genesis, dates back to 2010, with a group in Asia that has now grown into a network of technology leaders in China, US, and European in the field of critical care, to manage and treat ischemic events, such as stroke, heart attacks, traumatic brain and traumatic shock events on a global scale - the unmet medical need to correct oxygen debt.

The group required high purity protein separations (in volume) to create a safe and effective alternative fluid therapy. With emerging technology advances in healthcare of continuous systemic monitoring and because healthcare expansion in managed care of blood supplies that gap and shortfall in the immediate **ischemic state of hypoxia** (lack of oxygen delivery) ...it has become evident that the nature of metabolic function is not supported well and cost effectively by present methods.

(What is the business) **With over 40 professionals worldwide and facilities being used and constructed to make it unique, high technology materials, the Business Summary could read as**MTAII's mission is to provide solutions for unmet medical needs for clinicians and emergency relief workers with a fluid therapy alternative that is safe, effective, and readily available that can bridge and or eliminate the need for life saving blood oxygen needs where and when blood transfusion logistics, efficacy and perfusion requirements are not effective and are not immediately available.

Total Available Market: There is an estimated worldwide shortage of blood cells for transfusions and blood oxygen related interventions amounting to 20 million units (~5 million liters) each year. The situation is further aggravated by declining number of donors, unsafe blood sources and failed quality management systems and blood supply outdated.

(Opportunity) **Customers:** Primary customers of MTAII's transfusion agent OX-Z9 are emergency care hospitals, field clinicians, transplant hospital environments and Governmental Agencies (international) and Healthcare relief and disaster and epidemic management support and care. Also high on MTAII's customer list is the immediate rapidly expanding veterinary field in general as there are no dedicated transfusion agents for animal care for companion animals or animals that are part of the various national and international support and care organizations. (SPCA and wildlife preserves)

Unmet need

- Companies in the area; orphan drug
- Rubius Therapeutics, Inc
- Global Blood Therapeutics
- Akebia

Presently MTAII has past and present committed capital over \$20,000,000. The Company has provisional patents and expanding into 4 different avenues of therapeutic value for one technology. Presently matched developmental funding of \$20 million USD external to US in co-development efforts. We anticipate filings for FDA and for CE marks within 12 months.

Loraine V. Upham, Chief Operating Officer

Thank you, Carl.

Today it is my pleasure to discuss a little about the history of Boston Therapeutics, and the recent changes that have set the stage for the proposed merger with MTA, our growth and value creation at Boston Therapeutics.

As some of you are long time shareholders, you know that Boston Therapeutics was founded in 2007 to develop compounds based on carbohydrate chemistry. Sugardown[®] was developed and a distribution partnership with Advanced Pharmaceutical Company (APC) in Hong Kong was formed. Through this partnership, the safety profile and efficacy were established with a number of clinical trials in US, Australia and Asia, and the product is now being distributed directly by APC’s subsidiary, Sugardown Co. Ltd and indirectly via social media in Asia. In the meantime, based on the former success of a similar non-systemic compound called Acarbose, the prescription formulation of Sugardown[®], which we call BTI-320 was established as an Investigational New Drug with the US FDA.

Previous studies have indicated that BTI-320 may be a better-tolerated formulation than Acarbose, a more suitable product for the US population. To confirm this and to further develop the compound as a drug, the Company has contracted renowned CROs to conduct a Phase II Clinical Study in 300 patients in the US. The plan is to market BTI-320 as a prescription drug for over the 700 million+ people with impaired glucose tolerance. This includes both type 2 diabetes and pre-diabetes who are at risk of developing type 2 diabetes. It is our intent to help stave off the start of this disease, its many health complications; and the unsustainable long-term health care costs associated with all of those.

BTI-320/SD Clinical Evidence

- In a controlled research study the consumption of galactomannan take as SUGARDOWN[®] tablets prior to a high glycemic index (GI) food significantly reduced the elevations in postprandial glucose and insulin response in over-weight but otherwise healthy volunteers.
- In another controlled research study, the consumption of SUGARDOWN[®] (SD) tablets (containing mannan polysaccharide (galactomannan) and sorbitol) prior to a sugary beverage significantly reduced the postprandial glucose and insulin responses to that beverage. The addition of 2 SD tablets (4g mannan polysaccharide and 3g sorbitol), produced a 10% reduction in GI and a 14% decrease in insulinemic index (II) of the Sprite[®] soft drink. The addition of 4 SD tablets (8g mannan polysaccharide and 6g sorbitol) produced a 14% and 18% decrease in GI and II, respectively, of the Sprite[®] soft drink. A dose response effect was observed, such that the higher dose of SUGARDOWN[®] produced greater reductions in postprandial responses to the soft drink.
- A clinical study designed to evaluate the safety and efficacy of BTI320 (SUGARDOWN[®]) added to oral diabetic agents or insulin showed that the compound is effective as an adjunct therapy in reducing postprandial glucose responses (“the after-meal sugar spike”) in 45% of T2DM patients.

The timing of this innovative treatment could not be better as we are seeing the emergence of broadly marketed continuous glucose monitoring systems (CGMs). These devices, designed to provide real-time information about glucose levels are poised to become consumer devices.

Apple, Fitbit, Abbott, Glutalor, Glucovation are a few companies we believe are working on making these devices available to everyone.

This is meaningful to us because both Sugardown[®] and BTI-320 have an immediate effect on post-meal glucose levels that will be seen in real time using these CGM devices. As the CNN, Fox News, the Boston Globe and the Albuquerque Journal among many others, warn people about hidden sugar in their diet, Sugardown[®] and BTI-320 will be the way to immediately decrease glucose spikes that occur in everyone with glucose intolerance and which will now be clearly seen by CGMs.

BTI-320/SD Status Update Recent Clinical Success

- On Sept 29, 2016, BTI announced positive topline data from proof of concept trial (Protocol Code: SG01) conducted at the Chinese University of Hong Kong (CUHK) which demonstrated a positive effect of BTI-320 on postprandial hyperglycemia in high risk prediabetic Chinese population.
- SG01 is a 16-week double-blind randomized placebo-controlled study designed to investigate the low (4g) and high (8g) dose of BTI-320 compared with placebo in Chinese subjects at high risk of diabetes (n=60) on **serum fructosamine** (*primary objective*), the **area under the curve** (when glucose is above 180mg/dL or 10mmol/L) and **HbA1c level** (*secondary objectives*).
- BTI-320 planned key supplementary analysis demonstrated **positive drug effects** and revealed a better understanding of diabetes management and care in the prevention of IGT and other pre-diabetic conditions.
- BTI-320 was shown to be **safe** and effective. Low dose BTI-320 (4g) demonstrated significant treatment effects in AUC, postprandial MBG at 1, 2, 3 hours and PMG. Significant reduction was also seen in MPMG compared with placebo. Significant treatment effects observed (in low dose group) on most glycemic parameters, variability and postprandial glucose excursions according to CGMS profiles obtained in the study. BTI-320 was generally safe and well-tolerated. Data suggest that both high and low dose BTI-320 are efficacious in reducing postprandial hyperglycemia and glycemic variability.

To the extent that we can help individuals at risk of developing diabetes to avoid the path of destruction that it represents, it is our intent to provide a safe and effective way to help consumers manage their long-term metabolic health.

While BTI-320 has been the focus of development for Boston Therapeutics, CureDM focused on developing a drug that has the ability to change the trajectory of diabetes – but from a different angle. Boston Therapeutics acquired CureDM in Feb, 2018 and added a second compound to the portfolio designed to change the treatment of diabetes worldwide. The peptide therapeutic drug is intended to provide a way to reverse diabetes in people who are on the other end of the diabetes spectrum: those who are well on their way down the path to the need for insulin therapy. Insulin injections can keep us alive, but it is the minute-by-minute control of insulin release that keeps us from suffering the long-term complications of high glucose in our blood stream and the life threatening down side of insulin, hypoglycemia.

The innovative peptide therapeutic stimulates the naturally insulin producing cells in the pancreas AND the control over the insulin produced. This mechanism, now called “Beta Cell Maturation”, is a new target for drug development, but CureDM has already established safety and efficacy of a peptide drug candidate that stimulates this very process: we call it BTI-410.

BTI-410 Clinical Evidence

In a Phase 1b, single center, randomized, double-blind, parallel group, placebo-controlled study, treatment with HIP2B resulted in:


- improvements in mean insulin concentrations measured by GGI from baseline to Day 46 that trended toward significance,
- mean change in pre-hepatic insulin secretion rate from baseline to Day 46 was **statistically significant** in the combined HIP2B treatment groups compared to placebo,
- improvements in mean insulin concentrations as measured by GGI and IVGTT, including some that seemed to persist during the post-treatment period.
- Improvements in insulin secretion levels, and improvements in **control** of insulin secretion under glucose challenge, is the benefit of beta cell maturation as a mechanism, which lead to improvement in HbA1c.

So, the merger of Boston Therapeutics and CureDM made sense scientifically since both compounds address the target disease from different angles. But it also made sense strategically as we now have new boots on the ground in the US to help drive the development of all compounds through the US FDA. We are especially excited to have immediately created a stellar Scientific Advisory Board that includes former Pfizer, Merck, Eli Lilly and NIH leadership team members.


In addition to the Phase II study for BTI-320 already underway, we are in the planning stages for two additional Phase II studies for BTI-410.

GETTING THERE


BTI Portfolio



LARGE UNMET MEDICAL NEED
425 million adults currently have diabetes and 629 million adults with impaired glucose tolerance




FIRST IN CLASS THERAPIES
BTI-410: 1st in addressing the key underlying pathology of T2D & BTI-320: 1st addressing the growing pre-diabetes market




LATE STAGE CLINICAL CANDIDATES
Efficacy confirmed in Phase 1b/2a Study w/clear safety profile


RAISING \$5M TO ACCELERATE PIVOTAL BTI-320 AND BTI-410 STUDIES



NEAR TERM REVENUE CAPABILITY
First-in-Class T1DM Potential Orphan Drug Candidate with OTC Formulation with established sales in Asia



EFFICIENT / VALUE ADD BUSINESS MODEL
Addressing metabolic diseases by novel mechanisms and creating uniquely synergistic combinations



BTI-320 / SUGARDOWN® MANANS PCT 2012 / 061675
CN/HK allowed (2011800643744)
Pending Divisional (2016105920841)
EU – Pending (11838852.9)
KR – Pending (10 - 2013 - 7014145)
US – Pending (13/938,409)
Chewable Tablets (PCT 2014/27243)

The first of these is targeting Type 1 diabetic patients who have undergone kidney transplants. Type 1 diabetes is an autoimmune disease that attacks new insulin producing cells and that is why for this form of diabetes, it is critical to have something to block the destruction of the newly formed cells. This indication is a potential fast track to approval and commercialization for this small but critical population of patients who are immune suppressed and can benefit from restoration of their endogenous insulin production through a course of BTI-410 therapy. A number of companies currently have immune tolerance therapies that are designed to be a more specific way to block the autoimmune component of Type 1 diabetes so that BTI-410 may also be eventually developed in combination with these for the broader population of Type 1 diabetic patients.

The second study is a follow on Phase II study in 120 Type 2 diabetic. Type 2 diabetics do not need immune suppression to benefit from a course of BTI-410, because the means by which their insulin producing cells were destroyed in the first place is much slower –taking place over the course of years. In the Phase Ib, we saw an increase in fasting insulin production and improved insulin control in response to treatment with BTI-410. Whereas most patients with diabetes, even those being treated with Metformin are on a downward path toward the need for insulin injections, patients in the treatment groups all started to come back toward their original pre-diabetic state by showing increased fasting insulin and more appropriate insulin secretion in response to a meal, which is that control.

We believe these are the kinds of bold compounds that can disrupt the marketplace and displace many of the giant moneymakers that only treat the symptoms of disease. You can see them every night during prime time TV.

We currently have two Phase II compounds as well as a revenue generating dietary supplement to help support their continued clinical development of these and other disruptive and novel compounds.

Now, we are really excited about the proposed MTA merger, as this would represent a huge step forward financially and strategically for Boston Therapeutics. This acquisition would allow us to expand our product portfolio into synergistic and related areas of organ transplantation, peripheral vascular health, stroke, and anemia, all on a global basis.

With that, I would like to open the phone lines for questions at this time.

Investor Relations Contact: Loraine V. Upham