UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2012**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number: 000-54586

BOSTON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**27-0801073**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1750 Elm Street, Suite 103, Manchester, NH	**03104**
(Address of principal executive offices)	(Zip Code)

603-935-9799
(Registrant's telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)
33 South Commercial Street Manchester, NH 03101

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

Securities registered under Section 12(g) of the Exchange Act:
(Title of Class)
Common Stock, $.001 par value per share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).
Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained here, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller Reporting Company	☒
(Do not check if a smaller reporting company)			

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

At June 30, 2012, the last business day of the registrant's most recently completed second quarter, the aggregate market value of the voting common stock held by non-affiliates of the Registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) was approximately $1,233,497.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at March 20, 2013
Common Stock, $0.001 par value per share	19,291,539 Shares

DOCUMENTS INCORPORATED BY REFERENCE:

None.

BOSTON THERAPEUTICS, INC.
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Except as otherwise required by the context, all references in this report to "we", "us", "our", "BTI" or "Company" refer to the consolidated operations of Boston Therapeutics, Inc., a Delaware corporation, formerly called Avanyx Therapeutics, Inc., and its wholly owned subsidiaries.

Special Note Regarding Forward Looking Statements

This Annual Report on Form 10-K, including "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include, among others, those concerning our expected financial performance and strategic and operational plans, as well as assumptions, expectations, predictions, intentions or beliefs about future events. You are cautioned that any such forward-looking statements are not guarantees of future performance and that a number of risks and uncertainties could cause actual results of the Company to differ materially from those anticipated, expressed or implied in the forward-looking statements. The words "believe," "expect," "plan," "estimate," "anticipate," "project," "targets," "optimistic," "potential," "intend," "aim," "may," "will," "continue" or similar expressions, or the negative thereof, are intended to identify forward-looking statements.

These forward-looking statements involve known and unknown risks and uncertainties. Our actual results may differ materially from those projected or assumed in such forward-looking statements. Among the factors, risks and uncertainties that could cause actual results to differ materially are the following:

- We may be unable to raise the capital we will need to maintain operations and fulfill our business objectives.
- We are subject to extensive and costly regulation by the FDA, which must approve our product candidates in development and could restrict the sales and marketing of such products in development.
- We may be unable to achieve commercial viability and acceptance of our proposed products.
- We may be unable to retain key members of our senior management.
- We may be unable to improve upon, protect and/or enforce our intellectual property.
- We may be unable to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates.
- We are subject to significant competition.
- As a public company, we must implement additional and expensive finance and accounting systems, procedures and controls as we grow our business and organization to satisfy public reporting requirements, which will increase our costs and require additional management resources.

For a discussion of these and additional factors, risks and uncertainties which could impact us and the statements contained herein, see "Risk Factors" in Item 1A of this Annual Report on Form 10-K, as may be supplemented in our Quarterly Reports on Form 10-Q. Readers are urged to carefully review and consider the various disclosures made by us in this Report and our other filings with the SEC. These reports attempt to advise interested parties of the risks and factors that may affect our business, financial condition and results of operations and prospects. All forward-looking statements and risk factors included in this Report are made as of the date hereof, based on information available to us as of the date hereof, and we assume no obligation to update any forward-looking statement or risk factor to reflect changes in our expectations, future events, new information or otherwise.

PART I

Item 1. Business.

1. **GENERAL ORGANIZATION AND BUSINESS**

Boston Therapeutics, Inc. (the "Company") was formed as a Delaware corporation on August 24, 2009 under the name Avanyx Therapeutics, Inc. On November 10, 2010, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Boston Therapeutics, Inc., a New Hampshire corporation ("BTI") providing for the merger of BTI into the Company with the Company being the surviving entity (the "Merger"), the issuance by the Company of 4,000,000 shares of common stock to the stockholders of BTI in exchange for 100% of the outstanding common stock of BTI, and the change of the Company's name to Boston Therapeutics, Inc. David Platt, the Company's Chief Executive Officer and Chief Financial Officer, is a founder of BTI and was a director and minority stockholder of BTI at the time of the Merger. Dr. Platt received 400,000 shares of the Company's common stock in connection with the Merger. Kenneth A. Tassey, Jr., who became the Company's President shortly after the Merger, was the Chief Executive Officer, President and principal stockholder of BTI at the time of the Merger. Mr. Tassey received 3,200,000 shares of our common stock in connection with the Merger. Boston Therapeutics, headquartered in Manchester, NH, (OTC: BTHE) is a leader in the field of complex carbohydrate chemistry. The Company's initial product pipeline is focused on developing and commercializing therapeutic molecules for diabetes: PAZ320, a non-systemic chewable therapeutic compound designed to reduce post-meal glucose elevation, and IPOXYN™, an injectable anti-necrosis drug specifically designed to treat lower limb ischemia associated with diabetes.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has limited resources and operating history. As shown in the accompanying financial statements, the Company has an accumulated deficit of approximately $2,697,000 and has working capital of approximately $154,000 as of December 31, 2012. The future of the Company is dependent upon its ability to obtain financing and upon future profitable operations from the development of its new business opportunities.

Management plans to seek additional capital through private placements and public offerings of its common stock. There can be no assurance that the Company will be successful in accomplishing its objectives. Without such additional capital, the Company may be required to cease operations.

These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts of and classification of liabilities that might be necessary in the event the Company cannot continue in existence.

Our Markets

In 2011, according the International Diabetes Federation, 366 million people are living with diabetes and that figure is projected to increase to 551 million by 2030. In the United States alone, the Center for Disease Control in 2010 estimated that there were 25.8 million people living with diabetes and an estimated 79 million people who are pre-diabetic. The Company entered PAZ320 into a clinical trial at Dartmouth Medical Center in Lebanon, NH to measure post-prandial elevation of blood glucose. We intend to leverage data from this study in the marketing of PAZ320. We intend to engage a medical advisory board consisting of leading physicians who have participated in relevant clinical studies and who are leaders in the field of diabetes, who will guide us through an ongoing clinical trials program. We may seek to enter into licensing or co-marketing agreements for parts or all of-the-world in order to avail the Company of the marketing expertise of one or more seasoned marketing and/or pharmaceutical companies. We recently hired a Chief Operating Officer to help accelerate the commercialization of our products and have engaged other marketing and sales professionals to help gain market awareness and sales, distribution and licensing agreements. We are currently under agreement with Advance Pharmaceutical Co. Ltd. to develop markets in Hong Kong, China and Macau. We have engaged in direct marketing efforts in the United States but have not yet entered into any agreements with third party distributors for U.S. sales.

Our Products

The Company's primary business is the development, manufacture and commercialization of therapeutic drugs with a focus on complex carbohydrate chemistry to address diabetes and inflammatory diseases. We are currently focusing on two products: PAZ320, a non-systemic, chewable drug candidate for the post-meal reduction of the elevation of blood glucose to address an unmet medical need for people to manage their blood sugar, especially people who are pre-diabetic and for people with Type 2 diabetes. PAZ320 recently completed a Phase ll clinical trial.

The Company is also developing IPOXYN™, an injectable drug candidate for prevention of necrosis and treatment of hypoxia. IPOXYN™ is a glyco-protein based therapeutic agent using proprietary processes and patented technology. Our IPOXYN™ drug consists of a stabilized glycoprotein composition containing oxygen-rechargeable iron, targeting both human and animal tissues and organ systems deprived of oxygen and in need of metabolic support.

According to market research analysts, the global market opportunity for anti-hypoxia or anti-necrosis technology is $86 billion. Early entry global markets include the following:

- Military
- Asia (replace Hepatitis C contaminated blood products)
- Africa (AIDS contaminated blood)
- Newborns
- Trauma
- Lower Limb Ischemia and other vascular complications of diabetes

PAZ320

PAZ320 is a non-systemic chewable drug candidate designed to reduce postprandial or post-meal elevation of blood glucose (PPG Regulator). PAZ320 is a proprietary polysaccharide intended to be taken before meals and works in the gastrointestinal tract to inhibit carbohydrate-hydrolyzing enzymes that release glucose from complex carbohydrates foods during digestion. This action reduces the availability of glucose for absorption into the bloodstream.

Status of Development of PAZ320

PAZ320 is fully developed as a drug candidate. In October 2011, the Company announced the initiation of its clinical trial at Dartmouth-Hitchcock Medical Center in New Hampshire to evaluate the safety and efficacy of PAZ320 when added to oral agents or insulin regimen in patients with Type 2 Diabetes Mellitus. In July 2012, the Company announced the completion of patient enrollment. In February 2013, the Company announced that PAZ320 reduced the elevation of post-meal blood sugar by 40% with no serious adverse events. The study evaluated PAZ320 in 24 patients with Type 2 diabetes between the ages of 18 and 75 with a body mass index (BMI) of 25-40 kg/m^2 and with HbA1c of less than or equal to nine percent. HbA1c is a lab test that shows the average level of blood sugar (glucose) over the previous three months.

Forty-five percent of patients responded with an average 40 percent reduction of post-meal glucose in the blood compared to baseline in a dose-dependent manner. Additionally, results showed the effect of PAZ320 does not correlate with duration of diabetes and works regardless of concurrent diabetes medications. There was no severe hypoglycemia and gastrointestinal side effects were mild. Satiety was also observed. There were no serious adverse events from the data analysis of the open-label dose escalation crossover trial on Type 2 diabetic patients.

The abstract for the clinical study is published in Epub Ahead of Print in the PubMed.gov website http://www.ncbi.nlm.nih.gov/pubmed/23425645. The full article is expected to be published in the July/August 2013 issue of *Endocrine Practice*, a peer-reviewed journal.

Competitive Products: PAZ320

Anti-diabetic drugs

Anti-diabetic drugs treat diabetes mellitus by lowering glucose levels in the blood. With the exceptions of insulin, exenatide marketed as **Byetta®**, **Bydureon®**, and pramlintide, marketed as Symlin®, all are administered orally and are thus also called oral hypoglycemic agents or oral anti-hyperglycemic agents. There are different classes of anti-diabetic drugs, and their selection depends on the nature of the diabetes, age and situation of the person, as well as other factors. The Company's non-systemic compound PAZ320 for pre-diabetes and diabetes is a Postprandial Glucose (PPG) Regulator which mechanism is the inhibition of carbohydrate-hydrolyzing enzymes.

Secretagogues

Secretagogues, which include **Sulfonylureas and Meglitinides**, help enhance insulin secretion.

Sulfonylureas were the first widely used oral hypoglycemic medications. They are *insulin secretagogues*, triggering insulin release by direct action on the KATP channel of the pancreatic beta cells**. Glipizide (Glucotrol®)** falls into this category with side effects including GI discomfort, diarrhea and hypoglycemia.

Meglitinides help the pancreas produce insulin and are often called "short-acting secretagogues." Their mode of action is original, affecting potassium channels. By closing the potassium channels of the pancreatic beta cells, they open the calcium channels, hence enhancing insulin secretion. They are taken with or shortly before meals to boost the insulin response to each meal. If a meal is skipped, the medication is also skipped. **Repaglinide (Prandin®**) falls into this category with side effects including hypoglycemia and hyperglycemia.

Sensitizers

Insulin sensitizers address the core problem in Type 2 diabetes—insulin resistance—and include **Biguanides and Thiazolidinediones**. Among oral hypoglycemic agents, insulin sensitizers are the largest category.

Biguanides reduce hepatic glucose output and increase uptake of glucose by the periphery, including skeletal muscle. Although it must be used with caution in patients with impaired liver or kidney function, metformin, a biguanide, has become the most commonly used agent for Type 2 diabetes in children and teenagers. Amongst common diabetic drugs, metformin is the only widely used oral drug that does not cause weight gain. **Metformin** is the most prescribed drug in this category whose side effects may be hypoglycemia and lactic acidosis.

Thiazolidinediones (TZDs), also known as "glitazones," bind to PPARγ, a type of nuclear regulatory protein involved in transcription of genes regulating glucose and fat metabolism. **Rosiglitazone (Avandia®)** and Pioglitazone (Actos®) fall into this category of anti-diabetic agent.

Alpha-glucosidase inhibitors

Alpha-glucosidase inhibitors are "diabetes pills" but not technically hypoglycemic agents because they do not have a direct effect on insulin secretion or sensitivity. These agents slow the digestion of starch in the small intestine, so that glucose from the starch of a meal enters the bloodstream more slowly, and can be matched more effectively by an impaired insulin response or sensitivity. These agents are effective by themselves only in the earliest stages of impaired glucose tolerance, but can be helpful in combination with other agents in Type 2 diabetes. Acarbose, marketed as Prandase® and Glucobay® is an Alpha-glucosidase Inhibitor.

Scientific Overview

Diabetes Mellitus

Diabetes Mellitus, known simply as Diabetes, is a chronic metabolic disorder in which a person has abnormally high levels of glucose in the circulating blood. This condition is caused by a failure of the pancreas to produce insulin and/or an inability of the body to respond adequately to circulating insulin. When glucose builds up in the blood instead of going into cells, it can lead to diabetes complications, which include limb Ischemia and neuropathy, retinopathy, kidney, cardiovascular and cerebrovascular diseases. According to the Centers for Disease Control and Prevention (CDC), diabetes affected approximately 26 million people in the United States in 2011. The estimated cost of diabetes in the United States alone is $245 billion, according to a study commissioned by the American Diabetes Association entitled, Economic Costs of Diabetes in the U.S. in 2012.

Pre-Diabetes

Pre-diabetes is the state in which a person has higher than normal blood glucose level, but not high enough to be diagnosed with Diabetes. While in this range between normal and diabetic, patients are at risk for not only developing Type 2 diabetes, but also for cardiovascular complications. According to the CDC, pre-diabetes affected an estimated 79 million Americans in 2010.

Diabetes Mellitus is categorized into three general areas:

Type 1 diabetes: results from the body's failure to produce insulin, and presently requires the person to inject insulin. Only 5-10% of people with diabetes have this form of the disease. It is considered an auto-immune disease, since the body's immune system attacks and destroys insulin producing beta cells in the pancreas.

Type 2 diabetes: results from insulin resistance by the body's cells, deficient insulin production by the Pancreas or a combination of both. Insulin resistance is a condition in which the cells in the body ignore or have become desensitized to insulin.

Gestational diabetes: is determined when pregnant women, who have never had diabetes before, have a high blood glucose level during pregnancy. It may precede development of Type 2 diabetes and affects approximately 4% of all pregnant women.

Type 2 and Type 1 people with diabetes generally manage their blood glucose level on a meal-to-meal basis. High levels of glucose in the bloodstream for prolonged periods can lead to complications of diabetes caused by reduced oxygen supply and nerve tissue damage to eyes, kidney, brain, heart and limbs.

Standard therapies for Diabetes include physician-recommended exercise and diet, oral hypoglycemic drugs such as Metformin for Type 2 diabetics, and insulin injection regimens for Type 1 diabetics. The objective of each is to maintain a daily blood glucose level range recommended by a physician.

Marketing:

PAZ320

We believe PAZ320 is a safe and effective drug compound for people living with diabetes and prediabetes for daily management of blood glucose, fulfilling an unmet medical need. We believe this compound may provide individuals with a means by which to slow the onset of Type 2 diabetes and/or the onset of diabetes complications such as heart disease, stroke, kidney damage, retinopathy and Diabetic Foot. As further described below under "Government Regulation - Drug Approval Process," PAZ320 will require FDA approval for marketing as a drug and will be subject to extensive regulation by governmental authorities in the United States and other countries.

IPOXYN™

We have also developed IPOXYN™, a glyco-protein-based an injectable therapeutic agent using proprietary processes and patented technology. Our IPOXYN™ anti-necrosis drug consists of a stabilized glycoprotein composition containing oxygen-rechargeable iron, targeting both human and animal tissues and organ systems deprived of oxygen and in need of metabolic support.

We have unrestricted access, subject to adequate funding, to both sufficient raw materials at commodity pricing and processing facilities to produce sufficient quantities of IPOXYN™ to complete pre-clinical pharmacokinetic, safety and efficacy studies in support of an investigative new drug ("IND") filing in the United States and Europe in 2013 or 2014. The primary raw material for IPOXYN™ is extracted from controlled sourced bovine blood which can be obtained from multiple sources at commodity prices under Good Manufacturing Practice (GMP). There are numerous facilities capable of processing source verified red blood cell extract. We expect to put in place agreements for obtaining and processing these materials upon funding.

In addition to potential uses for human patients, we also intend to file a registration for IPOXYN™ for veterinary applications under the name OXYFEX™. We are unaware of any drug currently on the market for animals that can deliver oxygen, and there is only limited "blood banking" for animals despite a constant need. OXYFEX™ can serve as the only available oxygen delivery mechanism for animals suffering ischemia or traumatic and surgical blood loss events.

We hope to be able to commence marketing OXYFEX™ for veterinary applications, which we view as a potentially lucrative market in 2014 in various locations around the world. We estimate that there are at least 15,000 small animal veterinary practices in the United States, another 4,000 mixed animal practices treating small and large animals in the United States and approximately 22,000 small animal practices in Europe. We believe that the average veterinary practice treats only a small percentage of canine anemia cases with red blood cell transfusion. The remaining animals receive either cage rest or treatment such as fluid administration, iron supplements, nutritional supplements or inspired oxygen. The FDA Center for Veterinary Medicine approved a bio-similar product to OXYFEX™ named Oxyglobin in 1998 and the European Commission approved Oxyglobin in 1999, in both cases for the treatment of canine anemia, regardless of the cause of the anemia. Oxyglobin is no longer in use. Based upon the prior, limited efforts of the now bankrupt third party that developed Oxyglobin, we believe that the potential veterinary market for OXYFEX™ in the United States alone could exceed $250 million in sales annually within a few years after introduction.

Our pharmaceutical agents are intended for intravenous administration into the circulatory system to target acute and late stage diseases that, we believe, have a great unmet medical need. Hypoxia conditions, which we intend to treat with IPOXYN™, result from a lack of oxygen supply to living cells. Hypoxia will lead to ischemia, inflammation and the death of living cells. Ischemia is a restriction in blood supply, generally due to factors in the blood vessels, with resultant damage or dysfunction of tissue. Diabetic foot ulcer, which occurs in 15% of patients with diabetes and precedes more than 80% of all lower leg amputations, is one of the major complications of diabetes mellitus. Two major risk factors that cause diabetic foot ulcer are diabetic neuropathy and micro/macro ischemia. Increases in mortality among diabetic patients observed over the past 20 years are considered to be due to the development of macro and micro vascular complications including the failure of the wound healing process. A failure of effective treatment of wounds in this population can often lead to infection, tissue death and amputation of the lower leg and foot as the only treatment option. We believe that IPOXYN™ represents a potentially effective treatment for lower limb complications of diabetes.

Scientific Overview - Hypoxia

Hypoxic conditions are detrimental to maintaining normal functionality in all living tissues. In mammals, red blood cells (RBCs) deliver oxygen throughout the body using hemoglobin, a protein responsible for carrying and releasing oxygen to the body's tissues. Under normal conditions, approximately 98% of oxygen is delivered by hemoglobin in the RBCs, while less than two percent is dissolved in the plasma, the fluid part of the blood.

As the heart pumps blood, RBCs take up oxygen in the lungs and carry it to various parts of the body. Blood travels through progressively smaller blood vessels to the capillaries, some of which are so narrow that RBCs can only pass through them in single file. Most of the oxygen release occurs in the capillaries. Oxygen depleted RBCs return to the lungs to be reloaded. Adequate blood flow, pressure and RBC counts are crucial to this process. Hypoxia, or oxygen deprivation, even for several minutes, can result in cell damage, organ dysfunction and, if prolonged, death.

The causes of inadequate tissue oxygenation generally can be classified into three major categories:

Ischemia -- inadequate RBC flow for tissue oxygenation. Ischemia may be caused by obstructed or constricted blood vessels and can lead to stroke, heart attack or other organ or tissue dysfunction.

Cardiopulmonary failure -- impaired function of the heart or lungs. Cardiopulmonary failure may be 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. This condition can be caused by chronic disorders affecting RBCs functionality or production like chemotherapy and radiation for treatment of cancer, or blood born diseases like bone marrow diseases. Anemia may be also caused by acute blood loss from accidental injury or surgery.

The standard therapy for acute anemia resulting from blood loss is infusion of RBCs mainly from supplies of donated blood. For prophylactic or long term treatment of anticipated or chronic anemia, medications that stimulate the creation of new RBCs are frequently used.

Presently, there is no substitute for human blood to deliver oxygen to the body; and transfusions involve certain risks and limitations. Despite the effort by blood banks around the world to screen the blood supply for HIV, hepatitis and other blood borne diseases, there is a continuing risk of an unsafe blood supply in many parts of the world; donated blood continues to carry the risk of disease transmission.

Blood compatibility and handling and storage requirements and limitations limit the use of RBCs transfusions to hospital environment only. Shortages of certain types of blood thus occur due to seasonal factors or disasters. Since RBCs' oxygen-delivering capacity breaks down with storage (approximately 75% capacity remains after eight days of storage) their shelf-life is less than 42 days, limiting the ability for significant stockpiles of RBCs. In addition, for ischemic conditions due to constricted blood vessels where normal passage of RBCs is restricted or due to impaired heart or lung function, RBC transfusions are generally not effective.

IPOXYN™ and OXYFEX™

IPOXYN™ is designed for delivery as an intravenous solution, with the expectation that it can 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 - but without the limitations of compatibility, availability, short shelf life, volume and logistical challenges commonly associated with transfusions of whole blood. 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. We have not conducted any clinical trials to confirm the efficacy of, or filed any applications with the FDA with respect to, IPOXYN™. IPOXYN™ will not be ready for commercialization until these steps are completed. Preclinical animal study results for IPOXYN™ were presented at the XIII International Symposium on Blood Substitutes and Oxygen Therapeutics in July 2011.

We are planning to introduce this product in clinical trials for hypoxic medical conditions. Hypoxia promotes resistance to conventional treatments, as well as treatments for other diseases. IPOXYN™ has the potential to greatly improve survival of patients in multiple indications in which hypoxia is a factor. Hypoxia is a condition in which cells lack sufficient oxygen supply to support metabolic function. It is widely known through research that lack of oxygen will result in a cascade of biochemical reactions which promote resistance to many helpful therapeutic substances and which interfere with the body's own repair mechanisms. Antibiotics for the treatment of infection are less effective when hypoxic conditions are involved. Similarly, hypoxic cancer cells are resistant to chemotherapy treatments; most chemotherapy drugs rely on rapid cell division which requires normal oxygenation of cells, but in a hypoxic condition, cells divide slowly and therefore resist many chemotherapy treatments.

Another unmet clinical need is in various acute ischemic conditions, where hypoxia can develop from a local restriction of constrained blood vessels, or poor and compromised flow which leads to insufficient supply of oxygen by otherwise well-oxygenated and distributed RBCs, e.g. cerebral ischemia, ischemic heart disease and intrauterine hypoxia which is an unchallenged cause of perinatal death. In these cases IPOXYN™, as a rechargeable soluble oxygen delivery agent, may not be restrained whereas well-oxygenated RBCs may be prevented from flow and delivery of oxygen. This is so because RBCs are large biological structures compared to the size of IPOXYN™, which is a modified single-protein function oxygen carrier. In ischemic and hypoxic conditions, RBCs may not be able to penetrate the small vessels which have lost their integrity to support RBC distribution and thus oxygen availability. Due to its small molecular size, IPOXYN™ can carry and distribute oxygen widely without risk of clot formation and flow stoppage.

In veterinary medicine applications, OXYFEX™ will be used as an oxygen delivery agent similar to a blood substitute for ischemia and trauma, as well as for blood loss during surgery.

Status of development of IPOXYN™

We are in the process of developing IPOXYN™ for pre-clinical studies, in order to conduct clinical trials and to file applications with the FDA as applicable.

Competitive Products

Many biotechnology and pharmaceutical companies are developing new technologies for the treatment of hypoxia and other diseases. The standard therapy for reversing hypoxia due to acute blood loss may be blood infusion, RBCs or hyperbaric oxygen. Hyperbaric medicine, also known as hyperbaric oxygen therapy (HBOT), is the medical terminology for using oxygen at a level higher than atmospheric pressure. There are many conditions being treated using this approach including acute blood loss (Hart GB, Lennon PA, Strauss MB. (1987) "Hyperbaric oxygen in exceptional acute blood-loss anemia". J. Hyperbaric Med 2 (4): 205–210). In the United States, HBOT is recognized as a reimbursable treatment for 14 "approved" conditions and an HBOT session can cost anywhere from $200 in private clinics, to over $1,000 in hospitals. The sessions require the use of a heavy chamber. The most common intervention in hypoxic patients is RBC transfusion. The need for intervention to reduce hypoxia can also be affected by medical conditions such as ischemia or cardiopulmonary failure, claudication (cramping caused by blocked arteries in the leg), poor perfusion and other indications, where a combination of below optimal flow and capacity are compromising oxygen delivery.

When compared to RBC transfusion we believe IPOXYN™ has the following advantages:

- **Availability:** readily available, with a two year shelf-life, much longer than the two week shelf life for RBCs and easier to perfuse.
- **Stability:** stored at room temperature for months while maintaining its full capacity for oxygen delivery and release and logistical convenience
- **Sterile:** when manufactured and processed consistently through good manufacturing practices, free of infectious agents and unnecessary elements.
- **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**: IPOXYN™ can be safely applied outside the hospital to treat or prevent ischemic conditions in cases like shock and trauma, heart attack or stroke where low flow or suspended local flow are disrupted. A readily available infusion package makes it a straightforward tool for emergency medical teams to use on site in order to save a patient's life, when time is of the essence for survival.

- **Molecular structure**: Chemically IPOXYN™ features a small molecular size compared to RBCs, so it possesses better flow characteristics and circumvents constricted vessels that restrict flow of RBCs and thus the supply of oxygen to tissues and organs.

- **Oxygenation**: Due to its high solubility, it has high capacity and faster exchange of oxygen in tissues, as well as facilitating the release of oxygen from RBCs for overall unparalled efficiency.

For chronic anemia situations, erythropoietin-based formulations are available from two suppliers. Erythropoietin stimulates the erythropoietic system in the bone marrow to produce its own RBCs. These products are slow acting, and only administered in anticipation of blood loss during surgery, and are not effective for temporary use or in emergency situations when acute blood loss requires RBC infusion to deliver oxygen.

The fields of treatment of oxygen-deprived states have been approached in many ways for the past 70 years. These include such techniques at high oxygen concentration, hyperbaric chambers, as well as the more mechanical approaches of vessel dilation and blood thinning. All have met with minor measures of improvement. In the early 1980's a number of companies focused on creating specific oxygen carriers that were either (a) blood derived elements, (b) synthetics consisting of Perfluoro chemicals or (c) elements created using recombinant and molecular engineering approaches (red cell modifiers). Companies including Baxter, Abbot, and Biopure, and now OPK in Cambridge, MA, for example, used the blood derived approach; Green Cross, Alliance Pharmaceuticals and Synthetic blood focused on synthetics, and Somatogen and Allos Therapeutics tried recombinant and molecular engineering. All of these approaches were early attempts to meet a need whose main focus has been on a "blood substitute". Our approach is fundamentally different. Instead of a blood substitute, we are offering a new chemical entity that will deliver oxygen to hypoxic cells.

We expect IPOXYN™ to compete with traditional therapies and with other oxygen delivery pharmaceuticals. Some of our competitors and potential competitors may have greater financial and other resources to develop, manufacture and market their products. We believe the most immediate competition comes from companies currently conducting clinical trials of investigational hemoglobin solutions. Privately held Sangart Inc. uses hemoglobin extracted from human red blood cells as the raw material for its products. Sangart reports that it has completed a 90-patient clinical safety trial in Sweden in patients undergoing hip replacement and is conducting a single-center Phase 2 safety trial in the U.S. in cancer patients undergoing radical prostatectomies. It appears that a privately held company may begin a Phase 2 trial of a human-derived hemoglobin solution in the U.S. for treatment of cardiogenic shock.

We are aware of other companies researching the use of hemoglobin as a therapeutic, including programs in China and Japan. We believe that these programs are in the preclinical stage of development, although China's government-funded initiative may enter clinical testing as early as this year. In the field of perfluorocarbons, publicly traded Synthetic Blood International Inc. has recently completed an open-label, proof-of-concept Phase 2a clinical trial in eight patients with traumatic brain injury. Alliance Pharmaceutical Corporation has received regulatory authorization in France to initiate a Phase 2 clinical trial to prevent post-operative ileus resulting from hypoxia during major surgery. We believe that the Russian open joint-stock company Scientific and Production Firm "Perftoran" has received regulatory approval to market its perfluorocarbon in Russia, Ukraine, Kazakhstan and Mexico. In 2009, a company called OPK Biotech bought certain assets of now defunct Biopure Corporation and continues to develop Hemopure for human use. In the cardiovascular area we expect competition from medical devices and drugs on the market or which are currently under development. For example, privately held KAI Pharmaceuticals Inc. has reported the completion of a Phase 1/2 clinical trial of its protein kinase C (PKC) inhibitor to reduce ischemia and reperfusion injury during treatment of acute myocardial infarction. We believe that our use of bovine red blood cells for the production of IPOXYN™ is an advantage over products made from donated human red blood cells stored for a long period of time and other competitive approaches because of the availability, abundance, ability to control source, cost and relative safety of bovine red blood cells.

Marketing:

IPOXYN™

We believe IPOXYN™ is a safe and effective intervention for reversing acute hypoxia, fulfilling an unmet clinical need; and that IPOXYN™ can 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. Our belief about the safety and efficacy of IPOXYN™ is 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. We understand that this testing of GLP produced bio-similar materials or, for that matter, pre-clinical testing, will not necessarily predict levels of toxicity and efficacy in humans. However, if clinical trials ultimately support this belief, in many clinical situations IPOXYN™ could become a significant new management tool to moderate the inconsistencies of RBC transfusion and become the treatment of choice in critical situations when RBCs are not immediately available.

In addition to the expansive and broad application development in the field of human medical management, we envision a sizable market in the veterinary field and expect to make a registration filing for this market as soon as we can complete pre-clinical safety and efficacy studies. Clinical safety and efficacy studies under Good Manufacturing Practices have not yet been initiated by the Company.

Preliminary data from animal testing conducted by third parties suggests successful use of IPOXYN™ in hypoxia and critical anemic situations, where hypoxic conditions were critical to animal survival. Early experiments with dogs suggest intervention with IPOXYN™ will significantly improve survival in induced canine anemia models. This veterinary treatment of canine anemia will be our first target for seeking early regulatory approval in the European Union. As there is substantial commonality between the metabolic functions of humans and other mammals, animal testing becomes a starting point for many clinical development programs that can directly translate into clinical development programs for humans. The third party testing described here was conducted by a company that developed a bio-similar product to IPOXYN™. Testing included repeated intravenous infusions of the product in dogs that was reported in well documented literature and regulatory filings, and the testing did not result in reported mortality/morbidity of the subject animals. Reports concerning anemic dogs infused with the bio-similar product showed increased plasma hemoglobin levels resulting in an increase of the oxygen carrying capacity of the treated animals. We have no agreements with the third party that conducted these toxicity tests, or its successors.

We intend 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 that will guide us in other indications. We do not currently have agreements with any potential candidates for such board. We may seek to enter into licensing or co-marketing agreements for parts or all of the world in order to avail the Company of the marketing expertise of one or more seasoned pharmaceutical companies. Alternatively, we may engage contract sales organizations from vendors, contract pharmaceutical companies that supply sales services.

Similarly in the veterinary market, we may engage wholesale distributors on national or regional levels. Marketing programs may include web based advertising, direct mail, educational seminars, conference calls and attendance at trade shows. We may establish a core group of veterinary practices that will start to use the product regularly. These veterinarians can serve as effective advocates of the product when interacting with other veterinarians.

SUGARDOWN®

We developed SUGARDOWN®, a non-systemic complex carbohydrate-based dietary food supplement to moderate post-meal blood glucose using proprietary processes and technology. We have unrestricted access to both sufficient raw materials at commodity pricing and processing facilities to produce sufficient supply of SUGARDOWN® to support product distribution across multiple sales channels as a dietary supplement. Our SUGARDOWN® dietary supplement consists of a complex carbohydrate composition.

Status of Development of SUGARDOWN®

We completed development of SUGARDOWN® as a dietary food supplement. We filed a structure and function claim application with the United States Food and Drug Administration (FDA) with respect to SUGARDOWN® which describes the proposed mechanism of action of SUGARDOWN® in reducing post-meal elevation of glucose in the blood. The Company submitted 30 (thirty) structural and functional claims with the FDA. We filed a provisional patent with the United States Patent and Trademark Office with regard to SUGARDOWN®. We received a registered mark for SUGARDOWN®. General Product Liability Insurance for SUGARDOWN® has been in effect since April 2010. On December 29, 2011 the Company announced that it secured its first purchase order for distribution of SUGARDOWN® in Italy. On January 24, 2012 the Company announced the clinical trial results in healthy volunteers performed at the University of Sydney on SUGARDOWN®. On January 28, 2013, the Company announced the final results of the study conducted at the University of Sydney that showed 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. This resulted in a reduction of up to 56% in post-meal elevation of blood glucose compared with the rice consumed alone. On average, there was 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. No severe adverse effects were reported or observed during the study.

Marketing:

SUGARDOWN®

We believe SUGARDOWN® is a safe and effective dietary supplement for assisting people who are considered to be at risk of developing diabetes and people living with diabetes in their daily management of blood glucose levels. We believe this supplement may provide individuals with a non-systemic tool to reduce post-meal elevation of blood glucose. The product is ready for limited market release and is currently available for distribution in Asia and Europe, and in the U.S. through the website, www.sugardown.com.

BTI-7

In July 2011, we submitted a petition to file an Abbreviated New Drug Application (ANDA) for a chewable metformin with the U.S. Food and Drug Administration (FDA). In October 2012, the FDA approved the Company's petition to file an Abbreviated New Drug Application (ANDA) for a new chewable formulation for the diabetes drug metformin hydrochloride. In addition, the FDA ruled that no further clinical investigation is necessary to demonstrate the safety and effectiveness of this proposed product. The Reference Listed Drug at the FDA is Bristol –Myers Squibb's product, Glucophage®. As an added component of the new formulation, the Company optimized the chemistry of complex carbohydrates known as mannans. Metformin acts by increasing the sensitivity of liver, muscle, and fat tissue to the effects of insulin ,thereby lowering the level of glucose in the blood. The drug is indicated for the treatment of Type 2 diabetes. Of the options available today in oral therapy for Type 2 diabetes, metformin is currently the standard of care, and the Company's new delivery format may expand usage. Although this proposed product is subject to the Pediatric Research Equity Act (PREA) of 2007, which would require an assessment of safety and effectiveness before the new formulation could be used in the pediatric population, the FDA has ruled that, in this case, no such assessment will be required because the proposed product is "PREA-fulfilled".

According to market analysts, metformin is the most widely prescribed diabetes drug in the world. In the U.S. alone, approximately 50 million prescriptions for metformin were filled in 2010.

Our Strengths and Strategies

Leverage Extensive Regulatory Expertise. Dr. Platt, a Ph.D. chemical engineer, has approximately 20 years experience in the development of therapeutic drugs and holds many patents. He has been substantially involved in the FDA approval process for a number of drugs, and we anticipate that his expertise shall be crucial as we develop our drugs through the clinical trial and approval process.

Focus on Novel Therapeutic Opportunities Provided by Carbohydrates. We believe our company is one of the pioneers focused on development of carbohydrate-based anti-necrosis or hypoxia therapeutics and carbohydrate-based dietary supplements for blood glucose management. As a result of their structural complexity, carbohydrates have not received as much scientific attention as nucleic acids and proteins.

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. We believe this offers a largely untapped area for treatment by utilizing hemoglobin as modified by carbohydrate chemistry to deliver oxygen to cells in a necrosis or hypoxic condition.

Subsidiaries

We currently have no subsidiaries.

Employees

The Company currently has five full-time employees. Mr. Kenneth Tassey, Jr., our President, and Mr. Jonathan Rome, our Chief Operating Officer, have entered into written employment agreements with the Company. Dr. David Platt, our Chief Executive Officer and Chief Financial Officer and two other full time employees do not have written employment agreements with the Company.

Facilities

We currently lease an office located at 1750 Elm Street, Suite 103, Manchester, NH 03104.

Manufacturing

We currently manufacture PAZ320 and SUGARDOWN® in the United States at a Good Manufacturing Practices (GMP) compliant facility. We expect to have 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) / FDA approval, but no agreement for such access is currently in place. We intend to only utilize manufacturing facilities that we believe are fully compliant with Good Manufacturing Practices (GMP) as required by the regulatory authorities in Europe or the United States.

Environmental Regulation

Pharmaceutical research and development involves the controlled use of hazardous materials. Biotechnology and pharmaceutical companies must comply with laws and regulations governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. We do not anticipate building in-house research, development or manufacturing facilities, and, accordingly, do not expect to have to comply directly with environmental regulation. However, our contractors and others conducting research, development or manufacturing activities for us may be required to incur significant compliance cost, and this could in turn could increase our expense or delay our completion of research or manufacturing programs.

Lack of Major Customers

To date we have had limited sales of our products and have one significant customer. We have entered into an agreement with Advance Pharmaceutical Co. Ltd., a Hong Kong-based pharmaceutical company, for distribution of SUGARDOWN® in Hong Kong and mainland China markets. There can be no assurances that this agreement will lead to significant sales.

Patents, Trademarks and Licenses

Patents, trademarks, trade secrets, technological know-how and other proprietary rights are important to our business.

Our proprietary technologies embodied in IPOXYN™ and OXYFEX™ include claims under patent number 6,245,316 (Enhancement of Delivery of Radioimaging and Radioprotective Agents) which expires in 2018, and a provisional patent relating to a Hybrid Hemoglobin Molecule and Methods of Use, Application No. 61/285,281, both of which were assigned to the Company by our CEO.

Our CEO also has assigned the trademarks IPOXYN™ (U.S. Trademark Application No. 77754473) and Avanyx Therapeutics™ (U.S. Trademark Application No. 77806120) to the Company. Our CEO and our President have assigned the trademark SUGARDOWN® (U.S. Trademark Reg. No. 3,955,414, registered May 3, 2011) to the Company.

It is not economically practicable to determine in advance whether our products, product components, manufacturing processes or the intended uses for our products infringe the patent rights of others. It is likely that, from time to time, we will receive notices from others of claims or potential claims of intellectual property infringement or we may be called upon to defend a customer, vendee or licensee against such third-party claims. Responding to these kinds of claims, regardless of merit, could consume valuable time, result in costly litigation or cause delays, all of which could harm our business.

Responding to these claims could also require us to enter into royalty or licensing agreements with third parties claiming infringement. Such royalty or licensing agreements, if available, may not be available on terms acceptable to us.

Government Regulation

New drug approval for clinical use requires extensive research, manufacturing, pre-clinical and clinical studies, packaging, labeling, advertising, promotion, export and marketing, among other things. Both PAZ320 and IPOXYN™ will be subject to extensive regulation by governmental authorities in the United States and other countries. As a therapeutic product administered by intravenous infusion IPOXYN™ will be regulated as a drug and will require extensive safety and efficacy studies for regulatory approval before it may be commercialized.

Drug Approval Process

In the United States, IPOXYN™ is a new chemical entity and will require FDA approval. PAZ320, as a drug candidate, will also require FDA approval. Before final approval for marketing for either IPOXYN™ or PAZ320 could occur, the following steps must be completed: preclinical safety animal studies, GMP manufacturing, submission of Investigational New Drug, or IND application for extensive clinical trials to show proof of concept to significant health benefit.

After approval and during clinical studies FDA can put the drug on "clinical hold." In such case, the IND sponsor and the FDA must resolve any outstanding concerns before the use of the drug can proceed. FDA may stop marketing, or clinical trials, or particular types of trials, by imposing a clinical hold because of safety concerns and potential risk to patients.

Clinical trials involve the administration of the investigational products to healthy volunteers or patients under the supervision of a qualified principal investigator consistent with an informed consent. Each clinical protocol is submitted, reviewed and approved by an independent Institutional Review Board, or IRB, or Ethical Committee (EC) at a participating hospital at which the study will be conducted. The IRB/EC will consider, among other things; ethical factors, safety to human subjects and the possible liability of the institution.

Clinical trials required for FDA approval typically are conducted in three sequential phases, but the phases may overlap. In Phase I, the initial introduction of the drug into human subjects, the drug is usually tested for safety or adverse effects, dosage tolerance, absorption, metabolism, distribution, excretion and pharmacodynamics.

Phase II clinical trials usually involve studies in a limited patient population to evaluate the efficacy of the drug for specific, targeted indications, determine dosage tolerance and optimal dosage and identify possible adverse effects and safety risks.

Phase III clinical trials generally further evaluate clinical efficacy and test further for safety within an expanded patient population and at multiple clinical sites.

After FDA approval, Phase IV clinical trials may be conducted to gain additional experience from the treatment of patients in the intended therapeutic indication. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as Phase III/IV post-approval clinical trials.

The results of the pre-clinical studies and clinical trials, together with detailed information on the manufacture and composition of the product, are submitted to the FDA in the application requesting approval to market the product. The FDA may delay approval of any product submitted by the Company. The FDA may limit the indicated uses for which an approval is given.

New Drug Approval for Veterinary Use

The use of new drugs for companion animals requires the filing of a New Animal Drug Application, or NADA, with and approval by, the FDA. The requirements for approval are similar to those for new human drugs, exclusive of human trials. Obtaining NADA approval often requires safety and efficacy clinical field trials in the applicable species and disease, after submission of an Investigational New Animal Drug Application, or INADA, which for non-food animals becomes effective upon acceptance for filing.

Dietary Supplements

We currently offer SUGARDOWN® as a dietary supplement. We are not required to obtain FDA approval in order to offer SUGARDOWN® in this manner. We are required to either comply with certain FDA guidelines with respect to certain marketing claims for SUGARDOWN®, or to file those claims with the FDA. We believe that we comply with those guidelines and have voluntarily filed structural and functional claims with the FDA.

Pervasive and Continuing Regulation

Any FDA approvals that may be granted will be subject to continual review, and newly discovered or developed safety or efficacy data may result in withdrawal of products from marketing. Moreover, if and when such approval is obtained, the manufacture and marketing of our products remain subject to extensive regulatory requirements administered by the regulatory bodies, including compliance with current Good Manufacturing Practices, serious adverse event reporting requirements and the FDA's general prohibitions against promoting products for unapproved or "off-label" uses.

We are subject to inspection and market surveillance by the FDA for compliance with these regulatory requirements. Failure to comply with the requirements can, among other things, result in warning letters, product seizures, recalls, fines, injunctions, suspensions or withdrawals of regulatory approvals and termination of marketing. Any such enforcement action could have a material adverse effect on us. Unanticipated changes in existing regulatory requirements, state and local work and environmental laws or the adoption of new requirements could also have a material adverse effect on us.

Foreign Regulation

We will be subject to a variety of regulations governing clinical trials and sales of our products in the United States and outside the United States. Whether or not FDA approval has been obtained, approval of a product by the comparable non-U.S. regulatory authorities must be obtained prior to the commencement of marketing of the product in any country.

The approval process varies from country to country and can be complicated and time consuming; the time needed to secure approval may be longer or shorter than that required for FDA approval. For example, the European Union requires approval of a Marketing Authorization Application by the European Medicines Evaluation Agency. These applications require the completion of extensive preclinical studies, clinical studies and manufacturing and controls information.

Reimbursement

Our ability to successfully commercialize our human products also may depend on the extent to which reimbursement of the cost of such products and related treatment will be approved by the government health administration authorities, private health insurers and other health providers' organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products. As third-party payors are increasingly challenging the price of medical products, there can be no assurance that adequate reimbursement of the cost will be available to enable us to maintain price levels sufficient for realization of an appropriate return on its investment.

Recently the public and the federal government have focused significant attention on reforming the health care system in the United States. A number of health care reform measures have been suggested, including price controls on therapeutics. Public discussion of such measures is likely to continue, and concerns about the potential effects of different possible proposals have been reflected in the volatility of the stock prices of companies in the health care and related industries.

Item 1A. Risk Factors.

The following important factors, and the important factors described elsewhere in this report or in our other filings with the SEC, could affect (and in some cases have affected) our results and could cause our results to be materially different from estimates or expectations. The following and these other risks could materially and adversely affect our business, operations, results or financial condition.

RISKS RELATED TO OUR COMPANY

IF WE DO NOT RECEIVE ADDITIONAL FUNDING, WE WOULD HAVE TO CURTAIL OR CEASE OPERATIONS.

We have incurred losses totaling approximately $2,697,000 since inception through December 31, 2012, of which approximately $1,484,000 was incurred during the fiscal year ended December 31, 2012. As of December 31, 2012, the Company had approximately $552,000 cash on hand. Our Chief Executive Officer and President have made loans to the Company to fund operations, and the Company raised approximately $1,147,000 in private and public placements in 2012. To stay in business, we will need to raise additional capital through public or private sales of our securities, debt financing or short-term bank loans, or a combination of the foregoing.

We will need additional capital to fully implement our business, operating and development plans. However, additional funding from an alternate source or sources may not be available to us on favorable terms, if at all. To the extent that money is raised through the sale of our securities, the issuance of those securities could result in dilution to our existing security holders. If we raise money through debt financing or bank loans, we may be required to secure the financing with some or all of our business assets, which could be sold or retained by the creditor should we default in our payment obligations. If we fail to raise sufficient funds, we 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 our ability to obtain additional sources of capital and financing. Our Chief Executive Officer intends to provide us with minimal cash to fund critical needs until we are able to raise additional capital from an offering of securities but there is no guarantee that he will do so or will do so for any extended period of time. We recently hired a Chief Operating Officer to accelerate the commercialization of our products. If we are unable to receive additional financing, we may be required to cease operations. There is no guarantee that we will be able to generate sufficient revenues from the sale of our products in the near term to fund our operations. If we are unable to generate sufficient revenues or receive additional financing, we may be required to cease operations.

WE ARE A COMPANY WITH LIMITED OPERATING HISTORY WHICH MAKES IT DIFFICULT TO EVALUATE OUR CURRENT BUSINESS AND FUTURE PROSPECTS.

We are a company with limited operating history, and our operations are subject to all of the risks inherent in establishing a new business enterprise. The likelihood of our 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 we will operate. We have made initial sales of our SUGARDOWN® product as a dietary supplement and, while we expect to continue selling that product, we have no other products currently available for sale, and none are expected to be commercially available for at least eighteen months, if at all. We may never obtain Food and Drug Administration ("FDA") approval of our products in development and, even if we do so and are also able to commercialize our products, we may never generate revenue sufficient to become profitable. Our failure to generate revenue and profit would likely cause our securities to decrease in value and/or become worthless.

ADDITIONAL FINANCING REQUIRED TO IMPLEMENT OUR BUSINESS PLAN MAY NOT BE AVAILABLE ON FAVORABLE TERMS OR AT ALL, AND WE MAY HAVE TO ACCEPT FINANCING TERMS THAT WOULD ADVERSELY AFFECT OUR SHAREHOLDERS.

We will need to continue to conduct significant research, development, testing and regulatory compliance activities for PAZ320 and IPOXYN™ that, together with projected general and administrative expenses, we expect will result in operating losses for the foreseeable future. We do not expect to be generating sales or other revenue from SUGARDOWN® alone to fund operations and will remain dependent on outside sources of financing until that time and we will need to raise funds from additional financing. We have no commitments for any financing at this time, and any financing commitments may result in dilution to our existing stockholders. We may have difficulty obtaining additional funding, and we may have to accept terms that would adversely affect our stockholders. For example, the terms of any future financings may impose restrictions on our right to declare dividends or on the manner in which we conduct our business. Additionally, we may raise funding by issuing convertible notes, which if converted into shares of our common stock would dilute our then shareholders interests. Lending institutions or private investors may impose restrictions on a future decision by us to make capital expenditures, acquisitions or significant asset sales. If we are unable to raise additional funds, we may be forced to curtail or even abandon our business plan.

OUR ABILITY TO GROW AND COMPETE IN THE FUTURE WILL BE ADVERSELY AFFECTED IF ADEQUATE CAPITAL IS NOT AVAILABLE.

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

OUR PRODUCTS ARE BASED ON NOVEL, UNPROVEN TECHNOLOGIES.

Our 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 and trauma and other diseases. Carbohydrates are difficult to synthesize, and we may not be able to synthesize carbohydrates that would be usable as delivery vehicles for the anti-hypoxia drugs we are working with or other therapeutics we intend to develop. Although we have completed certain animal studies that we believe were successful, pre-clinical results in animal studies are not necessarily predictive of outcomes in human clinical trials. Clinical trials are expensive, 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 our products progress successfully through initial human testing, they may fail in later stages of development. We may engage others to conduct our clinical trials, including clinical research organizations and, possibly, government-sponsored agencies. These trials may not start or be completed as we forecast, or may not achieve desired results.

WE MAY BE UNABLE TO COMMERCIALIZE OUR PRODUCTS.

Even if our current and anticipated products achieve positive results in clinical trials, we may be unable to commercialize them. Potential products may fail to receive necessary regulatory approvals, and such products, along with products which 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. Our inability to commercialize our products would substantially impair the viability of our company.

WE HAVE ESTABLISHED 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 ("Board of Directors") 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 shares of Series A 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.

OUR MANAGEMENT AND TWO SIGNIFICANT SHAREHOLDERS COLLECTIVELY OWN A SUBSTANTIAL MAJORITY OF OUR COMMON STOCK.

Collectively, our officers, our directors and two significant shareholders own or exercise voting and investment control approximately 85% of our outstanding common stock. As a result, investors may be prevented from affecting matters involving the Company, including:

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

- any determinations with respect to mergers or other business combinations;
- our acquisition or disposition of assets; and
- our 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 our stockholders. This significant concentration of share ownership may also adversely affect the trading price for our common stock because investors may perceive disadvantages in owning stock in a company that is controlled by a small number of stockholders.

WE ARE DEPENDENT UPON OUR TWO OFFICERS FOR MANAGEMENT AND DIRECTION AND THE LOSS OF THESE PERSONS COULD ADVERSELY AFFECT OUR OPERATIONS AND RESULTS.

We are dependent upon both Dr. David Platt and Mr. Ken Tassey for implementation of our proposed expansion strategy and execution of our business plan. The loss of Dr. Platt or Mr. Tassey could have a material adverse effect upon its results of operations and financial position. We do not maintain "key person" life insurance for Dr. Platt or Mr. Tassey.

OUR LACK OF OPERATING EXPERIENCE MAY CAUSE US DIFFICULTY IN MANAGING OUR GROWTH WHICH COULD LEAD TO OUR INABILITY TO IMPLEMENT OUR BUSINESS PLAN.

We have limited experience in manufacturing or procuring products in commercial quantities, conducting other later-stage phases of the regulatory approval process, selling pharmaceutical products, or negotiating, establishing and maintaining strategic relationships. Any growth of our company will require us to expand our management and our operational and financial systems and controls. If we are unable to do so, our business and financial condition would be materially harmed. If rapid growth occurs, it may strain our operational, managerial and financial resources.

WE WILL DEPEND ON THIRD PARTIES TO MANUFACTURE AND MARKET OUR PRODUCTS AND TO DESIGN TRIAL PROTOCOLS, ARRANGE FOR AND MONITOR THE CLINICAL TRIALS, AND COLLECT AND ANALYZE DATA.

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

In addition, we have limited experience in marketing, sales or distribution, and we recently hired an experienced sales and marketing executive to commercialize our pharmaceutical products. We currently have an agreement with Advance Pharmaceutical Co. Ltd. to develop markets in Hong Kong, China and Macau and have received a commercial purchase order from a distributor in Italy for SUGARDOWN®. If we develop additional commercial products, we will need to rely on licensees, collaborators, joint venture partners or independent distributors to market and sell those products and we may need to rely on additional third parties to market our products.

Moreover, as we develop products eligible for clinical trials, we contract 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 our products may be conducted by government-sponsored agencies and will be dependent on governmental participation and funding. Our dependence on independent parties and clinical sites involves risks including reduced control over the timing and other aspects of our clinical trials.

WE ARE EXPOSED TO PRODUCT LIABILITY, PRE-CLINICAL AND CLINICAL LIABILITY RISKS WHICH COULD PLACE A SUBSTANTIAL FINANCIAL BURDEN UPON US, SHOULD WE BE SUED.

Our business exposes us 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 us. In addition, the use in our clinical trials of pharmaceutical formulations and products that our potential collaborators may develop and the subsequent sale of these formulations or products by us or our potential collaborators may cause us to bear a portion of or all product liability risks. A successful liability claim or series of claims brought against us could have a material adverse effect on our business, financial condition and results of operations.

We currently maintain product liability insurance. There is no guarantee that such insurance will provide adequate coverage against our potential liabilities. Since we do not currently have any FDA-approved products or formulations, we do not currently have any other product liability insurance covering commercialized products. We 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 our potential liabilities. Furthermore, our current and potential partners with whom we have collaborative agreements or our future licensees may not be willing to indemnify us 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 us could have a material adverse effect on our business, financial condition and results of operations.

In addition, we may be unable to obtain or to maintain clinical trial or directors and officers 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 we develop.

IF USERS OF OUR PROPOSED PRODUCTS ARE UNABLE TO OBTAIN ADEQUATE REIMBURSEMENT FROM THIRD-PARTY PAYERS, OR IF NEW RESTRICTIVE LEGISLATION IS ADOPTED, MARKET ACCEPTANCE OF OUR PROPOSED PRODUCTS MAY BE LIMITED AND WE 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 health care may affect our future revenues and profitability, and the future revenues and profitability of our 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 health care, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of prescription pharmaceuticals and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could materially harm our business, financial condition and results of operations.

Our ability to commercialize our proposed products will depend in part on the extent to which appropriate reimbursement levels for the cost of our 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 health care in the U.S. and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and drugs, as well as legislative proposals to reform health care or reduce government insurance programs, may all result in lower prices for or rejection of our products.

THERE ARE RISKS ASSOCIATED WITH OUR RELIANCE ON THIRD PARTIES FOR MARKETING, SALES AND DISTRIBUTION INFRASTRUCTURE AND CHANNELS.

We expect that we will be required to enter into agreements with commercial partners to engage in sales, marketing and distribution efforts around our products in development. We 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 our competitors. If we do not enter into relationships with third parties for the sales and marketing of our proposed products, we will need to develop our own sales and marketing capabilities.

We may be unable to engage qualified distributors. Even if engaged, these distributors may:

- fail to satisfy financial or contractual obligations to us;
- fail to adequately market our products;
- cease operations with little or no notice to us; or
- offer, design, manufacture or promote competing formulations or products.

If we fail to develop sales, marketing and distribution channels, we would experience delays in generating sales and incur increased costs, which would harm our financial results.

WE WILL BE SUBJECT TO RISKS IF WE SEEK TO DEVELOP OUR OWN SALES FORCE.

If we choose at some point to develop our own sales and marketing capability, our experience in developing a fully integrated commercial organization is limited. If we choose to establish a fully integrated commercial organization, we will likely incur substantial expenses in developing, training and managing such an organization. We 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, we will compete with many other companies that currently have extensive and well-funded marketing and sales operations. Our marketing and sales efforts may be unable to compete against these other companies. We may be unable to establish a sufficient sales and marketing organization on a timely basis, if at all.

IF WE ARE UNABLE TO CONVINCE PHYSICIANS AS TO THE BENEFITS OF OUR PROPOSED PRODUCTS, WE MAY INCUR DELAYS OR ADDITIONAL EXPENSE IN OUR ATTEMPT TO ESTABLISH MARKET ACCEPTANCE.

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

RISKS RELATED TO OUR INDUSTRY

WE WILL NEED REGULATORY APPROVALS TO COMMERCIALIZE OUR PRODUCTS AS DRUGS.

If we choose to offer PAZ320, IPOXYN™, or any other product as a drug, we are required to obtain approval from the FDA to sell our products in the U.S. and from foreign regulatory authorities to sell our products in other countries. The FDA's review and approval process is lengthy, expensive and uncertain. Extensive pre-clinical 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 our proposed products, we will have to demonstrate that our 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 us 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 our product candidates, which would prevent, defer or decrease our receipt of revenues. In addition, if we receive initial regulatory approval, our 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 pre-clinical studies and clinical trials do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical trials. Moreover, pre-clinical 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 our business. Our clinical trials may not demonstrate sufficient levels of safety and efficacy necessary to obtain the requisite regulatory approvals for our drugs, and thus our proposed drugs may not be approved for marketing.

OUR COMPETITIVE POSITION DEPENDS ON PROTECTION OF OUR INTELLECTUAL PROPERTY.

Development and protection of our intellectual property are critical to our business. All of our intellectual property, patented or otherwise, has been invented and/or developed by our CEO, Dr. David Platt. If we do not adequately protect our intellectual property, competitors may be able to practice our technologies. Our success depends in part on our ability to obtain patent protection for our products or processes in the U.S. and other countries, protect trade secrets, and prevent others from infringing on our 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, we cannot be certain that we are the first to make the inventions to be covered by our 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 has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents.

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

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

PRODUCTS WE DEVELOP COULD BE SUBJECT TO INFRINGEMENT CLAIMS ASSERTED BY OTHERS.

We cannot assure that products based on our patents or intellectual property that we license from others will not be challenged by a third party claiming infringement of its proprietary rights. If we were not able to successfully defend our patents or licensed rights, we may have to pay substantial damages, possibly including treble damages, for past infringement.

WE FACE INTENSE COMPETITION IN THE BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES.

The biotechnology and pharmaceutical industries are intensely competitive. We face direct competition from U.S. and foreign companies focusing on pharmaceutical products, which are rapidly evolving. Our 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 we do. In addition, academic and government institutions are increasingly likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to market commercial products based on technology developed at such institutions. Our competitors may succeed in developing or licensing technologies and products that are more effective or less costly than ours, or succeed in obtaining FDA or other regulatory approvals for product candidates before we do. 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 OUR PROPOSED PRODUCTS IS RAPIDLY CHANGING AND COMPETITIVE, AND NEW DRUGS AND NEW TREATMENTS WHICH MAY BE DEVELOPED BY OTHERS COULD IMPAIR OUR ABILITY TO MAINTAIN AND GROW OUR BUSINESS AND REMAIN COMPETITIVE.

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render our proposed products noncompetitive or obsolete, or we 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, our resources are limited and we 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 our proposed products. Our competitors may develop drugs that are safer, more effective or less costly than our proposed products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our proposed products, even if commercialized. Many of our 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 our technologies, formulations and products to receive widespread acceptance if commercialized.

HEALTH CARE COST CONTAINMENT INITIATIVES AND THE GROWTH OF MANAGED CARE MAY LIMIT OUR RETURNS.

Our ability to commercialize our products successfully may be affected by the ongoing efforts of governmental and third-party payers to contain the cost of health care. These entities are challenging prices of health care 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 we succeed in bringing any products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing.

RISKS RELATING TO OUR SECURITIES

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 our common stock may adversely affect, among other things, the interest in our stock by purchasers on the open market and our ability to raise capital.

WE HAVE A LIMITED MARKET FOR OUR COMMON STOCK, WHICH MAKES OUR SECURITIES VERY SPECULATIVE.

We currently have a limited market for the Company's common stock. Because of this, it is hard to determine exactly how much our securities are worth.

WE HAVE NOT PAID ANY CASH DIVIDENDS IN THE PAST AND HAVE NO PLANS TO ISSUE CASH DIVIDENDS IN THE FUTURE, WHICH COULD CAUSE THE VALUE OF OUR COMMON STOCK TO HAVE A LOWER VALUE THAN OTHER SIMILAR COMPANIES WHICH DO PAY CASH DIVIDENDS.

We have not paid any cash dividends on our common stock to date and do not anticipate any cash dividends being paid to holders of our common stock in the foreseeable future. While our 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 our future expansion. As we have no plans to issue cash dividends in the future, our common stock could be less desirable to other investors and as a result, the value of our common stock may decline, or fail to reach the valuations of other similarly situated companies who have historically paid cash dividends in the past.

OUR STOCK PRICE MAY BE VOLATILE.

We anticipate that a market for our common stock would be subject to wide fluctuations in response to several factors, including, but not limited to:

(1) actual or anticipated variations in our results of operations;
(2) our ability or inability to generate new revenues;
(3) increased competition; and
(4) conditions and trends in the pharmaceutical industry and/or the market for our pharmaceutical products in general.
(5) changes in regulatory policies.

Further, our common stock is traded on the over the counter bulletin board, as is our intention, our stock price may be impacted by factors that are unrelated or disproportionate to our 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 our common stock.

INVESTORS MAY FACE SIGNIFICANT RESTRICTIONS ON THE RESALE OF OUR COMMON STOCK DUE TO FEDERAL REGULATION OF PENNY STOCKS.

Our common stock is currently quoted on the OTC Bulletin Board under the symbol BTHE. Our common stock is subject to the requirements of Rule 15(g)-9, promulgated under the Securities Exchange Act as long as the price of our 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.

Item 1B. Unresolved Staff Comments.

Item 1B is not applicable to us because we are a smaller reporting company.

Item 2. Properties.

We currently do not own any real property. We currently lease approximately 1,200 square feet of office space with access to common areas located at 1750 Elm Street, Suite 103, Manchester, NH 03104 on a three-year lease that expires on July 1, 2015. The base rent for this facility is currently $2,125 per month, increasing to $2,208 in 2013 and to $2,291 in 2014. In February 2013 the Company agreed to increase the amount of office space it will lease effective April 1, 2013 and to increase the lease term through March 31, 2018. As a result of this amendment to its lease agreement the Company agreed to increase its monthly minimum rent to $4,878 for the period April 1, 2013 through March 31, 2014, $5,051 for the period April 1, 2014 through March 31, 2015, $5,225 for the period April 1, 2015 through March 31, 2016, $5,404 for the period April 1, 2016 through March 31, 2017 and $5,591 for the period April 1, 2017 through March 31, 2018.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our Common Stock is listed to trade in the over-the-counter securities market through the Financial Industry Regulatory Authority ("FINRA") Automated Quotation Bulletin Board System, under the symbol "BTHE". We have been eligible to participate in the OTC Bulletin Board since February 28, 2012.

The following table sets forth the quarterly high and low bid prices for our Common Stock during the last two fiscal years, as reported by a Quarterly Trade and Quote Summary Report of the OTC Bulletin Board (the "OTCBB"). The quotations reflect inter-dealer prices, without retail mark-up, markdown or commission, and may not necessarily represent actual transactions.

	Bid Prices ($)	
2011 Fiscal Year	**High**	**Low**
March 31, 2011	n/a	n/a
June 30, 2011	n/a	n/a
September 30, 2011	n/a	n/a
December 31, 2011	n/a	n/a
2012 Fiscal Year		
March 31, 2012*	$0.25	$0.25
June 30, 2012	$1.05	$0.35
September 30, 2012	$0.60	$0.30
December 31, 2012	$0.60	$0.30

*For the period beginning February 28, 2012 (commencement of listing on the OTCBB) through March 31, 2012.

On March 18, 2013, the closing price for the common stock on the OTCBB was $0.35 per share.

Our common shares are issued in registered form. The registrar and transfer agent for our shares is:

Worldwide Stock Transfer, LLC
433 Hackensack Ave - Level L
Hackensack, NJ 07601
Phone: 201-820-2008
Fax: 201-820-2010

Securities Authorized for Issuance Under Equity Compensation Plans

The following table includes the information as of the end of 2012 for our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders (1)	578,400	$0.68	4,421,600
Equity compensation plans not approved by security holders (2)	7,130,000	$0.40	4,870,000
Total	**7,708,400**		**9,291,600**

(1) Consists of our 2010 Stock Plan (the "2010 Plan"). See Note 5 —"Stock Option Plan and Stock-Based Compensation" of the Notes to the Financial Statements included in this Annual Report on Form 10-K. The Company's stockholders approved the 2010 Plan by written consent on June 16, 2010.

(2) Consists of our 2011 Non-Qualified Stock Plan (the "2011 Plan"). See Note 5 —"Stock Option Plan and Stock-Based Compensation" of the Notes to the Financial Statements included in this Annual Report on Form 10-K. The 2011 Plan has not been presented to the Company's stockholders for their consent.

Holders

As of March 1, 2013, there were 1,678 sholders of record of our common stock. The number of record holders does not include persons, if any, who hold our common stock in nominee or "street name" accounts through brokers.

Dividends

We have not declared any dividends since incorporation and do not anticipate that we will do so in the foreseeable future. Our intention is to retain future earnings for use in our operations and the expansion of our business.

Recent Sales of Unregistered Securities

During the year ended December 31, 2012, we made the following sales of unregistered securities that have not previously been reported on a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K. On December 12, 2012, we issued 125,000 shares of our common stock to a consultant for public relations services rendered to the Company. On December 12, 2012, we issued 22,500 shares of our common stock to a consultant for investor relations services rendered to the Company. Each of the issuances was made in reliance upon the exemption from registration afforded by Rule 506 of Regulation D promulgated under Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"). In connection with the sale of these securities, the Company relied on each of the recipient's written representations that it was an "accredited investor" as defined in Rule 501(a) of the Securities and Exchange Commission. In addition, neither the Company nor anyone acting on its behalf offered or sold these securities by any form of general solicitation or general advertising. As the shares were issued for services, we received no cash proceeds for the issuance of the shares. At the time of their issuance, the shares were deemed to be restricted securities for purposes of the Securities Act, and the certificates representing the securities bear legends to that effect. The securities may not be resold or offered in the United States without registration or an exemption from registration.

Repurchase of Equity Securities

None.

Item 6. Selected Financial Data.

Item 6 is not applicable to us because we are a smaller reporting company.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis is based on, and should be read in conjunction with our financial statements, which are included elsewhere in this Form 10-K. Management's Discussion and Analysis of Financial Condition and Results of Operations contains statements that are forward-looking. These statements are based on current expectations and assumptions that are subject to risk, uncertainties and other factors. These statements are often identified by the use of words such as "may," "will," "expect," "believe," "anticipate," "intend," "could," "estimate," or "continue," and similar expressions or variations. Actual results could differ materially because of the factors discussed in "Risk Factors" elsewhere in this Form 10-K, and other factors that we may not know.

Overview

The Company was formed on August 24, 2009.

Our Chief Executive Officer ("CEO") and founder contributed a provisional patent, a patent and know-how to the Company. In accordance with ASC 845-1-S99, *Transfers of Non-Monetary Assets from Promoters or Shareholders*, the transfer of non-monetary assets to a company by its shareholders in exchange for stock prior to the Company's initial public offering should be recorded at the transferor's historical cost basis determined under GAAP. Because no records exist to support a historical cost basis in accordance with GAAP, the patent, provisional patent and know-how were valued at the CEO's historical cost basis of zero.

On November 10, 2010, we entered into an Agreement and Plan of Merger with Boston Therapeutics, Inc. ("BTI"). BTI was in the business of developing, manufacturing and selling, among other things, dietary supplements including its initial product, SUGARDOWN®, a complex carbohydrate based dietary supplement based upon BTI's proprietary processes and technology. SUGARDOWN® is currently in the initial stage of market introduction, and in June 2011 we entered into an agreement with Advance Pharmaceutical Co. Ltd. to develop markets in Hong Kong, China and Macau.

We issued 4,000,000 shares of common stock to the stockholders of BTI in exchange for all the outstanding common stock of BTI, and the Company's name was changed to Boston Therapeutics, Inc. The CEO is also a founder of BTI and was a 10% shareholder of BTI at the time of the merger. A valuation of the Company's common stock was performed resulting in a fair value per share of $0.2466. Based on the 4,000,000 shares of common stock issued for BTI the total consideration was valued at $986,400. However, because the Company's CEO was a 10% shareholder of BTI, 10% of BTI was valued at his historical cost basis and 90% of BTI was valued at fair value.

We must raise new capital to continue our business operations and intend to use the provisional patent, patent and know-how contributed by our CEO and the assets acquired from BTI (as described in Notes 1 and 7 to the audited financial statements included elsewhere in this Form 10-K) to raise capital. Our CEO may provide minimal cash to fund critical needs until shares are sold to raise capital. We anticipate the need for approximately $2,000,000 to $8,000,000 in additional funding to support the planned expansion of our operations over the next 12 months to 24 months. There is no guarantee that we will be successful in raising additional funds.

Results of Operations

Year ended December 31, 2012

Revenue for the year ended December 31, 2012 was $42,254 compared to $4,112 in the prior year, an increase of $38,142 primarily because SUGARDOWN® was sold for a full year. Sales in 2012 included approximately $31,000 of sales to two customers for resale and approximately $11,200 of sales to individual customers through our website. Cost of goods sold for the year ended December 31, 2012 was $56,859 compared to $6,375 in the prior year, an increase of $50,484 primarily due to a full year of cost related to the sales of SUGARDOWN®. The Company's negative gross profit is attributable to cost of goods sold outpacing sales as a result of additional fixed costs related to moving to a new fulfillment operation, and manufacturing scale-up from small to production grade equipment.

Research and development expense for the year ended December 31, 2012 was $178,938 compared to $194,276 in the prior year, a decrease of $15,338. Product development expense increased approximately $10,000 over the prior year and direct research and development expenses decreased approximately $25,000 compared to the prior year.

Sales and marketing expense for the year ended December 31, 2012 was $232,411 compared to $206,517 in the prior year, an increase of $25,894. Advertising and promotion costs increased approximately $35,000, marketing decreased approximately $11,000, travel increased approximately $8,000 and stock based compensation decreased approximately $6,000.

General and administrative expense for the year ended December 31, 2012 was $1,036,566 compared to $408,454 in the prior year, an increase of $628,112. The overall increase is primarily the result of consulting and investor relations expenses increased approximately $200,000, filing fees increased approximately $30,000, stock based compensation increased approximately $336,000 payroll expenses increased approximately $20,000 and rent expense increased approximately $17,000.

Liquidity and Capital Resources

As of December 31, 2012, we had cash of approximately $552,000 and accounts payable and accrued expenses of approximately $441,000.

We have received minimal revenues from our SUGARDOWN® product. Without substantial revenue and known, adequate and available financing, there is uncertainty regarding the Company's ability to continue as a going concern.

Management plans to seek additional capital through private placements and public offerings of its common stock. There can be no assurance that the Company will be successful in accomplishing its objectives. Without such additional capital, the Company may be required to cease operations.

Our CEO may continue to provide minimal cash to fund critical needs until shares are sold to raise capital.

Our CEO also contributed a provisional patent, a patent and know-how to the Company. We intend to use these assets and SUGARDOWN® and the other assets acquired from our merger with BTI to raise the additional capital required to fund operations.

Other than our CEO's intention to provide minimal cash, we have no current commitment from our officers and directors or any of our shareholders, to supplement our operations or provide us with financing in the future. Although our CEO intends to provide us with minimal cash to fund critical needs until we are able to raise additional capital from an offering of securities there is no guarantee that he will do so or will do so for any extended period of time. If we are unable to raise additional capital from conventional sources and/or additional sales of stock in the future, we may be forced to curtail or cease our operations. Even if we are able to continue our operations, the failure to obtain financing could have a substantial adverse effect on our business and financial results. In the future, we may be required to seek additional capital by selling debt or equity securities, and we may be required to cease operations, or otherwise be required to bring cash flows in balance when we approach a condition of cash insufficiency. The sale of additional equity or debt securities, if accomplished, may result in dilution to our then shareholders. We provide no assurance that financing will be available in amounts or on terms acceptable to us, or at all.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Item 7A is not applicable to us because we are a smaller reporting company.

Item 8. Financial Statements and Supplementary Data.

The financial statements listed in Item 15(a) are incorporated herein by reference and are filed under this Item 8 as a part of this report and follow the signature pages to this Annual Report on Form 10-K on page 1-F.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Evaluation of Disclosure Controls and Procedures.

Pursuant to Rules 13a-15(b) under the Securities Exchange Act of 1934, the Company carried out an evaluation, with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer ("CEO/CFO") (the Company's principal financial and accounting officer), of the effectiveness of the Company's disclosure controls and procedures (as defined under Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon the evaluation of the disclosure controls and procedures at the end of the period covered by this report, the Company's CEO/CFO concluded that the Company's disclosure controls and procedures were not effective due to a material weakness in the Company's internal control over financial reporting as discussed below.

Management Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on the evaluation performed, our management concluded that the Company's internal control over financial reporting was not effective as of December 31, 2012 due to the following material weakness:

As of December 31, 2012, there was a material weakness in the Company's internal control over financial reporting due to the fact that the Company did not have a process established to ensure adequate levels of review of accounting and financial reporting matters, which resulted in our closing process not identifying all required adjustments in a timely fashion.

Although the Company has hired consultants to assist with SEC reporting and accounting matters, we expect that the Company will need to hire accounting personnel with the requisite knowledge to improve the levels of review of accounting and financial reporting matters. The Company may experience delays in doing so and any such additional employees would require time and training to learn the Company's business and operating processes and procedures. For the near-term future, until such personnel are in place, this will continue to constitute a material weakness in the Company's internal control over financial reporting that could result in material misstatements in the Company's financial statements not being prevented or detected.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the SEC adopted as of September 21, 2010 that permit the Company to provide only management's report in this annual report.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal controls over financial reporting, other than those stated above, during the fiscal period to which this report relates that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The Company's management, including the Company's CEO/CFO, does not expect that the Company's internal control over financial reporting will prevent all errors and all fraud. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive and Corporate Governance.

Directors

Set forth below is information regarding our current directors. Except as set forth below, there are no family relationships between any of our directors or executive officers. Each director holds his office until he resigns or is removed and his successor is elected and qualified.

Name	Age	Position	Term as a Director
David Platt, Ph.D.	59	Chief Executive Officer, Chief Financial Officer Treasurer and Chairman	August 2009 to the Present
Kenneth A. Tassey, Jr.	52	President and Director	November 2010 to the Present
Dale H. Conaway, D.V.M.	58	Director	September 2009 to the Present
Rom E. Eliaz	41	Director	September 2009 to the Present
Henry J. Esber, Ph.D.	74	Director	December 2011 to the Present
Carl L. Lueders	62	Director	September 2009 to the Present

David Platt, Ph.D. is our Chief Executive Officer, Chief Financial Officer, Treasurer and Chairman. He also served as our President from the inception of the Company 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., a public company with shares traded on the NYSE Alternext US (formerly the American Stock Exchange) that he co-founded and for which he was the co-developer of their 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. Dr. Platt received a Ph.D. in Chemistry in 1988 from Hebrew University in Jerusalem. In 1989, Dr. Platt 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. is our President and a Director of the Company since November 2010, was President, CEO and co-founder of Boston Therapeutics, Inc., a New Hampshire corporation, from June 2009 until its acquisition by the Company in November 2010. From March 2007 thru March 2009 Mr. Tassey was President of TKCI, a consultant for commercial finance projects. From March 2005 thru June 2007 Mr. Tassey was President of Liberty Shore LLC, a consultant to businesses and commercial and residential lenders.

Dale H. Conaway, D.V.M., a Director of the Company 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, Dr. Conaway 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. From May 2001 to February 2009, Dr. Conaway was a director of Pro-Pharmaceuticals, Inc., a public company with shares traded on the NYSE Alternext US. Dr. Conaway received a D.V.M. degree from Tuskegee Institute and an M.S. degree in pathology from the College of Veterinary Medicine at Michigan State University.

Dr. Rom E. Eliaz, Ph.D., MBA, a Director of the Company since September 2009, has been a President and CEO of JJ Pharma Inc. since September 2009. He has also been CEO and Managing Director of Elrom Ventures Corp. since May 2007 and a strategic partner in The Colmen Group since June 2009. From January 2007 to October 2007 Dr. Eliaz was a Senior Director of Development at Intradigm Corp. From March 2004 to December 2006 Dr. Eliaz was a Director of Development at Pfizer Inc. (Rinat Neuroscience).

Henry J. Esber, Ph.D., a Director of the Company since December 2011, has been a Principal in Esber D&D consulting since 2005. From 2003 to 2005, Dr. Esber 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., a public company with shares traded on the NASDAQ Capital Market. From April 2006 to February 2009, Dr. Esber was a director of Pro-Pharmaceuticals, Inc., a public company with shares traded on the NYSE Alternext US. 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. degree in biology/pre-med from the College of William and Mary, an M.S. degree 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.

Carl L. Lueders, a Director of the Company since September 2009, has a broad range of experience in finance, operations, short- and long-term planning, forecasting, performance measurement, SEC reporting, and controls. Mr. Lueders served as Chief Financial Officer (CFO) for Micronetics, Inc. a manufacturer of microwave and radio frequency products for commercial wireless, defense and aerospace applications from 2008 until August 2012 at which time Micronetics was sold. Prior to that, he was CFO for Pro-Pharmaceuticals and before that CFO for R.F. Morse & Son, a privately held agri-based company. Prior to that Mr. Lueders spent 22 years with publicly held Polaroid in various finance positions, including Vice President and Controller, Treasurer and acting Chief Financial Officer. Mr. Lueders is a CPA and received his B.A. in Economics from the University of Massachusetts at Amherst and his M.B.A. from Babson College.

Our Directors are elected annually and each holds office until the annual meeting of the shareholders of the Company and until their respective successors are elected and qualified. Our officers, including any officers we may elect moving forward, will hold their positions at the pleasure of the Board of Directors, absent any employment agreement. In the event we employ any additional officers or directors of the Company, they may receive compensation as determined by the Company from time to time by vote of the Board of Directors. Vacancies in the Board will be filled by majority vote of the remaining directors or in the event that our sole Director vacates his position, by our majority shareholders. Our Directors may be reimbursed by the Company for expenses incurred in attending meetings of the Board of Directors.

Executive Officers

Set forth below is information regarding our current executive officers. Except as set forth below, there are no family relationships between any of our executive officers and our directors. Executive officers are elected annually by our Board of Directors. Each executive officer holds his office until he resigns or is removed by the Board or his successor is elected and qualified.

Name	Age	Position	Term as a Officer
David Platt	59	Chief Executive Officer, Chief Financial Officer, Treasurer and Chairman	August 2009 to the Present
Kenneth A. Tassey, Jr.	52	President and Director	November 2010 to the Present
Jonathan Rome	56	Chief Operating Officer	November 2012 to the Present

Jonathan Rome is our chief Operating Officer since November 2012. Mr. Rome, 56, was the Founder, President and Chief Executive Officer of ThePharmaNetwork, LLC, a New Jersey company focused on pharmaceutical portfolio development, licensing, sales, marketing and distribution of pharmaceuticals and active pharmaceutical ingredients, where he worked from 2000 to August 2012. Mr. Rome also was the Founder, President and Chief Executive Officer of Ascend Laboratories, LLC, a pharmaceutical business development, sales and marketing company, selling finished products under the Ascend label to all major U.S. customers and classes of trade, where he worked from 2000 to 2012. Mr. Rome has more than 30 years of experience in the pharmaceutical industry as an executive, entrepreneur and globally networked executive with experience throughout the global supply chain.

Additional information regarding Dr. David Platt and Kenneth A. Tassey, Jr. is set forth above under the caption "Directors".

Section 16(a) Beneficial Ownership Reporting Compliance

For the year ended December 31, 2012, based on a review of SEC filings, the following directors, executive officers and holders of more than 10% of our shares of Common Stock did not make the following required reports under Section 16(a) of the Exchange Act. David Platt, Dale H. Conaway, Rom E. Eliaz, Henry Esber and Carl L. Lueders did not file Form 4s in connection with their grant of stock options in November 2012 described in Item 11 below. Jonathan Rome did not file a Form 3 with respect to his becoming Chief Operating Officer of the Company and his concurrent grant of stock options described in Item 11 below.

Code of Ethics

A code of business conduct and ethics is a written standard designed to deter wrongdoing and to promote (a) honest and ethical conduct, (b) full, fair, accurate, timely and understandable disclosure in regulatory filings and public statements, (c) compliance with applicable laws, rules and regulations, (d) the prompt reporting violation of the code and (e) accountability for adherence to the code. We are not currently subject to any law, rule or regulation requiring that we adopt a code of ethics; however, we intend to adopt one in the near future.

Board of Directors Independence

Our Board of Directors consists of six members. We are not currently subject to any law, rule or regulation requiring that all or any portion of our Board of Directors include "independent" directors. Four of the members of the Board of Directors, Dale H. Conaway, D.V.M., Rom E. Eliaz, Henry J. Esber and Carl Lueders, are "independent" as defined in Section 4200(a)(15) of NASDAQ Stock Market Rules.

Audit Committee

We have established an audit committee, which members are comprised of Carl Lueders, Dale Conaway and Henry Esber. Mr. Lueders serves as the chairman of the audit committee. The audit committee is primarily responsible for reviewing the services performed by our independent auditors and evaluating our accounting policies and our system of internal controls. Mr. Lueders serves as our "audit committee financial expert." The Company believes that while the members of the committee are collectively capable of analyzing and evaluating financial statements and understanding internal control over financial reporting and disclosure controls procedures, the Board of Directors has determined that only Mr. Lueders qualifies as an "audit committee financial expert" who is "independent" as defined in Item 407(d)(5) of Regulation S-K of the Securities Exchange Act of 1934, as amended.

Nominating and Corporate Governance Committee

The Company has established a nominating and corporate governance committee, which members are comprised of Henry Esber, Dale Conaway, and Carl Lueders. Mr. Esber acts as chairman of the nominating and corporate governance committee. The functions of the nominating and corporate governance committee include the following:

- identifying and recommending to the Board of Directors individuals qualified to serve as members of our Board of Directors and on the committees of the Board;
- advising the Board with respect to matters of Board composition, procedures and committees;
- developing and recommending to the Board a set of corporate governance principles applicable to us and overseeing corporate governance matters generally including review of possible conflicts and transactions with persons affiliated with directors or members of management; and overseeing the annual evaluation of the Board and our management.

Compensation Committee

The Company has established a compensation committee, which members are comprised of Carl Lueders, Dale Conaway and Henry Esber. Mr. Lueders serves as the chairman of the compensation committee. The compensation committee is primarily responsible for overseeing and administering our compensation plans and executive compensation matters.

The Board of Directors established each of the above-referenced committees in December 2011. The Board is in the process of preparing charters for the committees but none of the committees currently has a formal charter.

Compensation Committee Interlocks And Insider Participation

The Compensation Committee of the Board is comprised of Messrs. Lueders (chair), Conaway and Esber, each a non-employee director of the Company. None of our executive officers serves on the Compensation Committee or board of directors of any other company of which any members of our Compensation Committee or any of our directors is an executive officer.

Audit Committee Report Regarding Audited Financial Statements

The Audit Committee of the Board is composed of three directors, all of whom are "independent" as defined in Section 4200(a)(15) of NASDAQ Stock Market Rules. The Audit Committee has prepared the following report on its activities with respect to the Company's audited financial statements for the fiscal year ended December 31, 2012 (the "Audited Financial Statements").

- The Audit Committee reviewed and discussed the Company's Audited Financial Statements with management;
- The Audit Committee discussed with McGladrey LLP ("McGladrey"), the Company's independent auditors for fiscal 2012, the matters required to be discussed by the Public Company Accounting Oversight Audit Committee in Rule 3200T;
- The Audit Committee received from the independent auditors the written disclosures regarding auditor independence, discussed with McGladrey its independence from the Company and its management, and considered whether McGladrey's provision of non-audit services to the Company was compatible with the auditor's independence; and
- Based on the review and discussion referred to above, and in reliance thereon, the Audit Committee determined that the Audited Financial Statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012, for filing with the U.S. Securities and Exchange Commission.

All members of the Audit Committee concur in this report.

Audit Committee:	Carl Lueders (Chairman)
	Dale H. Conaway, D.V.M.
	Henry J. Esber

Item 11. Executive Compensation

The following table sets forth information concerning all cash and non-cash compensation awarded to, earned by or paid to (i) all individuals serving as the Company's principal executive officers or acting in a similar capacity during the last two completed fiscal years, regardless of compensation level, and (ii) the Company's two most highly compensated executive officers other than the principal executive officers serving at the end of the last two completed fiscal years (collectively, the "Named Executive Officers").

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards (2)	Total Compensation
David Platt, Chief Executive Officer and Chief Financial Officer	2012	$ 2,500	$ -	$ 72,081	$ 74,581
	2011	$ -	$ -	$ -	$ -
Kenneth A. Tassey, Jr., President	2012	$ 37,000	$ -	$ -	$ 37,000
	2011	$ 19,800	$ -	$ -	$ 19,800
Jonathan Rome, Chief Operating Officer (1)	2012	$ -	$ -	$ 1,514,067	$ 1,514,067
	2011	$ -	$ -	$ -	$ -

(1) Mr. Rome became Chief Operating Officer of the Company in November 2012.
(2) Consists of grants of stock options. Details of the options are set forth on the table titled "GRANTS OF PLAN-BASED AWARDS IN FISCAL 2012" below.

Grants of Plan-Based Awards

The following table shows for the fiscal year ended December 31, 2012, certain information regarding grants of plan-based awards to the named executive officers.

GRANTS OF PLAN-BASED AWARDS IN FISCAL 2012

Name	Award Type	Grant Date	Approval Date	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards Target ($)	All Other Option Awards: Number of Securities Underlying Options (1)	Exercise or Base Price of Option Awards ($/Sh)(2)	Grant Date Fair Value of Stock and Option Awards ($)(3)
David Platt	Option	11/8/12	11/8/12	___	250,000	$ 0.50	$ 72,081
Jonathan Rome	Option	11/8/12	11/8/12	___	5,000,000	$ 0.50	$ 1,514,067

(1) Stock options were granted with an exercise price equal to 100% of the fair market value on the date of grant. The stock options granted in 2012 carry an exercise price of $0.50 per share, the closing price of Boston Therapeutics, Inc.'s common stock on the grant date.

(2) The dollar amounts in this column represent the grant date fair value of each stock option award granted to the named executive officers in 2012. These amounts have been calculated in accordance with ASC 718, using the Black-Scholes option-pricing model. Assumptions used in the calculation of these amounts are included in the notes to Boston Therapeutics, Inc.'s audited consolidated financial statements included in this Annual Report on Form 10-K for the year ended December 31, 2012.

(3) Annual stock options were granted under our 2011 Non-Qualified Stock Plan (the "2011 Plan").

Outstanding Equity Awards at December 31, 2012

The following table sets forth, for the fiscal year ended December 31, 2012, certain information regarding outstanding equity awards at fiscal yearend for the named executive officers.

OUTSTANDING EQUITY AWARDS AT 2012 FISCAL-YEAR END TABLE

	Option Awards			
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#)(1) Unexercisable	Option Exercise Price ($)	Option Expiration Date
David Platt	250,000	—	$ 0.50	11/08/2019
Jonathan Rome	416,667(1)	4,583,333	$ 0.50	11/08/2017

(1) In addition to the specific vesting schedule for each stock option award, each unvested stock option is subject to the general terms of the 2011 Plan including the potential for future vesting acceleration.

Option Exercises and Stock Vested in 2012

Our Named Executive Officers did not exercise any stock options during fiscal year 2012.

Director Compensation

The following table sets forth all compensation awarded to, earned by or paid to the non-employee directors in 2012 for service as directors:

Name	Fees Earned Or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Dale H. Conaway, D.V.M	$ -	-	$ 5,766	-	-	-	$ 5,766
Henry J. Esber, Ph.D.	$ -	-	$ 5,766	-	-	-	$ 5,766
Rom E. Eliaz	$ -	-	$ 5,766	-	-	-	$ 5,766
Carl L. Lueders	$ -	-	$ 5,766	-	-	-	$ 5,766

(1) The "Option Awards" column does not reflect a non-qualified option to purchase 98,000 shares of the Company's Common Stock at an exercise price of $0.50 for a period of 7 years granted effective January 1, 2013 and vesting on December 31, 2013 conditioned on the grantee having attended a minimum of 75% of the Board meetings in 2013 and subject to immediate vesting upon change of control. These grants were made to compensate directors for their service in 2013.

All compensation paid to our employee directors is set forth in the tables summarizing executive officer compensation above. For the 2012 fiscal year, non-employee directors were each granted a fully vested nonqualified stock option to purchase 20,000 shares of the Company's common stock at an exercise price of $0.50 per share, which option expires on November 8, 2019, 7 years from the date of grant.

The amounts reported in "Option Awards" represent the aggregate grant date fair value of stock options awarded in each year in accordance with Accounting Standards Codification (ASC) Topic 718, Compensation — Stock Compensation (formerly Statement of Financial Accounting Standards (SFAS) No. 123R). Assumptions used in the calculation of these amounts for the fiscal year ended December 31, 2012 are included in Note 5 "Stock Option Plan and Stock-Based Compensation" to the Company's audited financial statements for the fiscal year ended December 31, 2012 included in this Annual Report on Form 10-K.

The Company cautions that the amounts reported in the Director Compensation Table for these awards may not represent the amounts that the directors will actually realize from the awards. Whether, and to what extent, a director realizes value will depend on the Company's actual operating performance, stock price fluctuations and the director's continued service.

Other than the grant of options for 2013 described in the table above, there are currently no agreements in effect entitling the non-employee directors to compensation.

Employment Contracts

In August 2011, Mr. Tassey entered into an employment contract with the Company, pursuant to which he is engaged to serve as President and Chief Operating Officer for annual compensation in the amount of $36,000. In December 2012, the Company increased Mr. Tassey's annual compensation to $60,000. The terms of the employment contract include the following:

The employment agreement between the Company and Mr. Tassey provides for the lump-sum payment of 50% of Mr. Tassey's annual salary then in effect in the event the agreement is terminated by the Company without cause other than as a result of the death or disability, which would result in a payment of $30,000 to Mr. Tassey based on his current salary level. In the event of the termination of the agreement as a result of Mr. Tassey's death or disability, he or his estate is entitled to receive payment of his salary for the balance of the month in which such termination occurs, which would result in a payment of no more than $5,000 to Mr. Tassey based on his then current salary level. In both instances, Mr. Tassey is entitled to receive any unpaid non-discretionary bonus for the year prior to the year in which the termination occurs.

The employment agreement between the Company and Mr. Tassey further entitles Mr. Tassey to receive benefits on the same basis as employee benefits are generally made available to other senior executives of the Company, including among other items, health, life and disability insurance and participation in any non-discretionary executive bonus or similar plans.

The employment agreement between the Company and Mr. Tassey provides that if he is terminated without cause within 6 months after a change of control he is entitled to receive the lump-sum payment of 50% of Mr. Tassey's annual salary then in effect in the event the agreement is terminated by the Company without cause other than as a result of the death or disability, which would result in a payment of $30,000 to Mr. Tassey based on his current salary level. There are no material terms of the contract that provide for payments in connection with the resignation, retirement or other termination of Mr. Tassey or in connection with a change of control. In December 2012, the Compensation Committee approved an increase to Mr. Tassey's monthly wage to $5,000.

In November 2012, Mr. Jonathan Rome was named Chief Operating Officer. Mr. Tassey continues as President.

In November 2012, the Company and Jonathan Rome entered into an employment agreement, pursuant to which he was engaged to serve as the Company's Chief Operating Officer to assist in driving the sales of the Company's products. The terms of the employment agreement include the following:

In lieu of cash compensation, the Company agreed to issue a non-qualified stock option to Mr. Rome for the purchase of 5,000,000 shares of the Company's common stock, at an exercise price of $0.50 per share (the "Option"). The Option will "vest" and become exercisable in 12 increments over a period of approximately three years, with the initial installment vesting upon grant, and subsequent installments vesting on the last day of each calendar quarter beginning with the quarter ending March 31, 2013, during which time Mr. Rome will provide best efforts to drive sales of the Company's products. The Option shall be exercisable to the extent vested at any time prior to the close of business on November 7, 2017. The Option will not have a cashless exercise feature. Notwithstanding the vesting schedule, (a) upon separation from employment with the Company for any reason, the Options will cease vesting at the end of the last day of the calendar quarter following the quarter in which such separation occurs, (b) if the separation is for cause, then the Options will cease vesting on the date of separation. "Cause" is defined as including failure to meet certain performance standards enumerated in the agreement. The agreement provides that if Mr. Rome is terminated without cause prior to November 6, 2013, then the Options will continue to vest through March 31, 2014 in accordance with the vesting schedule. Mr. Rome is eligible for the Company's standard employee benefits as are or in the future will be generally provided by the Company to employees of similar position at the Company.

Other than the agreement with Messrs. Tassey and Rome described above, there currently are no employment or consulting contracts between the Company and its Named Executive Officers or Directors. There are no arrangements or plans in which we provide pension, retirement or similar benefits for Named Executive Officers or Directors. Our Named Executive Officers and directors receive stock options at the discretion of our Board of Directors. We do not have any material bonus or profit sharing plans pursuant to which cash or non-cash compensation is or may be paid to our Named Executive Officers or directors, except that stock options may be granted at the discretion of our board of directors from time to time.

Other than the agreements with Messrs. Tassey and Rome described above, there are no arrangements between the Company and the Named Executive Officers that provide for payments in connection with the resignation, retirement or other termination of a Named Executive Officer or in connection with a change of control or any other arrangements with any Named Executive Officer with respect to termination of employment or change of control transactions.

Compensation Risk Assessment

We formed a Compensation Committee. Prior to the formation of the committee, compensation decisions, including the contract with Mr. Tassey described above, were made by the full Board. In setting compensation, the Compensation Committee considers (and the Board previously considered) the risks to the Company's stockholders and to achievement of its goals that may be inherent in its compensation programs. The Compensation Committee (and the Board previously) reviewed and discussed its assessment with management and outside legal counsel and concluded that the Company's compensation programs are within industry standards and are designed with the appropriate balance of risk and reward to align employees' interests with those of the Company and do not incent employees to take unnecessary or excessive risks. We believe our compensation plans are appropriately structured and are not reasonably likely to result in a material adverse effect on the Company.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table includes the information as of the end of 2012 for our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a) (c)
Equity compensation plans approved by security holders (1)	578,400	$0.68	4,421,600
Equity compensation plans not approved by security holders (2)	7,130,000	$0.40	4,870,000
Total	**7,708,400**		**9,291,600**

(1) Consists of our 2010 Stock Plan (the "2010 Plan"). See Note 5—"Stock Option Plan and Stock-Based Compensation" of the Notes to the Financial Statements included in this Annual Report on Form 10-K. The Company's stockholders approved the 2010 Plan by written consent on June 16, 2010.

(2) Consists of our 2011 Non-Qualified Stock Plan (the "2011 Plan"). See Note 5 —"Stock Option Plan and Stock-Based Compensation" of the Notes to the Financial Statements included in this Annual Report on Form 10-K. The 2011 Plan has not been presented to the Company's stockholders for their consent.

Security Ownership of Beneficial Owners and Management

The following table sets forth certain information as of March 20th, 2013 with respect to the beneficial ownership of shares of the Company's common stock by (i) each person or group known to us, to beneficially own more than 5% of the outstanding shares of such stock (as we do not have a class of securities registered under Section 12 of the Exchange Act, holders of 5% or more of the outstanding shares of our common stock are not currently required to file Schedule 13D or Schedule 13G with the Securities and Exchange Commission), (ii) each director; (iii) each of our executive officers named in the summary compensation table under "Director and Executive Compensation" currently serving as an executive officer; and (iv) the executive officers and directors as a group. Except as otherwise indicated, all persons listed below have (i) sole voting power and investment power with respect to their shares of common stock (the only class of outstanding stock), except to the extent that authority is shared by spouses under applicable law, and (ii) record and beneficial ownership with respect to their shares of stock. The percentage of beneficial ownership is based upon 19,291,539 shares of common stock outstanding as of March 20th, 2013. Except as otherwise indicated in the footnotes to the table, the persons and entities named in the table have sole voting and investment power with respect to all shares beneficially owned, subject to community property laws, where applicable.

Name and Address of Beneficial Owner	Number of Shares	Percent of Class (1)
David Platt (2)**	8,603,585 (3)	44.03% (3)
Kenneth A. Tassey, Jr.(2)**	3,040,000	15.76%
Jonathan Rome (2)**	2,716,334 (4)	13.50% (4)
Offer Binder Via Armand Fedeli 121 Perugia PG 06132 Italy	2,000,000	10.37%
Advance Pharmaceutical Company Ltd.(5) Rm A 2- 3F, Dai Fu Street Tai Po Industrial Est. Tai Po, New Territories, Hong Kong	2,549,800	13.22%
Dale H. Conaway(2)**	22,100 (6)	*% (6)
Rom E. Eliaz(2)**	20,100 (6)	*% (6)
Henry J. Esber(2)**	24,000 (6)	*% (6)
Carl L. Lueders(2)**	20,000 (6)	*% (6)
All Officers and Directors as a Group (7 persons)	14,446,119(7)	70.62% (7)

* Less than 1%

** Directors and Officers

(1) Except as otherwise expressly stated, the percentages shown in the table are based on 19,291,539 shares of Common Stock outstanding on March 20, 2013.

(2) The business address for these individuals is 1750 Elm Street, Suite 103, Manchester, NH 03104.

(3) Includes 520,000 shares owned by Dr. Platt's wife and 250,000 shares issuable pursuant to an outstanding stock option within 60 days after March 20, 2013. Excludes 20,000 shares held by Dr. Platt's daughter as to which Dr. Platt disclaims beneficial ownership.

(4) Includes 833,334 shares issuable pursuant to an outstanding stock option within 60 days after March 20th, 2013. Includes 625,000 shares issuable pursuant to an outstanding warrant to purchase common stock within 60 days after March 20, 2013.

(5) Includes 1,799,800 shares owned by Sugardown Co., LTD., a wholly-owned subsidiary of Advance Pharmaceutical Company Ltd. Includes 500,000 shares owned by CJY Holdings Limited and includes 250,000 shares issuable pursuant to an outstanding warrant to purchase common stock within 60 days after March 20th, 2013.

(6) Includes 20,000 shares issuable pursuant to an outstanding stock option within 60 days after March 20th, 2013.

(7) Includes 520,000 shares owned by Dr. Platt's wife, 625,000 issuable pursuant to outstanding warrants within 60 days after March 20, 2013 and 1,163,334 shares issuable pursuant to outstanding stock options within 60 days after March 20, 2013. Excludes 20,000 shares held by Dr. Platt's daughter as to which Dr. Platt disclaims beneficial ownership.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

During the last two fiscal years, we have not entered into any material transactions or series of transactions that would be considered material in which any officer, director or beneficial owner of 5% or more of any class of our capital stock, or any immediate family member of any of the preceding persons, had a direct or indirect material interest. There are no transactions presently proposed, except as follows:

1. Between July 3, 2009 and May 7, 2012, David Platt, the Company's CEO and CFO and Ken Tassey, President, loaned an aggregate of $297,820 to the Company and BTI to fund start-up costs and current operations of the Company and BTI pursuant to a series of unsecured promissory notes. The Company assumed BTI's obligations on the notes issued by BTI to Dr. Platt when BTI merged into the Company in November 2009. The notes carry interest at 6.5%. The notes initially became due and payable at various times between March 31, 2011 and June 30, 2012. On August 6, 2012, the maturity dates of each of the notes were amended to June 29, 2014.

Item 14. Principal Accountant Fees and Services.

McGladrey LLP ("McGladrey") is our independent registered public accounting firm engaged to examine our financial statements for the fiscal years ended December 31, 2012 and 2011. During the Company's most two recent fiscal years ended December 31, 2012 and 2011 and through April 4, 2013, the Company did not consult with McGladrey on (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that may be rendered on the Company's financial statements, and McGladrey did not provide either a written report or oral advice to the Company that was an important factor considered by the Company in reaching a decision as to any accounting, auditing, or financial reporting issue; or (ii) the subject of any disagreement, as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions, or a reportable event within the meaning set forth in Item 304(a)(1)(v) of Regulation S-K.

The table below shows the fees that we paid or accrued for the audit and other services provided by McGladrey for the fiscal years ended December 31, 2012 and 2011.

Fee Category	2012	2011
Audit Fees	$83,968	$73,645
Audit-Related Fees	$17,180	$12,246
Tax Fees	$ -	-
All Other Fees	$ -	-

Audit Fees

This category includes the audit of our annual financial statements, review of financial statements included in our annual and quarterly reports and services that are normally provided by the independent registered public accounting firms in connection with engagements for those fiscal years. This category also includes advice on audit and accounting matters that arose during, or as a result of, the audit or the review of interim financial statements.

Audit-Related Fees

This category consists of assurance and related services by the independent registered public accounting firms that are reasonably related to the performance of the audit or review of our financial statements and are not reported above under "Audit Fees". The services for the fees disclosed under this category include services relating to our registration statement and consultation regarding our correspondence with the SEC.

Tax Fees

This category consists of professional services rendered for tax compliance and tax advice.

All Other Fees

This category consists of fees for other miscellaneous items.

Pre-Approved Services

The Audit Committee requires pre-approval of audit, audit-related and tax services to be performed by the independent auditors. As the Audit Committee was not established until December 2011, the services, as described above, were not pre-approved by the Audit Committee but were approved by the Board as a whole pursuant to Section 3(a)(58) of the Securities Exchange Act of 1934. The Audit Committee approved the audit, audit-related and tax services to be performed by independent auditors and tax professionals in 2012.

The Audit Committee has not expressly adopted rules permitting the Audit Committee to delegate to one or more of its members pre-approval authority with respect to permitted services nor has the Audit Committee actually delegated such authority to its members. To the extent it elects to do so in the future, the Board expects that such delegation will be subject to the requirement that the decisions of any Audit Committee member to whom pre-approval authority is delegated must be presented to the full Audit Committee at its next scheduled meeting.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements

See Index to Consolidated Financial Statements commencing on Page 1F.

(a)(2) Financial Statement Schedules

All supplemental schedules have been omitted since the required information is not present in amounts sufficient to require submission of the schedule, or because the required information is included in the consolidated financial statements or notes thereto.

(b) Exhibits

The following exhibits are filed as part of this report:

Exhibit No.	Title of Document
3.1	Certificate of Incorporation, as amended (filed as Exhibit 3.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-164785) filed with the SEC on June 24, 2010 and incorporated herein by reference)
3.2	Bylaws (filed as Exhibit 3.2 to the Company's Registration Statement on Form S-1 (File No. 333-164785) filed with the SEC on February 8, 2010 and incorporated herein by reference)
10.1	Technology Assignment Agreement dated as of August 24, 2009 by and between the Company and David Platt (filed as Exhibit 10.1 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-164785) filed with the SEC on June 24, 2010 and incorporated herein by reference)
10.2	Avanyx Therapeutics, Inc. 2010 Stock Plan (filed as Exhibit 10.2 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-164785) filed with the SEC on June 24, 2010 and incorporated herein by reference)

10.3	Promissory Note dated as of February 9, 2010 issued by the Company to David Platt (filed as Exhibit 10.3 to Amendment No. 1 to the Company's Registration Statement on Form S-1 (File No. 333-164785) filed with the SEC on June 24, 2010 and incorporated herein by reference)
10.4	Agreement and Plan of Merger dated November 10, 2010 by and among Avanyx Therapeutics, Inc. and Boston Therapeutics, Inc. (filed as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on November 18, 2010 and incorporated herein by reference)
10.5	Certificate of Merger (filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on November 18, 2010 and incorporated herein by reference)
10.6	Form of Subscription Agreement dated June 21, 2011, among Boston Therapeutics, Inc. and the Investors named therein (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on June 22, 2011 and incorporated herein by reference)
10.7	License and Manufacturing Agreement between Boston Therapeutics, Inc. and Advance Pharmaceutical Company Limited effective as of June 24, 2011 (filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 15, 2011 and incorporated herein by reference)*
10.8	Employment Agreement between Boston Therapeutics, Inc. and Ken Tassey dated as of August 11, 2011 (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 15, 2011 and incorporated herein by reference)
10.9	Amended and Restated Boston Therapeutics, Inc. 2011 Non-Qualified Stock Plan (filed as Exhibit 10.1 to the Company's Registration Statement on Form S-8 (File No. 333-185355) filed with the SEC on December 7, 2012 and incorporated herein by reference)
10.10	Employment Agreement between Boston Therapeutics, Inc. and Jonathan Rome dated as of November 8, 2012 (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 13, 2012 and incorporated herein by reference)
23.1	Consent of McGladrey LLP
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended**
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d 14(a), promulgated under the Securities and Exchange Act of 1934, as amended**
32.1	Certification pursuant to Section 906 of Sarbanes Oxley Act of 2002 (Chief Executive Officer)***
32.2	Certification pursuant to Section 906 of Sarbanes Oxley Act of 2002 (Chief Financial Officer)***
101	The following financial statements from this Annual Report on Form 10-K of Boston Therapeutics, Inc. for the year ended December 31, 2011 formatted in XBRL: (i) Condensed Balance Sheets, (ii) Condensed Statements of Operations , (iii) Statement of Changes in Stockholders' Equity, (iv) Condensed Statements of Cash Flows, and (v) Notes to Condensed Financial Statements (unaudited), tagged as blocks of text.*

* Certain parts of this document have been omitted based on a confidential treatment approved by the SEC. The non-public information that has been omitted from this document has been separately filed with the SEC. Each redacted portion of this document is indicated by a "[***]". The redacted information is confidential information to the Registrant.

**Filed as an exhibit hereto.

***These certificates are furnished to, but shall not be deemed to be filed with, the Securities and Exchange Commission.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, there unto duly authorized.

BOSTON THERAPEUTICS, INC.

Date: April 4, 2013

By: /s/ David Platt
David Platt
Chief Executive Officer and Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David Platt David Platt	Director, Chief Executive Officer and Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer))	April 4, 2013
/s/ Kenneth A. Tassey, Jr. Kenneth A. Tassey, Jr.	President	April 4, 2013
/s/ Dale H. Conaway Dale H. Conaway	Director	April 4, 2013
/s/ Rom E. Eliaz Rom E. Eliaz	Director	April 4, 2013
/s/ Henry J. Esber Henry J. Esber	Director	April 4, 2013
/s/ Carl L. Lueders Carl L. Lueders	Director	April 4, 2013

Boston Therapeutics, Inc.
FINANCIAL STATEMENTS

For the years ended December 31, 2012 and 2011

C O N T E N T S

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and stockholders of
Boston Therapeutics, Inc.
Manchester, New Hampshire

We have audited the accompanying balance sheets of Boston Therapeutics, Inc. as of December 31, 2012 and 2011, and the related statements of operations, changes in stockholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Boston Therapeutics, Inc. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's limited resources and operating losses raise substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ McGladrey LLP

Boston, Massachusetts
April 4, 2013

Boston Therapeutics, Inc.

Balance Sheets
December 31, 2012 and 2011

	December 31, 2012	December 31, 2011
ASSETS		
Cash	$ 552,315	$ 225,995
Accounts receivable	17,351	-
Prepaid expenses and other current assets	9,073	5,331
Inventory	16,809	23,596
Total current assets	595,548	254,922
Property and equipment, net	7,075	-
Intangible assets	760,714	825,000
Goodwill	69,782	69,782
Other assets	2,125	-
Total assets	$ 1,435,244	$ 1,149,704
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 294,187	$ 341,873
Accrued expenses and other current liabilities	146,774	125,316
Total current liabilities	440,961	467,189
Advances - related parties	297,820	257,820
Total liabilities	738,781	725,009
COMMITMENTS AND CONTINGENCIES (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized,		
none issued and outstanding	-	-
Common stock, $0.001 par value, 100,000,000 shares authorized,		
18,745,706 and 16,223,206 shares issued and outstanding		
at December 31, 2012 and 2011, respectively	18,746	16,223
Additional paid-in capital	3,375,116	1,621,756
Accumulated deficit	(2,697,399)	(1,213,284)
Total stockholders' equity	696,463	424,695
Total liabilities and stockholders' equity	$ 1,435,244	$ 1,149,704

The accompanying notes are an integral part of these financial statements.

Boston Therapeutics, Inc.

Statements of Operations
For the Years Ended December 31, 2012 and 2011

	December 31, 2012	December 31, 2011
Revenue	$ 42,254	$ 4,112
Cost of goods sold	56,859	6,375
Gross margin	(14,605)	(2,263)
Operating expenses:		
Research and development	178,938	194,276
Sales and marketing	232,411	206,517
General and administrative	1,036,566	408,454
Total operating expenses	1,447,915	809,247
Operating loss	(1,462,520)	(811,510)
Interest expense	(18,384)	(15,658)
Foreign currency loss	(3,211)	-
Net loss	$ (1,484,115)	$ (827,168)
Net loss per share- basic and diluted	$ (0.09)	$ (0.05)
Weighted average shares outstanding basic and diluted	16,873,903	15,147,196

The accompanying notes are an integral part of these financial statements.

Boston Therapeutics, Inc.

Statement of Changes in Stockholders' Equity
For the Years Ended December 31, 2012 and 2011

	Common Stock		Additional Paid-in Capital	Accumulated Earnings (Deficit)	Total
	Shares	Amount			
Balance December 31, 2010	14,041,236	$ 14,041	$ 905,964	$ (386,116)	$ 533,889
Issuance of common stock	2,091,470	2,091	520,906	-	522,997
Issuance of common stock in exchange for consulting services	90,500	91	45,159	-	45,250
Stock based compensation	-	-	149,727	-	149,727
Net loss	-	-	-	(827,168)	(827,168)
Balance December 31, 2011	16,223,206	16,223	1,621,756	(1,213,284)	424,695
Issuance of common stock	2,270,000	2,270	1,011,957	-	1,014,227
Issuance of common stock warrants	-	-	132,773	-	132,773
Issuance of common stock in exchange for consulting services	252,500	253	128,522	-	128,775
Stock based compensation	-	-	480,108	-	480,108
Net loss	-	-	-	(1,484,115)	(1,484,115)
Balance December 31, 2012	18,745,706	$ 18,746	$ 3,375,116	$ (2,697,399)	$ 696,463

The accompanying notes are an integral part of these financial statements.

Boston Therapeutics, Inc.

Statements of Cash Flows
For the Years Ended December 31, 2012 and 2011

	December 31, 2012	December 31, 2011
Cash flows from operating activities:		
Net loss	$ (1,484,115)	$ (827,168)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	64,968	64,286
Stock based compensation	480,108	149,727
Issuance of common stock for consulting services	128,775	45,250
Changes in:		
Accounts receivable	(17,351)	-
Inventory	6,787	(19,447)
Prepaid expenses	(3,742)	(3,603)
Other assets	(2,125)	-
Accounts payable	(47,686)	295,956
Accrued expenses	21,458	(97,196)
Net cash used in operating activities	(852,923)	(392,195)
Cash flows from investing activities:		
Purchase of property and equipment	(7,757)	-
Net cash used in investing activities	(7,757)	-
Cash flows from financing activities		
Proceeds from advances - related parties	40,000	80,000
Proceeds from issuance of common stock and warrants	1,147,000	522,997
Net cash provided by financing activities	1,187,000	602,997
Net increase in cash and cash equivalents	326,320	210,802
Cash and cash equivalents, beginning of period	225,995	15,193
Cash and cash equivalents, end of period	$ 552,315	$ 225,995
Supplemental disclosure of cash flow information		
Cash paid during the period for		
Interest	$ -	$ -
Income taxes	$ -	$ -

The accompanying notes are an integral part of these financial statements.

1. GENERAL ORGANIZATION AND BUSINESS

Boston Therapeutics, Inc. (the "Company") was formed as a Delaware corporation on August 24, 2009 under the name Avanyx Therapeutics, Inc. On November 10, 2010, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Boston Therapeutics, Inc., a New Hampshire corporation ("BTI") providing for the merger of BTI into the Company with the Company being the surviving entity (the "Merger"), the issuance by the Company of 4,000,000 shares of common stock to the stockholders of BTI in exchange for 100% of the outstanding common stock of BTI, and the change of the Company's name to Boston Therapeutics, Inc. David Platt, the Company's Chief Executive Officer and Chief Financial Officer, is a founder of BTI and was a director and minority stockholder of BTI at the time of the Merger. Dr. Platt received 400,000 shares of the Company's common stock in connection with the Merger. Kenneth A. Tassey, Jr., who became the Company's President shortly after the Merger, was the Chief Executive Officer, President and principal stockholder of BTI at the time of the Merger. Mr. Tassey received 3,200,000 shares of our common stock in connection with the Merger.

The Company's primary business is the development, manufacture and commercialization of therapeutic drugs with a focus on complex carbohydrate chemistry to address unmet medical needs in diabetes and inflammatory diseases. We have brought one product, SUGARDOWN®, to market and have begun to make initial sales. We are currently focused on the development of two additional drug products: PAZ320, a non-systemic, chewable tablet for reduction of post-meal blood glucose in people living with diabetes and prediabetes that is fully developed, and IPOXYN™, an injectable anti-necrosis, anti-hypoxia drug that we are currently developing.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has limited resources and operating history. As shown in the accompanying financial statements, the Company has an accumulated deficit of approximately $2,697,000 as of December 31, 2012. The future of the Company is dependent upon its ability to obtain financing and upon future profitable operations from the development of its new business opportunities.

Management has plans to seek additional capital through private placements and public offerings of its common stock. There can be no assurance that the Company will be successful in accomplishing its objectives. Without such additional capital, the Company may be required to cease operations.

These conditions raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts of and classification of liabilities that might be necessary in the event the Company cannot continue in existence.

The Company has reassessed its status as a development stage entity in accordance with Accounting Standards Codification (ASC) 915, *Development Stage Entities*, as defined by Financial Accounting Standards Board (FASB), and has determined that its emergence from the development stage occurred during the year ended December 31, 2012 based on the accumulation of significant events that occurred through December 31, 2012. Since inception the Company has sold approximately $46,794 of its over-the-counter product SUGARDOWN® . Furthermore, the Company has completed development of one consumer product for which it has executed distribution agreements with companies in Asia and Europe and established a web presence through which the Company sells directly to consumers. The Company has also completed development of one pharmaceutical drug candidate, for which it has completed Phase 2 clinical trials. The Company has raised approximately $1,147,000 in 2012 and has recently engaged an investment banking firm to raise additional funds for supporting additional clinical studies and to expand the company's operations capabilities. Accordingly, the Company has determined that it has commenced planned principal operations and is no longer a development stage entity. Previously, the Company has reported as a development stage entity through September 30, 2012. As a result of this change in reporting status, the Company has removed from these financial statements all 'cumulative since inception' financial information that is required by ASC 915.

2. SUMMARY OF SIGNIFICANT ACCOUNTING PRACTICES

Basis of Presentation

The financial statements have been prepared in conformity with accounting principles generally accepting in the United States of America ("US GAAP").

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Segment Information

Operating segments are identified as components of an enterprise about which separate, discrete financial information is available for evaluation by the chief operating decision-maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment.

Cash and Cash Equivalents

For purposes of reporting within the statement of cash flows, the Company considers all cash on hand, cash accounts not subject to withdrawal restrictions or penalties, and all highly liquid investments with original maturities of 90 days or less at the time of acquisition to be cash equivalents. The Company maintains its cash in institutions insured by the Federal Deposit Insurance Corporation.

Revenue Recognition

The Company generates revenues from sales of SUGARDOWN®. Revenue is recognized when there is persuasive evidence that an arrangement exists, the price is fixed and determinable, the product is shipped and collectability is reasonably assured.

Revenue is recognized as product is shipped from an outside fulfillment operation. Terms of product sales contain no contractual rights of return or multiple elements. In practice, the Company has not experienced or granted returns of product. Revenues are recorded net of local sales tax collected. Shipping fees charged to customers are included in revenue and shipping costs are included in costs of sales.

Accounts Receivable

Accounts receivable is stated at the amount management expects to collect from outstanding balances. Management establishes a reserve for doubtful accounts based on its assessment of the current status of individual accounts. Balances that remain outstanding after management has used reasonable collection efforts are written off against the allowance. As of December 31, 2012 and 2011 the allowance for doubtful accounts was $0.

Inventory

Inventory consists of raw materials and finished goods of SUGARDOWN®. Inventories are stated at the lower of cost (first-in, first-out) or market, not in excess of net realizable value. The Company adjusts the carrying value of its inventory for excess and obsolete inventory. The adjustments to the carrying value of inventory for the years ended December 31, 2012 and 2011 were $0 and $1,667, respectively. The Company continues to monitor the valuation of its inventories.

Property and Equipment

Property and equipment is depreciated using the straight-line method over the following estimated useful lives:

Asset Category	Estimated Useful Life
Office Furniture and Equipment	5 years
Computer Equipment and Software	3 years

The Company begins to depreciate assets when they are placed in service. The costs of repairs and maintenance are expensed as incurred; major renewals and betterments are capitalized. Upon sale or retirement, the cost and related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the statement of operations. For the years ended December 31, 2012 and 2011, the Company recorded depreciation expense of $682 and $0, respectively.

2. SUMMARY OF SIGNIFICANT ACCOUNTING PRACTICES …continued

Intangible Assets

Intangible assets consist of identifiable finite-lived assets acquired in business acquisitions. Acquired intangible assets are recorded at fair value on the date of acquisition and
are amortized over their economic useful lives on a straight line basis.

Goodwill

The Company follows the guidance of Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 350, *Goodwill and Other Intangible Assets*.
Under ASC 350, goodwill and certain other intangible assets with indefinite lives are not amortized, but instead are reviewed for impairment at least annually.

The Company tests goodwill for impairment in the fourth quarter of each year or more frequently if events or changes in circumstances indicate that the asset might be impaired. The test is based on a comparison of the reporting unit's book value to its estimated fair value. The Company has concluded that no impairment existed at the 2012 testing date. A considerable amount of judgment is required in calculating this impairment analysis, principally in determining financial forecasts and discount rates. Differences in actual cash flows as compared to the discounted cash flows could require the Company to record an impairment loss in the future.

Impairment of Long-lived Assets

The Company reviews long-lived assets, which include the Company's intangible assets, for impairment whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. Future undiscounted cash flows of the underlying assets are compared to the assets' carrying values. Adjustments to fair value are made if the sum of expected future undiscounted cash flows is less than book value. To date, no adjustments for impairment have been made.

Loss per Share

Basic net loss per share is computed based on the net loss for the period divided by the weighted average actual shares outstanding during the period. Diluted net loss per share is computed based on the net loss for the period divided by the weighted average number of common shares and common equivalent shares outstanding during each period unless the effect of such common equivalent shares would be anti-dilutive. Common stock equivalents represent the dilutive effect of the assumed exercise of certain outstanding stock options using the treasury stock method. The weighted average number of common shares for the year ended December 31, 2012 did not include consideration of 8,353,400 common stock options and warrants because of their anti-dilutive effect. The weighted average number of shares for the year ended December 31, 2011 did not include consideration of 1,578,400 common stock options because of their anti-dilutive effect.

Income Taxes

The Company accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which those temporary differences are expected to be recovered or be settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided when it is more likely than not that some portion of the gross deferred tax asset will not be realized. The Company records interest and penalties related to income taxes as a component of provision for income taxes. The Company did not recognize any interest and penalty expense for the years ended December 31, 2012 and 2011.

Research and Development Costs

Research and development expenditures are charged to the statement of operations as incurred. Such costs include proprietary research and development activities, purchased research and development, and expenses associated with research and development contracts, whether performed by the Company or contracted with independent third parties.

Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, accounts payable, accrued expenses, and notes payable. The carrying value of cash and cash equivalents, accounts payable and accrued expenses approximates fair value due to their short-term nature.

2. SUMMARY OF SIGNIFICANT ACCOUNTING PRACTICES…continued

Fair Value of Financial Instruments…continued

The carrying value of the advances payable as of December 31, 2012 and 2011, is not materially different from the fair value of the advances payable.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk are principally cash and cash equivalents. The Company places its cash and cash equivalents in highly rated financial institutions. The Company maintains cash and cash equivalent balances with financial institutions that occasionally exceed federally insured limits. The Company has not experienced any losses related to these balances, and management believes its credit risk to be minimal.

Stock-Based Compensation

Stock–based compensation, including grants of employee and non-employee stock options and modifications to existing stock options, is recognized in the income statement based on the estimated fair value of the awards. The Company uses the Black-Scholes option pricing model to determine the fair value of options granted and recognizes the compensation cost of share-based awards on a straight-line basis over the vesting period of the award.

The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by the stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The Company does not have a history of market prices of the common stock as, and as such volatility is estimated using historical volatilities of similar public entities. The expected life of the awards is estimated based on the simplified method. The risk-free interest rate assumption is based on observed interest rates appropriate for the terms of our awards. The dividend yield assumption is based on history and expectation of paying no dividends. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Stock-based compensation expense is recognized in the financial statements on a straight-line basis over the vesting period, based on awards that are ultimately expected to vest.

The Company grants stock options to non-employee consultants from time to time in exchange for services performed for the Company. Equity instruments granted to non-employees are subject to periodic revaluation over their vesting terms. In general, the options vest over the contractual period of the respective consulting arrangement and, therefore, the Company revalues the options periodically and records additional compensation expense related to these options over the remaining vesting period.

The fair value of stock options granted was calculated with the following assumptions:

	2012	2011
Risk-free interest rate	0.43-1.27%	0.28-0.77%
Expected dividend yield	0%	0%
Volatility factor	85 - 90%	90%
Expected life of option	3.5-7.0 years	4.75-5.0 years

The weighted-average fair value of stock options granted during the years ended December 31, 2012 and 2011, under the Black-Scholes option pricing model was $0.30 and $0.20 per share, respectively. For the years ended December 31, 2012 and 2011, the Company recorded stock-based compensation expense of $480,108 and $149,727, respectively, in connection with share-based payment awards. As of December 31, 2012, there was approximately $1,654,000 of unrecognized compensation expense related to non-vested stock option awards that is expected to be recognized over a weighted-average period of 2.50 years.

Recent Accounting Pronouncements

In July 2012, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2012-02, *Intangibles – Goodwill and Other (Topic 350): Testing Indefinite-Lived Intangible Assets for Impairment.* This ASU allows an entity to first assess qualitative factors to determine whether it is necessary to perform the quantitative impairment test for indefinite-lived intangible assets. An organization that elects to perform a qualitative assessment is required to perform the quantitative impairment test for an indefinite-lived intangible asset if it is more likely than not that the asset is impaired. This ASU, which applies to all public, private, and not-for-profit organizations, is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted, including for annual and interim impairment tests performed as of a date before July 27, 2012, if a public entity's financial statements for the most recent annual or interim period have not yet been issued or, for nonpublic entities, have not yet been made available for issuance. The adoption of this ASU did not have a material impact on the Company's consolidated financial statements, as it was intended to simplify the impairment assessment for indefinite-lived intangible assets. In February 2013, the FASB issued Accounting Standards Update No. 2013-2, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. The amendment, required to be applied prospectively for reporting periods beginning after December 15, 2012, requires entities to present, either on the face of the statement where net income is

presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line item of net income. Early adoption is permitted. Our financial statement presentation complies with this standards update.

3. INVENTORIES

Inventories consist of material, labor and manufacturing overhead and are recorded at the lower of cost, using the weighted average cost method, or net realizable value.

The components of inventories at December 31, 2012 and 2011, net of inventory reserves, were as follows:

	2012	2011
Raw materials	$ 13,125	$ 23,034
Finished goods	3,684	562
Total	$ 16,809	$ 23,596

The Company periodically reviews quantities of inventory on hand and compares these amounts to expected usage of each particular product or product line. The Company records, as a charge to cost of sales, any amounts required to reduce the carrying value to net realizable value.

4. STOCKHOLDERS' EQUITY

The Company is authorized to issue up to 5,000,000 shares of its $0.001 par value preferred stock and up to 100,000,000 shares of its $0.001 par value common stock.

Preferred Stock

No shares of preferred stock have been issued and the terms of such preferred stock have not been designated by the Board of Directors.

Common Stock

On August 26, 2009 the Company issued 10,000,000 shares of its $0.001 par value common stock to its two founders. Eight million shares were issued to the Company's Chief Executive Officer (CEO), Chairman of the Board of Directors and co-founder, in exchange for a patent, a provisional patent and know-how. In accordance with ASC 845-10-S99, *Transfers of Non-monetary Assets from Promoters or Shareholders*, the transfer of nonmonetary assets to a company by its shareholders in exchange for stock prior to the Company's initial public offering should be recorded at the transferor's historical cost basis determined under GAAP. As a result, the value of the patent, provisional patent and know-how was valued at the CEO's historical cost basis of zero because no records exist to support an historical cost basis in accordance with GAAP. The patent and provisional patent were assigned to the Company on December 10, 2009. The remaining 2,000,000 shares were issued to the co-founder for $10,000 in cash.

On March 31, 2010 the Company issued 20,000 shares of common stock for $10,000 cash to an investor. On April 9, 2010, the Company issued 11,236 shares of common stock in exchange for $11,236 to a related party. On October 4, 2010, the Company issued 10,000 shares for $10,000 cash to an investor. On November 6, 2010, the Company issued 4,000,000 shares of common stock in connection with the merger transaction described in Note 7.

On June 21, 2011 the Company sold 2,035,470 shares for $508,867 in a private placement offering. During August 2011, an additional 56,000 shares were sold for $14,130 in the private placement. On November 1, 2011, 80,500 shares were issued to a consultant for marketing services valued at $40,250. On December 22, 2011, 10,000 shares were issued to a consultant for services rendered valued at $5,000. No other issuances of preferred or common stock have been made.

On May 7, 2012, the Company issued 20,000 shares of common stock at a price per share of $1.10 and issued a warrant to purchase an additional 20,000 shares of common stock at $1.15 per share for gross proceeds of $22,000. The warrant associated with the subscription agreement is exercisable immediately and has a five year term. The Company estimated the relative fair value of the warrant to be $8,754 using the Black Scholes model, which has been recorded as a component of permanent equity in additional paid in capital.

4. STOCKHOLDERS' EQUITY…continued

Common Stock…continued

During May 2012 the Company entered into a consulting agreement under which it is required to pay the consultant a monthly fee consisting of 25,000 shares of restricted common stock beginning May 21, 2012 through May 21, 2013. As of December 31, 2012 the Company has issued 150,000 shares due under this agreement for services rendered during June through November 2012 with a fair value of $76,500. An accrual in the amount of $14,000 representing the fair value of the 33,333 unissued shares for services rendered in December 2012 is included in the accompanying December 31, 2012 balance sheet.

During June 2012 the Company issued 80,000 shares of its common stock with a fair value of $40,800 in exchange for professional consulting services.

On June 29, 2012 the Company issued 1,000,000 shares to an affiliate of Advance Pharmaceutical Co., Ltd. (APC) in a private placement for net proceeds of $500,000. APC is licensed to distribute SUGARDOWN® in Hong Kong, China and Macau. The Company reviewed the private placement issuance and determined that the issuance price of $0.50 per share approximates fair value as of the date of issuance.

During July 2012 the Company entered into a consulting agreement under which it is required to pay the consultant a monthly fee consisting of $4,000 paid in cash and 7,500 shares of restricted common stock. As of December 31, 2012 the Company has issued the 22,500 total shares due under this agreement for services rendered during July, August and September 2012 with an aggregate fair value of $11,475. The agreement was terminated as of September 30, 2012.

On December 12, 2012 the Company issued 1,250,000 shares of its common stock at a price per share of $0.50 and issued a warrant to purchase 625,000 additional shares for $1.00 per share for gross proceeds of $625,000. The warrant associated with the subscription agreement is exercisable immediately and has a five year term. The Company estimated the relative fair value of the warrant to be $124,019 using the Black Scholes model, which has been recorded as a component of permanent equity in additional paid in capital.

5. STOCK OPTION PLAN AND STOCK-BASED COMPENSATION

During the year ended December 31, 2010, the Company adopted a stock option plan entitled "The 2010 Stock Plan" (2010 Plan) under which the Company may grant options to purchase up to 5,000,000 shares of common stock. As of December 31, 2012, there were 578,400 options outstanding under the 2010 Plan.

During the year ended December 31, 2011, the Company adopted a non-qualified stock option plan entitled "2011 Non-Qualified Stock Plan" (2011 Plan) under which the Company may grant options to purchase 2,100,000 shares of common stock. In December 2012, the 2011 Plan was amended and restated to increase the number of shares of common stock issuable under the 2011 Plan to 12,000,000 shares. As of December 31, 2012, there were 7,130,000 options outstanding under the 2011 Plan.

Under the terms of the stock plans, the Board of Directors shall specify the exercise price and vesting period of each stock option on the grant date. Vesting of the options is typically three to four years and the options expire ten years from the date of grant.

5. STOCK OPTION PLAN AND STOCK-BASED COMPENSATION…continued

The following table summarizes the activity under the Stock Plans.

	Shares	Price per Share	Weighted Average Exercise Price
Outstanding, December 31, 2010	78,400	$ 1.85	$ 1.85
Granted	1,921,237	0.10 to 0.25	0.13
Exercised	-	-	-
Options forfeited/cancelled	(421,237)	-	0.25
Outstanding, December 31, 2011	1,578,400	0.10 to 1.85	0.19
Granted	6,130,000	0.10 to 0.50	0.48
Exercised	-	-	-
Options forfeited/cancelled	-	-	-
Outstanding, December 31, 2012	7,708,400	0.10 to $ 1.85	$ 0.42

The following table summarizes information about stock options that are vested or expected to vest at December 31, 2012:

Vested or Expected to Vest					Exercisable Options			
Exercise Price	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value	Number of Options	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Life (Years)	Aggregate Intrinsic Value
$ 0.10	1,800,000	$ 0.10	3.87	$ 576,000	1,306,250	$ 0.10	3.93	$ 418,000
1.85	78,400	1.85	2.75	-	78,400	1.85	2.75	-
0.50	5,830,000	0.50	5.13	-	934,167	0.50	5.95	-
$ 0.10-1.85	7,708,400	$ 0.42	4.81	$ 576,000	2,318,817	$ 0.32	4.71	$ 418,000

The weighted-average remaining contractual life for options exercisable at December 31, 2012 is 4.71 years. At December 31, 2012 the Company has 4,870,000 and 4,421,600 options available for grant under the 2011 Plan and 2010 Plan, respectively.

The intrinsic value for fully vested, exercisable options was $418,000 and $96,206 at December 31, 2012 and 2011, respectively. No actual tax benefit was realized from stock option exercises during these periods.

6. RELATED PARTY TRANSACTIONS

Through December 31, 2011, the CEO advanced $257,820 to BTI to fund start-up costs and operations of the Company. Advances by the CEO carry an interest rate of 6.5% and were due on June 29, 2013. On May 7, 2012, the Company's CEO and President entered into promissory notes to advance to the Company an aggregate of $40,000. The notes accrue interest at 6.5% per year were due June 30, 2013. As of December 31, 2012, and December 31, 2011, $44,090 and $25,641, respectively, of accrued interest had been included in accrued expenses on the accompanying balance sheet. On August 6, 2012, the outstanding notes of $297,820 were amended to extend the maturity dates to June 29, 2014. The CEO and President intend to, but are not legally obligated, to fund the Company's operations in this manner until the Company raises sufficient capital.

7. INTANGIBLE ASSETS

The SUGARDOWN® technology and provisional patents, which were obtained through the acquisition of BTI in 2010, are being amortized on a straight-line basis over their estimated useful lives of 14 years.

Intangible assets consist of the following:

	December 31, 2012	December 31, 2011
SUGARDOWN® technology and provisional patents	$ 900,000	$ 900,000
Less accumulated amortization	(139,286)	(75,000)
Intangible assets, net	$ 760,714	$ 825,000

Amortization expense for each of the years ended December 31, 2012 and 2011 was $64,286.

The estimated remaining amortization expense related to intangible assets with finite lives for each of the five succeeding years and thereafter is as follows:

Year ending December 31:	
2013	$ 64,286
2014	64,286
2015	64,286
2016	64,286
2017	64,286
Thereafter	439,284
	$ 760,714

8. PROVISION FOR INCOME TAXES

Temporary differences that give rise to significant deferred tax assets are as follows:

	December 31, 2012	December 31, 2011
Start-up costs	$ 21,786	$ 21,786
Net operating loss carryforward	1,064,457	466,803
Valuation allowance	(1,086,243)	(488,589)
Net deferred tax asset	$ -	$ -

As of December 31, 2012 and 2011, the Company had a deferred tax asset of $21,786 related to start-up costs which are amortizable for tax purposes. The Company also had a deferred tax asset related to net operating loss carryforwards of $2,697,399 and $ 1,213,284 that expire through 2032 as of December 31, 2012 and 2011, respectively.

The Company has provided a full valuation allowance for deferred tax assets since, based on the weight of available evidence, it is more likely than not that these benefits will not be realized. During 2012, the Company increased its valuation allowance by $597,654 due to the continued likelihood that realization of any future benefit from deductible temporary differences and net operating loss carryforwards cannot be sufficiently assured at December 31, 2012.

8. PROVISION FOR INCOME TAXES…continued

The primary factors affecting the Company's income tax rate for the years ended December 31, 2012 and 2011 are as follows:

	2012	2011
Tax benefit at U.S. statutory rate	(34.0) %	(34.0) %
State tax benefit	(6.3) %	(6.3) %
Valuation allowance	40.3 %	40.3 %
	0.0 %	0.0 %

The Company applies the provisions of ASC 740-10, *Income* Taxes, (originally issued as FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes*). The Company has not recognized any liability for unrecognized tax benefits and does not believe there is any uncertainty with respect to its tax position. The Company's policy with respect to unrecognized tax benefits is to recognize interest accrued related to unrecognized tax benefits in interest expense and penalties in operating expenses.

9. COMMITMENTS AND CONTINGENCIES

The Company entered into a three year lease agreement for their office facility commencing July 1, 2012, with escalating rental payments. The effects of variable rent disbursements have been expensed on a straight-line basis over the life of the lease. The Company recognized rent expense of $15,759 and $4,746 for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, there was $2,267 of deferred rent included in accrued expenses and other current liabilities in the accompanying balance sheets.

Future minimum lease payments under all non-cancelable operating leases as of December 31, 2012, are as follows:

Fiscal year	
2013	$25,917
2014	26,917
2015	16,042
	$68,876

10. SUBSEQUENT EVENTS

The Company has evaluated events and transactions that occurred from December 31, 2012 through the date of filing, for possible disclosure and recognition in the financial statements. Except as discussed below, the Company did not have any material subsequent events that impact its financial statements or disclosures.

On December 20, 2012, the Board of Directors approved a grant of non-qualified stock options to the independent directors of the Company to purchase an aggregate of 98,000 shares of the Company's common stock, with the grant to be effective January 1, 2013. The options were allocated among the directors based on service in, and chairmanship of, the Company's committees and service as lead independent director. The options vest as of December 31, 2013, provided that the directors remain directors on that date and have attended at least 75% of the scheduled meetings of the Board and the committees on which such directors serve during the 2013 calendar year.

Effective January 1, 2013, the Company granted a consultant a non-qualified stock option to purchase up to 120,000 shares of the Company's common stock at an exercise price of $1.00 per share as partial compensation for professional services. The option vests in four equal quarterly installments with the first installment vesting on March 31, 2013. The option expires on December 31, 2018.

In February 2013, the Company agreed to increase the amount of office space it will lease effective April 1, 2013 and to increase the lease term through March 31, 2018. As a result of this amendment to its lease agreement the Company agreed to increase its monthly minimum rent to $4,878 for the period April 1, 2013 through March 31, 2014, $5,051 for the period April 1, 2014 through March 31, 2015, $5,225 for the period April 1, 2015 through March 31, 2016, $5,404 for the period April 1, 2016 through March 31, 2017 and $5,591 for the period April 1, 2017 through March 31, 2018.

On February 27, 2013, CJY Holdings Limited, an affiliate of Advance Pharmaceutical Co. Ltd., made a $250,000 investment in the Company pursuant to the S-1 Registration Statement. CJY Holdings Limited received 500,000 shares of common stock priced at $0.50 and 250,000 warrants to purchase common stock with an exercise price of $1.00 and a five-year term.

In March 2013, the Company's Board of Directors voted to amend its Certificate of Incorporation to increase the authorized number of

common shares from 100,000,000 to 200,000,000; and to submit the amendment to the Company's stockholders for their approval. The amendment will not take effect unless approved by the stockholders.

In March 2013, the Company's Board of Directors amended the Company's 2010 Stock Plan to increase the number of shares in the plan to 7,500,000; and to increase the Company's 2011 Non-Qualified Stock Option Plan to increase the number of shares in the plan from 12,000,000 to 17,500,000. The amendment to the 2010 Stock Plan will not take effect unless approved by the stockholders. The amendment to the 2011 Non-Qualified Stock Option Plan took effect upon approval by the Board of Directors.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statements (No. 333-185355 and 333-177171) on Form S-8 of Boston Therapeutics, Inc. of our report dated April 4, 2013, relating to our audit of the financial statements, which appear in this Annual Report on Form 10-K of Boston Therapeutics, Inc. for the year ended December 31, 2012. Our report dated April 4, 2013 relating to the financial statements includes an emphasis paragraph relating to an uncertainty as to the Company's ability to continue as a going concern.

/s/ McGladrey LLP

Boston, Massachusetts
April 4, 2013

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14

I, David Platt, certify that:

1. I have reviewed this Annual Report on Form 10-K of Boston Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: April 4, 2013

By: /s/ David Platt

David Platt

Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14

I, David Platt, certify that:

1. I have reviewed this Annual Report on Form 10-K of Boston Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: April 4, 2013

By: /s/ David Platt

David Platt
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEYACT OF 2002

In connection with the Annual Report on Form 10-K of Boston Therapeutics, Inc. (the "Company") for the year ending December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), David Platt, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 4, 2013

By: /s/ David Platt

David Platt
Chief Executive Officer

This certification accompanies each Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEYACT OF 2002

In connection with the Annual Report on Form 10-K of Boston Therapeutics, Inc. (the "Company") for the year ending December 31, 2012 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), David Platt, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: April 4, 2013

By: /s/ David Platt

David Platt
Chief Financial Officer

This certification accompanies each Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.