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, 2018**

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.)
354 Merrimack Street #4, Lawrence, MA	**01843**
(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)

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 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 or any amendment to this Form 10-K ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐	Smaller Reporting Company	☒
		Emerging Growth Company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised fi nancial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 29, 2018, 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 $3,580,585.

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 April 12, 2019
Common Stock, $0.001 par value per share	111,131,373 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 operations of Boston Therapeutics, Inc., a Delaware corporation, formerly called Avanyx Therapeutics, Inc.

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; and if we are successful in raising capital, such capital may not be on acceptable terms.
- 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.

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. On February 12, 2018, the Company acquired CureDM Group Holdings LLC ("CureDM"), for 47,741,140 shares of common stock of which 25,000,000 were delivered at closing and 22,741,140 shall be delivered in four equal tranches of 5,685,285 each upon the achievement of specific milestones. Boston Therapeutics, headquartered in Lawrence, MA, (OTCQB: BTHE) is a leader in the field of complex carbohydrate chemistry and peptide therapeutic drug discovery and development. The Company's initial product pipeline is focused on developing and commercializing therapeutic molecules for sugar control more specifically prediabetics and diabetes: investigative material BTI-320, a non- systemic, non-toxic, investigative therapeutic compound designed to reduce post-meal glucose elevation. In addition, under manufacturing control, SUGARDOWN®, a similar base material to BTI-320 has progressed into market testing as a dietary supplement designed to manage post-meal sugar spikes. Recently, with the acquisition of CureDM in the first quarter of 2018, a new investigative material BTI-410, an injectable peptide, may fulfill the medical need to replace injection of insulin by stimulating the beta cell maturation. And the adjunctive therapeutic material called IPOXYN, is an investigative intravenous fluid therapy for the prevention of necrosis and a treatment for ischemia, with an initial target indication of lower limb ischemic events often associated with diabetes. This covers a wider combined prevention and therapeutic option for the growing worldwide epidemic related to metabolic diseases with diabetes being the leader.

Going Concern

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 consolidated financial statements, the Company has an accumulated deficit of approximately $23.4 million and approximately $12,500 cash on hand as of December 31, 2018. Management is currently seeking additional capital through private placements and public offerings of its common stock. In addition, the Company may seek to raise additional capital through public or private debt or equity financings as well as collaboration activities in order to fund our operations. We raised $275,000 in gross proceeds from private placements of our Series A Preferred Stock during the first quarter of 2018. During the second quarter of 2018, we issued a note payable to a related party for $100,000. At the end of the third quarter of 2018, we approved a Private Placement Memorandum in an effort to raise additional funds. Also, at the end of the third quarter, the Company issued a Note Payable to CJY Holdings, Ltd, a related party, for $305,937. Also, in the fourth quarter of 2018, we increased the amount of the note payable to the related party noted above to $174,500. An additional $339,144 was advanced to the Company during April 2019 from these related parties. Management anticipates that cash resources will be sufficient to fund our planned operations into the second quarter of 2019. The future of the Company is dependent upon its ability to obtain continued financing and upon future profitable operations from the partnering, development and clarity of its new business opportunities.

The Company may seek to raise additional capital through public or private debt or public or private equity financings, and partnerships or licensing opportunities in order to fund our operations. 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 operations.

Overview

We are a pre-clinical and clinical-stage pharmaceutical company focused on the development, outsourced contract manufacture and test market commercialization of carbohydrate-based materials as supplements and drugs, and clinical stage of peptide therapeutic drugs. All agents are targeted designed to help manage blood sugar, treat pre-diabetes and diabetes related pathologies. Our present early market entry is under a dietary supplements regulation.

Currently, our lead pharmaceutical drug candidates are:

- BTI-320, a non-systemic carbohydrate-based compound designed to reduce "post-meal elevation" of blood glucose levels in pre-diabetes patients and type 2 diabetes patients; and
- BTI-410, a peptide injectable compound designed to stimulate beta cell maturation, which is the development of new insulin producing cells in the pancreas to alleviate stress on existing cells in type 2 diabetes patients and in type 1 patients who are on immunosuppression therapy after having undergone kidney transplant surgery.
- IPOXYN, a carbohydrate-based, injectable drug intended to prevent necrosis, or cell death, and to treat hypoxic conditions, such as diabetic foot ulcers and other vascular/neurological complications.

BTI-320

Following Phase II clinical trial results reported in 2013 and the Phase IIb clinical trial concluded in October 2014, the U.S. Food and Drug Administration ("FDA") accepted the Investigational New Drug Application (or IND), which we filed for BTI-320 to treat Type 2 diabetes and partial weight management in 2014. The filing has brought on 4 active sites while Joslin Diabetes Center in Boston MA and the site in New Mexico were dropped as lead clinics in the first phase of our multi-center, expanding to multi-country trial which commenced in the fourth quarter of 2018. The trial is anticipated to enroll up to 60 patients with the expansion of up to at least 360 patients in a 24 week evaluation study which is designed as a randomized, placebo-controlled, double blind "international" multi-center study with two treatment arms. The trial will employ precision medical monitoring and will target the primary efficacy endpoint of Post Prandial Glucose (PPG) or immediate blood sugar excursion reductions projected to have a mean change in HbA1c levels from baseline at 24 weeks. We anticipate enrollment at a number of international centers in Europe, Asia and Australia once the 4 centers located in the U.S. have completed the initial 60 patients. In addition, we have suspended one additional new trial and the China site that was to pioneer risk in pre-diabetic patients that was being set-up in Hong Kong. This was to employ a state of the art retinal image analysis to evaluate the compounds effect on reduction of stroke risk.

We continue to negotiate with Conroy Chi-Heng Cheng pursuant to which Mr. Cheng or an affiliate to Mr. Cheng will fund such trial. There is no guarantee that we will be able to successfully continue such financing. Mr. Cheng is a director and a shareholder of the Company and a director of Advance Pharmaceutical Company ("Advance Pharmaceutical"), a Hong Kong based, privately held company. On June 24, 2011, prior to his election to the Company's Board, the Company entered into a definitive Licensing and Manufacturing Agreement with Advance Pharmaceutical. In addition, CJY Holdings Limited, a Company controlled by Mr. Cheng's brother, Cheng Chi Him, holds a significant amount of convertible debentures payable by the Company.

BTI-410

Following successful IND application in 2012, a Phase 1a First-in-Man study was completed in which ascending doses of BTI-410, ranging from 60 mg to 720 mg, appeared to be safe and well tolerated by all subjects in the study. Phase 1b, entitled "A Randomized, Double-blind, Placebo-controlled Study of the Effect of 49 days of Treatment with Repeated Subcutaneous Doses of HIP2B (BTI-410) to Assess Safety, Tolerability and Measures of islet β-cell Function in Subjects with Type 2 Diabetes Mellitus Treated with Metformin", was completed in 2015. Two new pivotal clinical trials are designed for the study of BTI-410. One Phase II study may be conducted in 36 type 1 patients on immunosuppression therapy after kidney transplant surgery. A second Phase II study may be conducted in 120 type 2 diabetes patients pending the appropriate funding and/or the appropriate material manufacture. A China based Peptide Company was contacted several times over the last year to quote on the synthesis of material needed for these studies, however, it should be clear that this program has received another set-back with the resignation of our COO and the inability to execute in a timely manner without financing during 2018 and with the loss of the firm collaboration to make the material. We did progress and locate a CRO, that we believe could execute in a timely manner once a clinical trials material has been established and the FDA IND has been reactivated. We are considering unwinding the merger with CureDM Holdings that was done in the first quarter of 2018. At the time of this filing we are still in discussions with CureDM Inc., the former parent company of CureDM Holdings. Certain parties associated with CureDM Inc., have initiated litigation against us to unwind the merger. We are still determining the impact of the filed litigation.

Development of IPOXYN remains is in the pre-clinical planning stage. The patent was progressed, however, no inhouse work has been done to date due to lack of financial resources. The Company is exploring a partnering alliance for the participation with a funded program in China. We anticipate activity will occur with support funding later this year.

In addition, we currently test marketing and selling SUGARDOWN® in the US (Amazon.com), this non-systemic, polysaccharide based dietary supplement designed to support healthy blood glucose levels, is incrementing sales over the Internet and by targeted purchase orders through a piloting program in specialty independent pharmacies in one city. With improved management focus on these sales, we are seeking a partnering opportunity this year for SUGARDOWN®.

Novelty of Complex Carbohydrate Science

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:

- in the case of BTI-320 and SUGARDOWN®, modified mannan (a polymer found in plants) to lower the rapid rise and peak amplitude in post-prandial blood glucose (PPG, or post-meal blood sugar), and
- in the case of IPOXYN, stabilized hemoglobin as modified by carbohydrate chemistry to deliver oxygen to cells in hypoxic condition sustaining vascular integrity.

We use naturally occurring, available processed plant extracts as starting material to create proprietary complex carbohydrate formulations with specific molecular weights and other pharmaceutical properties. We have received our first patent in the EU. These complex carbohydrate molecules are then formulated into acceptable pharmaceutical material through establishment of dose effect and stability. Using these novel carbohydrate-based candidate compounds that largely bind and inhibit enzymes, we are undertaking the focused pursuit of developing therapies for metabolic diseases like diabetes and other serious diseases in which enzyme activity have a demonstrated role in disease management.

Our management team, including most notably our Board Member and Chief Executive Officer Carl W. Rausch, who has played a role in the applications associated with the development of complex carbohydrate science in Asia and is arranging a possible pipeline of carbohydrate-based therapeutics in cell metabolism and with other protein chemistries which can address a variety of unmet medical needs. We believe this expertise is particularly valuable as we progress with specialty processes and clinical development of our products. The Company is working to expand, to partner and to build Company and market awareness of these technologies through the introductory sales of SUGARDOWN®.

New for Boston Therapeutics: Novelty of Human Peptide Therapeutics and Proteomic Platform Technology

Following the completion of the human genome project, certain human proteins that are in low availability and only transiently expressed became known. The REG3A protein is known to be a trigger in the development pathway of endocrine function in the pancreas. BTI-410 was derived from the active region of this larger protein, stabilized for use as a therapeutic and extensively studied in vitro and in animal models. The human proteomic pathway was established using a novel proteomic approach to discovery of potential new mechanisms of action.

Peptides are recognized for being highly selective and efficacious and, at the same time, relatively safe and well tolerated. In general, peptides are selective and efficacious signaling molecules and given their attractive pharmacological profile and intrinsic properties, peptides represent an excellent starting point for the design of novel therapeutics and their specificity has been seen to translate into excellent safety, tolerability, and efficacy profiles in humans. This aspect might also be the primary differentiating factor of peptides compared with traditional small molecules. Furthermore, peptide therapeutics are typically associated with lower production complexity compared with protein-based biopharmaceuticals and, therefore, the production costs are also lower, generally approaching those of small molecules. Thus, in several ways, peptides are in the sweet spot between small molecules and biopharmaceuticals.

Using human protein interaction technology and public and proprietary databases to elucidate pathways of interest, BTI-410 was discovered and developed at CureDM. Preclinical data showed the unique specificity and efficacy of the compound with respect to a novel mechanism of beta cell maturation and the US Food and Drug Administration (FDA) accepted the application for Investigational New Drug (IND) in 2012. Subsequently, Phase 1a studies in healthy human subjects proved that the drug was very well-tolerated and lead to no adverse events. Phase 1b study in type 2 diabetes patients resulted in statistically significant increases in pre-hepatic insulin secretion, increases in fasting insulin and improved response to glucose challenge.

The cause of both type 1 and type 2 diabetes mellitus (T1DM and T2DM) is the loss of functional pancreatic islet mass due to abnormally high rates of destruction that outpace the natural mechanisms for replacement of the islet mass. Currently, there is no treatment option that promotes the regeneration of islets and maturation of beta cells to impact the underlying causes of this disease. BTI-410 is such a compound. Clinical studies will be conducted to show efficacy by this mechanism.

BTI-320 and SUGARDOWN® Mechanisms of Action

Diabetes is a chronic disease in which a patient's inability to produce the hormone insulin in sufficient amounts is compromised if not totally lost. This defect leads to high levels of glucose in the blood stream, which in turn leads to many systemic vascular and organ complications such as heart, kidney and retina dysfunction and even premature death. To address this overload the modified mannan in BTI-320 formulation, works to lower the immediate rise in post-meal blood glucose from processed foods and free sugar loads in several ways. First, we have evidence that it binds to long-chain starch polysaccharides in foods and also to the digestive enzymes that cleave these large sugars into glucose. Second, it appears to temporarily coat the inside of the small intestine to slow the early absorption of glucose. Together, these mechanisms have been shown to lower the rate and the availability for glucose absorption in the small intestine and thus slows the amount entering the blood. This delays the exposure time for the digestive process to a region lower in the gut.

This effect of BTI-320 is measured by monitoring the amount of glucose absorption as a difference in sugar increases in the bloodstream over time and in peak height. Most anti-diabetes drugs, also considered to cause hypoglycemic events if not managed well, force blood sugar levels down from the presence in the blood streams by targeting organ systems such as the pancreas, the liver, the kidneys and the body's cells, thereby increasing the risk of serious side effects if not carefully managed. This has been evidenced in recent FDA findings and concerns for cardiac insult, kidney disease, and even brain dysfunction. In contrast, BTI-320 targets enzymes in the mouth and small intestine to reduce the uptake of glucose during the digestion of carbohydrate foods. We believe this preemptive, non-systemic approach to blood sugar management provides for a broader safety profile as well as the ability to work with other systemic blood lowering agents like insulin. All this leads to lower prescription drug dosing and longer-term effectiveness. The BTI-320 profile is enhanced due to its GRAS (Generally Regarded as Safe) classification of its components. SUGARDOWN® has a similar mechanism of action and designation.

In February 2013, we reported positive results from a Phase II clinical study conducted at Dartmouth-Hitchcock Medical Center that evaluated the safety and efficacy of BTI-320. The study evaluated BTI-320 in 24 patients with Type 2 diabetes between the ages of 18 and 75 with a body mass index (BMI) of 25-40 kg/m2 and with a HbA1c (a lab test that shows the average level of blood glucose over the previous three months) of less than or equal to 9 percent. The primary endpoint of this study was to demonstrate a reduction of incremental area under the curve (AUC) of post-meal blood glucose by 20%.

In this study, forty-five percent (45%) of patients responded positively with a forty percent (40%) reduction of post-meal glucose in the blood compared to baseline in a dose-dependent manner. Additionally, results showed the effect of BTI-320 does not correlate with duration of diabetes, and worked safely regardless of concurrent diabetes medications. There was no severe hypoglycemia (low blood sugar episodes), gastrointestinal side effects were mild and satiety (fullness) was observed. In the article published in the July/August 2013 issue of the peer reviewed journal, *Endocrine Practice*, there were no serious adverse events (SAEs) from the data analysis of the open-label dose escalation crossover trial on patients with Type 2 diabetes.

In 2012, with Advance Pharmaceutical Ltd, Hong Kong, we conducted a clinical study glycemic test at the University of Sydney in Australia. The results showed the post-meal incremental area under the curve (iAUC) for glucose and insulin were significantly lower following consumption of SUGARDOWN® prior to a controlled high carbohydrate meal of rice in a dose-dependent manner. This resulted in a reduction of up to 61 percent in post-meal elevation of blood glucose compared with the rice consumed alone. On average, there was a 32 percent reduction in the post-meal iAUC for glucose and a 24 percent reduction in post-meal insulin response for the volunteers in the study. No severe adverse effects were reported or observed during the study. SUGARDOWN® was tested in healthy, but overweight, adults with a mean body mass index (BMI) value of 27.3 kg/m2. This clinical study indicated that SUGARDOWN® can maintain healthy glucose levels even after meals, when sugar tends to spike. (Studies are under monograph review)

In October 2014, we reported results from a pilot Phase IIb study of BTI-320 in patients with Type 2 diabetes conducted in the U.S. by Accumed Research Associates. The trial enrolled 23 patients with Type 2 diabetes diagnosed for at least one year and who were on a stable daily dose of Metformin for at least three months. The patients were administered BTI-320 and Metformin using a randomized, double-blind, placebo-controlled, dose-ranging, three-way cross-over study design. Of the 23 patients that completed the trial, 15 patients did not demonstrate a measurable difference in response by reporting a significant reduction from normal to the rice test meal. The remaining eight patients responded to BTI-320 with up to a 34% reduction in post meal blood glucose levels. Patients were given one to two BTI-320 tablets, half of the dose of the Dartmouth study and one third the dose of the University of Sydney trial. The results of the trial showed BTI-320 as safe and well tolerated, with no serious adverse events reported and provided information on different patient populations to be used to design the appropriate protocols for future clinical trials. This also demonstrated the value and the need for continuous glucose monitoring as a way to capture the post prandial effect on sugar reduction, an effect not seen with the present medications in the US.

In 2016, Advance Pharmaceuticals Ltd. HK, completed and reported the 60 patient continuous glucose monitoring (CGM) proof of concept trial, and reported no increases in fructosamine, a short term measure of glycation of plasma protein (none was anticipated due to the non-diabetic population), and a significant decrease in the *post prandial* blood glucose acute rise in blood sugar in high risk Asia pre-diabetic patients. The trial was fully reported on Clinicaltrials.gov and the abstract was accepted and presented at the June 2017 American Diabetic Association meeting in June. The data sets were embargoed and the manuscript has been submitted for publication.

We began a new clinical trial during the fourth quarter of 2018. The trial is anticipated to enroll up to 60 patients with the expansion of up to at least 360 patients in a 24 week evaluation study which is designed as a randomized, placebo-controlled, double blind “international” multi-center study with two treatment arms. The trial will employ precision medical monitoring and will target the primary efficacy endpoint of Post Prandial Glucose (PPG) or immediate blood sugar excursion reductions projected to have a mean change in HbA1c levels from baseline at 24 weeks. We anticipate enrollment at a number of international centers in Europe, Asia and Australia once the 4 centers located in the U.S. have completed the initial 60 patients.

We began a proof of concept trial for vascular effect by the proprietary analysis of retinal vasculature in 2018. This study which is being performed with 40% grant funds from the Hong Kong granting agency, may demonstrate the use of BTI-320 to reduce risk of vascular disease. The Company is in licensing discussions to secure rights for the use of the proprietary technology.

BTI-410 Mechanism of Action

Both type 1 and type 2 diabetes are the result of a loss of endogenous islet structures, in which mature beta cells are housed in the pancreas. Type 1 diabetes is an autoimmune disease in which the immune system destroys existing insulin producing cells rendering the patient immediately insulin dependent for life. Type 2 diabetes is a slow progressive destructive process of over taxing and "wearing out" of insulin producing cells that leads eventually to insulin dependence. Most medications currently on the market for diabetes are either and insulin derivative or a treatment that affects only the symptoms of diabetes, and not the underlying pathology for the destruction of insulin production and proper control. This beta cell burn out results from insufficient islet mass and function.

BTI-410 or Human proIslet peptide (HIP) has been shown to increase islet mass and insulin secretion. Islet mass includes functional mature beta cells which are the cells that secrete insulin. However, the mechanism of action is still being fully elucidated and appears to be a complicated pathway with several potential modulators. HIP is an active binding fragment of the REG3a protein that is encoded by the REG3a gene (Dusetti *et.al.*, 1994). REG3a binds to the membrane bound receptor EXTL3 on the surface of progenitor cells in the pancreas. This pathway is key in the development of new insulin producing islet structures in the pancreas. These structures contain all cell types required for insulin secretion, its control and appropriate response to glucose in the blood. Increased insulin production and appropriate control has been at least partially restored after treatment with BTI-410 in a 32 patient Phase 1b study in type 2 diabetes. A further definitive Phase II study in type 2 diabetes will provide pivotal outcome results.

In 2012, a Phase 1a First-in-Man study was completed in which ascending doses of BTI-410, ranging from 60 mg to 720 mg, appeared to be safe and well tolerated by all subjects in the study.

In 2014 a Phase 1b, entitled "A Randomized, Double-blind, Placebo-controlled Study of the Effect of 49 days of Treatment with Repeated Subcutaneous Doses of HIP2B (BTI-410) to Assess Safety, Tolerability and Measures of islet β-cell Function in Subjects with Type 2 Diabetes Mellitus Treated with Metformin", was initiated.

In 2015, BTI-410 (HIP2B) Phase 1b was completed. Despite the small sample size, compared to treatment with placebo, treatment with HIP2B resulted in improvements in mean insulin concentrations measured by GGI from baseline to Day 46 that trended toward significance. Similarly, mean change in pre-hepatic insulin secretion rate from baseline to Day 46 was statistically significant in the combined HIP2B treatment groups compared to placebo. Trends in increased mean insulin concentrations (as measured via GGI and IVGTT) continued following the cessation of treatment to the follow-up visit in the HIP2B dosing groups.

A study with a larger sample size powered for efficacy along with a longer duration of treatment will be required to more fully describe the magnitude of efficacy of HIP2B on glycemic and insulin secretion parameters.

Based on post-hoc subgroup analyses, subjects with low FPG and HbA_{1c} levels at baseline showed a more consistent response to HIP2B with respect to changes in insulin and C-peptide levels when compared to placebo. In addition, when data were analyzed by excluding three hyperinsulinemic subjects, the effects of HIP2B on fasting insulin levels measured during the study achieved statistical significance after 84 days. These data also suggest that the effects of HIP2B continue for at least one month after stopping treatment.

IPOXYN and OXYFEX

IPOXYN (research investigative material) is a carbohydrate-based protein associated material, intravenous injectable solution that potentially can prevent hypoxic conditions and cell death due to oxygen debt. Treating these hypoxic conditions may also relate to wound healing (both internal and external) such as diabetic foot ulcers and other vascular complications of diabetes. IPOXYN, an oxygen carrier blood substitute or red blood cell bridging agent, has a very broad range of potential applications, including but not limited to, tissue death prevention, wound healing, traumatic blood loss, traumatic brain injury, stroke, cancer, surgery, transplant and anemia. In addition, since donated human blood needs refrigeration and has a shelf life of less than one month, IPOXYN can serve as an adjunct to or immediate replacement for donated blood in trauma and surgery cases when there are human blood supply deficiencies.

Hypoxia is a condition in which cells lack sufficient oxygen delivery to support metabolic function. As evidenced by the well-established record of data relating to similar products, the IPOXYN carbohydrate molecule contains oxygen rechargeable iron which picks up oxygen in the lungs, is 1,000 times smaller than a red blood cell (or RBC), and can reach hypoxic tissue more effectively than RBCs. IPOXYN is stable at room temperature, has a three year shelf life and requires no blood type matching. We plan to introduce this product in clinical trials for hypoxic medical conditions.

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. Acute hypoxic 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.

Upon raising the appropriate capital, we intend to develop OXYFEX, a veterinary analog to IPOXYN. 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.

IPOXYN and OXYFEX consist 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 not conducted any clinical trials to confirm the efficacy of or filed any applications with the FDA with respect to, 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. Our goal is to file an IND application with the FDA, provided we obtain adequate funding. We expect to have access to the pilot-scale manufacturing facility of a third party with adequate capacity to produce IPOXYN for clinical trials and market introduction.

We have 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 in 2018. 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.

Drug Development Status

BTI-320 is one of our lead product candidates and is currently in Phase II clinical development. We have contracted a CRO (contract research organization) in New York City and plan to initiate trials in the first half of 2018 subject to raising adequate capital. Following Phase II clinical trial results reported in 2013 and the Phase IIb clinical trial concluded in October 2014, the FDA accepted the first Investigational New Drug Application (or IND) We proposed for BTI-320 to treat Type 2 diabetes and weight management. Joslin Diabetes Center in Boston may serve as a lead clinic for the multi-center, multi-country trial that is planned to commence in 2018 subject to use receiving adequate funding. The trial may enroll up to 360 patients in the 24-week study which is being designed as a randomized, placebo-controlled, double blind international multi-center study with two treatment arms. One of the primary endpoints of efficacy of the trial is the mean change in HbA1c levels from baseline at 24 weeks. This is anticipated to be conducted at a number of international centers located possibly in the U.S., Europe, Asia and Australia. BTI-410 is our other lead product candidate and, pending production of new Active Pharmaceutical Ingredient (API) material, is ready for Phase II development in both type 1 and type 2 diabetes patients, pending sufficient funding. Development of IPOXYN is in the pre-clinical planning stage and further development is on hold pending the securing of adequate funding.

BTI-320

In March 2014, following the successful results of the Dartmouth study, we received and additional Institutional Review Board (IRB) approval to initiate a clinical study of BTI-320 in the United States. In October 2014, we completed a Phase II trial in the United States and we are currently delaying any additional Phase II trial efforts in France due to enrollment performance issues and lack of resources to support the effort. These trials were designed to add CGM (continuous glucose monitoring) and better define PPG effects that support the results from our Dartmouth study for BTI-320. In the Dartmouth study, BTI-320 was well tolerated in patients taking various anti-diabetic agents, including Metformin. The recent additional clinical trial in the U.S. showed BTI-320 was safe and well tolerated with no serious adverse events reported. The FDA has accepted an IND, which was filed for BTI-320 to treat Type 2 Diabetes and weight management. Subject to adequate funding, we tentatively are planning to commence additional future clinical trials for BTI-320.

BTI-410

In January 2018, Boston Therapeutics acquired the exclusive worldwide rights to the patent portfolio for the HIP2B peptide. In 2012, a Phase 1a study established a good safety and tolerability profile of BTI-410. In 2015, with the completion of Phase 1b study and based on promising results in type 2 diabetes patients, the company is planning two pivotal clinical studies pending sufficient funding. One study will be in type 1 diabetes patients who are immunosuppressed after having undergone kidney transplant, and one study will be in type 2 diabetes patients on metformin, but who are still experiencing post-prandial high glucoses and remain on the trajectory toward the need for insulin.

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 that is proposed to be 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 intent investigative materials 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 and logistics of RBC transfusion in all parts of the world.

In addition to the expansive and broad application field development of human medical management, we envision a sizable and very accepting market in the veterinary field. We could 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.

Preliminary data from animal testing conducted by third parties as well as similarity testing suggests successful use of OXYFEX in hypoxia and critical anemic situations, where hypoxic conditions were critical to animal survival. Other early experiments with similarly experimental materials with dogs suggest intervention with OXYFEX will significantly improve survival in induced canine anemia models. This veterinary treatment of signs and symptom of canine anemia may be one of our first targets 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 OXYFEX. Testing included repeated intravenous infusions of the product in dogs that was reported in documented literature and private 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 materials 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. No further development work has been conducted on IPOXYN pending securing adequate funding and finalizing strategy as to the best development plan. We also will move forward with new designations at to these investigative similar materials as the funding or alliance partnering is secured. We recently were issued composition of matter patents in this line of material development. We also have secured a relationship with a company now making the base material. They may gain facility approval during 2019.

Market Opportunity

Diabetes and Metabolic Disease Related Illness

According to the International Diabetes Federation, in 2017, 425 million people worldwide are living with diabetes and that number is projected to increase to 629 million by 2045. In the United States alone, the Center for Disease Control estimated that there were 30.3 million people living with diabetes and an estimated 84 million people who were pre-diabetic in 2017. Standard therapies for diabetes include physician recommended diet and exercise, oral hypoglycemic drugs such as Metformin for Type 2 diabetes and insulin injection regimens for people with Type 1 diabetes. The objective of each is to manage a daily blood glucose level range recommended by a physician. Each of the current therapies alone has its limitations including numerous side effects and all treat the lack of control the system has to reduce the excesses of immediate sugar exposure absorbed in the gut.

According to Standard & Poor's, the diabetes drug market is estimated to be $26.8 billion in 2016 and is on pace to grow to more than $64 billion by 2025. Pharmaceutical companies have been investigating new approaches to treating diabetes and market value has been maintained in the industry due to the introduction of these new products. We believe that both BTI-320 and BTI-410 represents a near-term commercial opportunity in a large and growing diabetes market worldwide. BTI-320 is pharmacologically differentiated from commercially available PPG drugs via its apparent efficacy without severe side effect. BTI-410 is pharmacologically differentiated from commercially available diabetes treatments by virtue of its novel mechanism and long pharmacodynamics profile, and therefore short term treatment phase.

Hypoxia

Development of IPOXYN (investigational material) is in the pre-clinical stage and no work has been done in the past 2 years due to the lack of funding. Our injectable drug candidate, IPOXYN, will potentially compete with existing therapies for the treatment of hypoxia or anti-necrosis that according to Global Industry Analysts, Inc. has a global market opportunity of $1 billion. Hypoxia is a condition in which cells lack sufficient oxygen supply to support metabolic function. 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 red blood cells to deliver oxygen to the body; and transfusions involve many risks and limitations, the most significant is the ability to "deliver oxygen". The standard therapy for reversing hypoxia is blood infusion, RBCs or hyperbaric oxygen. Hyperbaric medicine or hyperbaric oxygen therapy (HBOT) is a medical term for using oxygen at a level higher than atmospheric pressure. The HBOT treatment can only be done at a medical facility and each session can cost from $200 to more than $1,000 for the 90-minute chamber exposure. For decades, oxygen carriers have been developed for perfusion and oxygenation of ischemic tissue; none have yet succeeded in becoming an artificial blood component or an immediate blood or oxygen carrier substitute for the RBC's. These past products were either expired blood-derived elements, synthetic perfluorocarbons, or red blood cell modifiers. According to a Brown University study, there is a global shortage of safe transfusion suitable blood of 110 million units, and the need for blood is rising 6-7% annually. IPOXYN, a blood substitute, has a broad range of potential applications, including but not limited to, tissue death prevention, wound healing, traumatic blood loss, traumatic brain injury, stroke, cancer, surgery, transplant and anemia.

Veterinary Market

Development of OXYFEX™ is in the pre-clinical stage and no work has been done to date due to the lack of funding. We plan to commence marketing OXYFEX™ for veterinary applications, which we view as a potentially lucrative market once we receive the necessary approvals in the U.S. and globally. As of now, no development work has been conducted on OXYFEX pending securing adequate funding and finalizing strategy as to the development plan. 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, dietary supplements or inspired oxygen.

Our Product Candidates

Our primary business is the development, manufacture and commercialization of therapeutic drugs with a focus on complex carbohydrate chemistry and peptide therapeutics to address diabetes and diabetes related complications. We are currently focusing on two drug candidates. BTI-320, a non-systemic, non-toxic, drug candidate taken before carbohydrate meals, is designed to improve post-meal blood sugar control in patients with Type 2 diabetes. BTI-410 is a peptide injectable compound designed to stimulate development of new insulin producing cells in the pancreas to alleviate stress on existing cells in type 2 diabetes patients and in type 1 diabetes patients who are on immune suppression after having undergone kidney transplant surgery. We intend to develop BTI-320 and BTI-410 to commercialization or commercial partnership to the extent that opportunities exist.

We intend to develop IPOXYN pending securing adequate financing and finalizing strategy, which may include partnerships, to establish the best development plan. We may also develop IPOXYN, an injectable drug candidate for prevention of necrosis and treatment of hypoxia. IPOXYN is a polysaccharide based therapeutic agent using proprietary processes and patented technology. Our IPOXYN drug consists of a stabilized polysaccharide 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 Global Industry Analysts, Inc., the global market opportunity for anti-hypoxia or anti-necrosis technology is $1 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

BTI-320

Overview

BTI-320 is one of our lead product candidates and is currently in Phase II clinical development. We began additional clinical trials during 2019.

BTI-320 acts in a similar fashion to a Carbohydrate Hydrolyzing Enzyme Inhibitors (CHEI) for treatment of patients with Type 2 diabetes. BTI-320 initially targets improved management of post-meal blood sugar excursions in patients currently taking Metformin and potentially other anti-diabetic agents

BTI-320, a non-systemic, non-toxic, drug candidate taken before carbohydrate meals, is designed to improve post-meal blood glucose control in patients with Type 2 diabetes. BTI-320 acts non-systemically in the gastrointestinal tract to inhibit the enzymes that cleave complex carbohydrates from foods into simple sugars, reducing available glucose during the period following a meal. BTI-320 initially targets improved management of post-meal blood sugar in patients currently taking Metformin and potentially other anti-diabetic agents.

According to the International Diabetes Federations 2011 report, Guideline for Management of Post-meal Glucose in Diabetes, addressing both post-meal plasma glucose and fasting plasma glucose is an important strategy for achieving optimal glucose control, and that evidence points to a relationship between an acute increase in blood sugar, particularly after a meal, and cardiovascular disease. We completed a BTI-320 Phase II clinical trial in patients with Type 2 diabetes.

Status of Development of BTI-320

BTI-320 is developed as a drug candidate. In October 2011, we announced the initiation of our clinical trial at Dartmouth-Hitchcock Medical Center in New Hampshire to evaluate the safety and efficacy of BTI-320 when added to oral agents or insulin regimen in patients with Type 2 Diabetes Mellitus. In July 2012, we announced the completion of patient enrollment. In February 2013, we announced that BTI-320 reduced the elevation of post-meal blood sugar by forty percent with no serious adverse events. The study evaluated BTI-320 in 24 patients with Type 2 diabetes between the ages of 18 and 75 with a body mass index (BMI) of 25-40 kg/m2 and with HbA1c of less than or equal to nine percent. HbA1c is a lab test that indicates the average level of blood sugar (glucose) over the previous three months.

Forty-five percent of patients responded with an average forty percent reduction of post-meal glucose in the blood compared to baseline in a dose-dependent manner. Additionally, results showed the effect of BTI-320 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 full article for the clinical study was published in the July/August 2013 issue of *Endocrine Practice*, a peer-reviewed journal.

In October 2014, we reported results from a Phase IIb study of BTI-320 in patients with Type 2 diabetes conducted in the U.S. by Accumed Research Associates. The trial enrolled 23 patients with Type 2 diabetes diagnosed for at least one year and who were on a stable daily dose of Metformin for at least three months. The patients were administered BTI-320 and Metformin using a randomized, double-blind, placebo-controlled, dose-ranging, three-way cross-over study design. Of the 23 patients that completed the trial, 15 patients did not yield measurement differences from normal to the rice test meal. The remaining eight patients responded to BTI-320 with up to a 34% reduction in post meal blood glucose levels. Patients were given one to two BTI-320 tablets, half of the dose of the Dartmouth study and one third the dose of the University of Sydney trial. The results of the trial showed BTI-320 as safe and well tolerated, with no serious adverse events reported and provided information on different patient populations to be used to design the proper protocols for future clinical trials. We are in the process of advancing this study to a publication.

BTI-410

Overview

BTI-410 is another of our lead product candidates and is currently seeking manufacture for Phase II clinical development. Subject to us obtaining adequate funding. We expect to begin the appropriate disposition of this material including a return to CureDM for timely execution.

BTI-410 is a Beta Cell Maturation Stimulator (BCMS) for treatment of patients with Type 2 diabetes and type 1 diabetes patients who are on immunosuppression. BTI-410 initially targeted improved insulin secretion in type 2 patients currently taking Metformin and potentially other anti-diabetic agents. However, type 1 patients who are immunosuppressed are a specific population in need of this type of treatment and may provide a faster path to approval.

BTI-410, a short term, injectable drug candidate taken twice daily, is designed to stimulate beta cell maturation in patients with Type 2 diabetes. BTI-410 acts in the pancreas to stimulate the pathway that leads to the differentiation of new islet structures that include new populations of beta cells. BTI-410 initially targets improved management insulin secretion in patients currently taking Metformin and potentially other anti-diabetic agents.

Status of Development of BTI-410

BTI-410 is developed as a drug candidate. In 2011, IND was established and Phase 1a was completed with Celerion in Lincoln, NE. In 2014, patient enrollment began and for Phase 1b in type 2 diabetes patients on Metformin with Profile Institute for Clinical Research in Chula Vista, CA. In 2015, dataset was locked and in 2016 results of this study were presented at the 77th Conference of the American Diabetes Association. Publication is being completed for submission in 2018.

As the primary objective, results indicated that twice daily subcutaneous injections of HIP2B at 400 mg and 600 mg for 49 days were well tolerated in subjects with T2DM on metformin, with no clinically significant changes in clinical laboratory values, ECGs or vital signs during the study, and no deaths or withdrawals due to AEs.

Despite the small sample size, compared to treatment with placebo, treatment with HIP2B resulted in improvements in mean insulin concentrations measured by GGI from baseline to Day 46 that trended toward significance, mean change in pre-hepatic insulin secretion rate from baseline to Day 46 was statistically significant in the combined HIP2B treatment groups compared to placebo, improvements in mean insulin concentrations as measured by GGI and IVGTT, including some that seemed to persist during the post- treatment period. Improvements in insulin secretion levels, and improvements in control of insulin secretion under glucose challenge, is the benefit of beta cell maturation as a mechanism, which lead to improvement in HbA1c. Based on these results, we plan a larger definitive Phase II study will quantitatively elucidate these effects of HIP2B as an important new treatment option for Type 2 Diabetes.

We also may plan a Phase II study in type 1 diabetes patients who are on immunosuppression as a function of a kidney transplant. This patient population produces almost no endogenous insulin, so stimulation of new insulin producing beta cells in this population will be transformative and a clear proof of concept for BTI-410 as an important therapeutic strategy in the treatment of diabetes.

Products Competitive with BTI-320 and BTI-410

Anti-diabetic drugs. Anti-diabetic drugs treat diabetes mellitus by lowering glucose levels in the blood. With the exceptions of insulin, insulin analogues and Glucagon-like Peptide-1 Agonists, 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. BTI-320 is the first compound in a new class of therapies called Carbohydrate-Hydrolyzing Enzyme Inhibitor (CHEI) for treatment of patients with Type 2 diabetes. BTI-320 acts non-systematically in the gastrointestinal tract to inhibit the enzymes that cleave complex carbohydrates from foods into simple sugars, reducing postprandial glucose excursion (post-meal blood sugar elevation). BTI-410 is a first in the new class compounds that stimulate beta cell maturation to regenerate endogenous insulin production and its control.

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.

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.

IPOXYN and OXYFEX™

Overview

Development of IPOXYN is in the pre-clinical stage and no work has progressed due to financial constraints. IPOXYN is designed for delivery as an intravenous solution, with the expectation that it can support an inadequate supply of RBC oxygen needed to maintain metabolic functions in the body. It may function without the limitations of compatibility, availability, short shelf life, volume and logistical challenges commonly associated with transfusions of whole blood and packed red blood cells. 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 carry oxygen. At present 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.

Upon securing adequate funding, we plan to introduce this investigational product into 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 normal metabolic functions. 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 proliferate by other pathways 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 due to size from free flow and distribution and thus the delivery of oxygen. 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 perfuse the small vessels which have lost their ability to permit RBC distribution and thus oxygen delivery. 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 an RBC replacement 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.

Products Competitive with IPOXYN

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 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 will have the following advantages:

- *Availability:* readily available, with at least three year shelf-life (much longer than the five week plus shelf life for RBCs) and easier to perfuse.
- *Stability:* stored at room temperature for years 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 and partially occluded 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. These include such techniques as 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 OPK Biotech, 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 are aware of other companies researching the use of hemoglobin as a therapeutic, including programs in China and Japan. 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.

We believe that these programs are still in the preclinical stage of development. We believe that our use of controlled source bovine materials for the production of IPOXYN is an advantage over products made from donated expired 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.

SUGARDOWN®

Overview

We have developed and currently produce and test market sell SUGARDOWN®, a non-systemic complex carbohydrate-based dietary food supplement to support healthy post-meal blood glucose using proprietary processes and technology. We will 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 regulated as a dietary supplement. Our SUGARDOWN® designated dietary supplement consists of a complex carbohydrate composition.

Status of Development of SUGARDOWN®

We completed development of SUGARDOWN® as an over the counter (OTC) dietary 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. We have submitted thirty structural and functional claims with the FDA. We currently have strategically filed national stage patent applications pending that are directed to the Composition of purified mannans, which are utilized in the formulation of SUGARDOWN®. We have also received a registered mark for SUGARDOWN®. General Product Liability Insurance for SUGARDOWN® has been in effect since April 2010. On January 24, 2012, we announced the clinical test results in healthy volunteers performed at the Sydney University Glycemic Institute for Research with SUGARDOWN®. On January 28, 2013, we 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 61% 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.

Licensing Agreement with Advance Pharmaceutical Company

On June 24, 2011, we entered into a definitive Licensing and Manufacturing Agreement (the "Agreement") with Advance Pharmaceutical Company ("Advance Pharmaceutical"), a Hong Kong-based, privately-held company and a significant stockholder of ours.

Under terms of the Agreement, we will manufacture and supply product in bulk for Advance Pharmaceutical. Advance Pharmaceutical may be responsible for the packaging, marketing and distribution of SUGARDOWN™ in Hong Kong, China and Macau. In November 2014, we agreed to expand their marketing agreement to include 12 additional countries: Korea, Taiwan, Singapore, Thailand, Malaysia, Vietnam, Philippines, Myanmar, Indonesia, Laos, Brunei and Cambodia. In March 2015, we agreed to expand their marketing agreement to include Japan. Advance Pharmaceutical will also have rights to develop and manufacture SUGARDOWN™ for commercial sale in these countries, subject to establishment of quality assurance and quality control standards set forth by us. The Agreement provides that Advance Pharmaceutical will pay royalties to us for SUGARDOWN™ and related products developed by us and a reduced royalty rate for products based on our intellectual property and developed by Advance Pharmaceutical. Revenue generated through this agreement for the years ended December 31, 2018 and 2017 were approximately $0 and $52,000 in sales and $0 and $7,000 in royalties, respectively.

Marketing SUGARDOWN®

We believe SUGARDOWN® is a safe and effective designated dietary supplement that can help support healthy after-meal blood sugar excursions out of normal ranges and support a weight management plan by helping to curb appetite if taken before meals. The product is ready for limited market release and is currently available for distribution in some Asian markets and is available for sale in the U.S. through our product website, www.sugardown.com.

To date, our marketing plan for SUGARDOWN® has been test marketing and to out-license marketing rights to strategic partners in their jurisdictions of expertise. In June 2011, we entered into an agreement with Advance Pharmaceutical Co. Ltd., our Hong Kong-based strategic partner that is also a significant stockholder of ours, to develop markets for SUGARDOWN® in Hong Kong, China and Macau. (See licensing partnership above)

Overview of Diabetes

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 sufficient 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 30.3 million people in the United States in 2017. 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 84 million Americans in 2017.

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.

People with Type 2 and Type 1 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.

Overview of 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 red blood cell contained (RBC) 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 borne 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.

Business Strategy

Our business strategy primarily consists of the following:

- to advance our leading clinical stage drug candidates, BTI-320, BTI-410, and IPOXYN/OXYFEX through staged regulatory approvals in the United States and the European Union and, if successful, to commercialize BTI-320 and BTI-410 either on our own or with one or more strategic partners in the U.S. and/or outside of the U.S.; and

- to drive brand awareness and increase sales of SUGARDOWN® in North America and globally in 2018 and beyond and to further study the potential beneficial characteristics of SUGARDOWN®.

We intend to establish and implement clinical development programs that add value to our business in the shortest period of time possible and to seek strategic partners when a program becomes advanced and requires additional resources. We intend to continue focusing our expertise and resources to develop novel formulations, and to leverage development partnerships to apply our complex carbohydrate chemistry and peptide therapeutic design in other medical indications. We may seek to enter into licensing, co-marketing, or co-development agreements across different geographic regions, in order to avail ourselves of the marketing expertise of one or more seasoned marketing and/or pharmaceutical companies. Our strategy is to leverage considerable industry experience, expertise in complex carbohydrate chemistry, peptide therapeutic discovery and development and clinical development experience to continue to identify, develop and commercialize product candidates with strong market potential that can fulfill unmet medical needs in the treatment of diabetes and diabetes related complications. We plan to further develop new and proprietary drug candidates to provide improved efficacy and safety by using novel development pathways specific to each candidate.

A core part of our strategy relies upon creating safe and efficacious drug formulations that can be administered as standalone therapies or in combination with existing medications. We believe our novel approach of creating safe and efficacious drug formulations that can be combined with existing therapies and potentially deliver valuable products in areas of high unmet medical needs. We intend to assemble a new scientific medical advisory board consisting of scientists and medical people with both academic and corporate research and development experience that will provide leadership and counsel in the medical, scientific, technological and regulatory aspects of our current and future projects.

We believe that our highly experienced drug development leadership provides us with a significant competitive advantage in designing highly efficient clinical programs to deliver valuable products in areas of high unmet medical needs.

Key Strengths

We believe that our key differentiating elements include:

- **Focus on novel therapeutic opportunities provided by carbohydrates:** We are focused on development of carbohydrate-based compounds to better manage blood glucose and diabetes related complications. As a result of its structural complexity, carbohydrates have not received as much scientific attention as nucleic acids and proteins. Carbohydrate-based therapeutics have proven to be efficacious and safe, while elimination many common side effects from other types of drugs.
    - **Focus on novel therapeutic opportunities provided by Peptides:** We are focused on development of peptide-based compounds to better manage blood glucose and diabetes related complications. Peptides are recognized for being highly selective and efficacious and, at the same time, relatively safe and well tolerated. In general, peptides are selective and efficacious signaling molecules and given their attractive pharmacological profile and intrinsic properties, peptides represent an excellent starting point for the design of novel therapeutics and their specificity has been seen to translate into excellent safety, tolerability, and efficacy profiles in humans.
- **Experienced management:** Carl Rausch is a leader in the field of oxygen therapeutics products and through the years was responsible for the only manufactured and tested, and approved materials in this field as supported through publications and product approvals in Russia and South Africa for the human version and for the Veterinary world in the European Union and for the US FDA.
- **Products are differentiated from other investigative materials and address significant unmet needs:** Our three lead product candidates, BTI-320, BTI-410 and IPOXYN, are well-differentiated diabetes-related formulations that address important unmet medical needs. Diabetes prevention and management, including excessive blood sugar management, regeneration of insulin production and control, and treatment of diabetes related complications, remains a critical area of unmet need. Increasingly, patients, physicians and the media are highlighting the deficiencies of current diabetes-related therapies and the growing population of affected individuals.

- **A multiple product portfolio with a balanced risk reward profile:** We have three lead product candidates and a dietary supplement product currently generating a small revenue with what we believe can lead to significant growth prospects. We have added a peptide therapeutic and peptide therapeutic discovery and development to our pipeline. Accordingly, we believe that the revenues we generate from our advanced products and drug candidates will offset costs related to developing our existing and future pipeline.
- **Efficient development strategy:** We believe that our strategy of development of the dietary supplement in parallel with BTI-320 will shorten the approval process of BTI-320 by providing a broad history of safety. We believe that a Phase II study of BTI-410 in type 1 patients with kidney transplants will provide a shortened path to approval based on the possibility of orphan drug approval. We believe that the FDA's 505(b)(2) regulatory pathway for IPOXYN and its veterinary analog, OXYFEX, lowers the risk of drug development of these drug candidates. Our strategy of combining these drugs, once approved, with novel delivery methods and pharmaceutical compositions is expected to significantly reduce clinical development time and costs and lowers regulatory risks, while delivering valuable products in areas of high unmet need to the market place.

Subsidiaries

Effective January 1, 2018, we acquired CureDM Group Holdings, LLC as a wholly owned subsidiary. This provides for our exclusive world-wide rights to the peptide composition and uses for both type 1 and type 2 diabetes. Because this acquisition was in 2018, it is not included in our consolidated financial statements at December 31, 2017. Due to our limited capital and management resources, during the first quarter of 2019, we have begun discussions with CureDM, Inc. to unwind the merger acquisition of CureDM Group Holdings, LLC. The discussions remain preliminary at this time.

Employees

The Company employs Carl W Rausch as our Chief Executive Officer. Mr. Rausch works under consultant contract with the Company for significant cost savings at the present time. The Company employs other consultants to assist with the operation of the business as needed.

Facilities

We do not lease office space at this time. We did lease office space at 354 Merrimack Street, Lawrence, MA 01843 on a month to month basis. This concluded in September 2018, although we do maintain mail service there. With the acquisition of CureDM, we now also lease office space on a month-to-month basis at The BioScience Center 5901 Indian School Rd., Albuquerque, NM 87110.

Manufacturing

We currently contract with a third-party to manufacture BTI-320 and SUGARDOWN® in the United States at a Good Manufacturing Practices (GMP) compliant facility. We are evaluating whether to gain access to a pilot-scale manufacturing facility with adequate capacity to produce IPOXYN for clinical trials and market introduction following FDA/European Medicines Evaluation Agency (EMEA) 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 GMP as required by the regulatory authorities in Europe or the United States. We in the evaluating a contract with Chinese Peptide Company (CPC) in Hangzhou, China to manufacture the Active Pharmaceutical Ingredient (API) of BTI-410 and the formulation, fill and finish will be completed through third-party suppliers in the US. CPC and all other contractors are fully FDA compliant and are required to pass regular FDA inspections.

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 in the United States. We have one significant customer, Advance Pharmaceutical Co. Ltd., the Hong Kong-based pharmaceutical company (alliance partner), a significant stockholder of ours, for distribution of SUGARDOWN® in Hong Kong, China and Macau. These authorized territories were recently expanded to include Korea, Taiwan, Singapore, Thailand, Malaysia, Vietnam, Philippines, Myanmar, Indonesia, Laos, Brunei, Cambodia and Japan. One of our directors, Conroy Chi-Heng Cheng, is also a director of Advance Pharmaceutical Co. Ltd.

Intellectual Property

Patents, trademarks, trade secrets, technological know-how and other proprietary rights are important to our business. Our patent portfolio is directed to four main areas, peptide composition of matter and uses, mannans, hemoglobin composition and methods of use, and taste masking in chewable tablets. The active ingredient in BTI-410 is a peptide derived from a human protein. It is synthesized chemically and not extracted or purified from a biologic source. It is stabilized and all compositions and modifications are patent protected. The uses of this peptide for the treatment of type 1 and type 2 diabetes is also protected. The active ingredient in BTI-320 is a mannan, and BTI-320 is a proprietary fractionated mannan. Mannans are a group of plant-derived complex carbohydrates, or polysaccharides, which consist mainly of polymers of the sugar mannose. Some of the plants from which mannans are derived are guar, locust bean, fenugreek, barley and konjac. Published studies on mannans have shown that they possess significant biological activity ranging from inhibition of cholesterol absorption to promoting wound healing and inhibiting tumor growth. Studies have also shown that consuming mannans before a meal may lessen the rise in blood glucose after the meal. Therefore, supplementation with mannans may be beneficial in the management of diabetes by supporting healthy blood sugar levels. We seek to strengthen our patent portfolio and increase market exclusivity as we progress in our clinical development process. During the clinical development and commercial scale up of our products, we anticipate additional intellectual property may be realized from the creation of novel therapeutic formulations, methods of manufacture, methods of use and novel quality control assays for each of our products. Our intellectual property estate directed to our technology and products consists of four international patent applications and their related national stage applications entitled: Composition of Purified Soluble Mannans for Dietary Supplements and Methods of Use Thereof (W02012/061675); Hemoglobin Compositions and Methods of Use (WO2012/78850); Encapsulation of Pharmaceuticals for Taste Masking in Chewable Tablets (PCT/US14/27243); and Compositions for Inhibiting Amylase Mediated Hydrolysis of Alpha (1-4) Linked Glucose Polymers (WO PCT/US16/31120). The international patent application entitled Hemoglobin Compositions and Methods of Use and its related national stage filings, which were assigned to us by Dr. Platt, are directed to our IPOXYN and OXYFEX technologies. National patent applications related to Hemoglobin Compositions have been recently allowed in the jurisdictions of Europe and China. Additional Hemoglobin Composition applications are pending in the United States and Hong Kong. The international patent application entitled Composition of Purified Soluble Mannans for Dietary Supplements and Methods of Use Thereof and its related national stage filings, which were assigned to us by Dr. Platt, are directed to our BTI-320 and SUGARDOWN® technologies. National patent applications related to the Purified Soluble Mannans have been recently allowed in China and Hong Kong. Additional Purified Soluble Mannans applications are pending in the United States, Korea and Europe. The international application entitled: Compositions for Inhibiting Amylase Mediated Hydrolysis of Alpha (1-4) Linked Glucose Polymers will enter its national phase in November of 2017. Dr. Platt also has assigned the trademarks IPOXYN (U.S. Trademark Application No. 77754473) and Avanyx Therapeutics™ (U.S. Trademark Application No. 77806120) to us. Dr. Platt and our former President Mr. Tassey have assigned the trademark SUGARDOWN® (U.S. Trademark Reg. No. 3,955,414, registered May 3, 2011) to us.

BTI-410 is protected under the following Issued Patents:

Methods and Pharmaceutical Compositions for Treating Type I Diabetes Mellitus and Other Conditions (11/367,682 8,211,430 U.S.); Peptides, Derivatives and Analogs Thereof, and Methods of Using Same (7,393,919 (11/441,491 U.S.) Peptides, Derivatives and Analogs Thereof, and Methods of Using Same (7,714,103 (12/121,123) and 7,989,415 (12/635,053) and 8,383,578 (13/168,461) and 8,829,158 (13/745706) and 2609667 Canada, and 2295066 Europe, 2295066 France, 60 2006 048 912.9 Germany, 2295066 Great Britain, 2295066 Ireland, 252532 India. Methods and Therapies Relating to Islet Cell Neogenesis (8,785,400 11/943,991 U.S. Compositions and Methods of Using ProIslet Peptides and Analogs Thereof 8816047 (12/674,573) U.S. and 2698100 Canada and 2008292913 Australia, 200880114452.5 (08798997.6) Europe, 2193142 China, France, Germany, Great Britain, Ireland, Italy, Netherlands, Spain, Switzerland, HK1144823 (10111411.6) Hong Kong, and 5960661 Japan

The following patents are also pending or granted for BTI-410:
Compositions and Methods of Using ProIslet Peptides and Analogs Thereof, 204183 Israel, 233024 Israel Div, PI2010000893 Malaysia, 308103 Mexico, 337147 Mexico, 159273 Singapore, 200880114452.5 China; Peptides, Derivatives and Analogs Thereof, and Methods of Using Same, 1926/MUMNP/2012 India

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. BTI-320, BTI-410 and IPOXYN will be subject to extensive regulation by governmental authorities in the United States and other countries. As a therapeutic drug administered by subcutaneous injection, BTI-410 will be regulated as a drug and will require extensive safety and efficacy studies for regulatory approval before it may be commercialized 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. BTI-320, as a drug candidate, will also require FDA approval. Before final approval for marketing for either IPOXYN or BTI-320 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. BTI-410 has achieved Investigational New Drug status and based on the phase 1a and Phase Ib safety profile, will proceed to Phase II study in type 2 diabetes, and Phase II study in type 1 diabetes patients with kidney transplants pending the establishment of protocols and FDA regulatory submission criteria.

After approval and during clinical studies the 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. The 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 or clinical site, 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 BUSINESS

We have incurred significant losses since our inception and expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We have incurred losses totaling approximately $23.4 million and have approximately $12,500 cash on hand as of December 31, 2018. Management is currently seeking additional capital through private placements and public offerings of its common stock. In addition, the Company may seek to raise additional capital through public or private debt or equity financings as well as collaboration activities in order to fund our operations. We raised $275,000 in gross proceeds from private placements of our Series A Preferred Stock during the first quarter of 2018. During the second quarter of 2018, we issued a note payable to a related party for $100,000. At the end of the third quarter of 2018, we approved a Private Placement Memorandum in an effort to raise additional funds. Also, at the end of the third quarter, the Company issued a Note Payable to CJY Holdings, Ltd, a related party, for $305,937. Also, in the fourth quarter of 2018, we increased the amount of the note payable to the related party noted above to $174,500. An additional $50,000 was advanced to the Company during April 2019. Management anticipates that cash resources will be sufficient to fund our planned operations into the second quarter of 2019. The future of the Company is dependent upon its ability to obtain continued financing and upon future profitable operations from the partnering, development and clarity of its new business opportunities. The Company may seek to raise additional capital through public or private debt or public or private equity financings, and partnerships or licensing opportunities in order to fund our operations. 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.

To stay in business, we will need to raise substantial additional capital through public or private sales of our securities, debt financing or short-term bank loans, or a combination of the foregoing. We anticipate that our expenses will increase substantially as we:

- conduct additional Phase II and Phase III clinical trials of, and further advance, our lead drug candidates BTI-320 and BTI-410, and potentially initiate pre-clinical and clinical trials for IPOXYN;
- continue the research and development of our other drug candidates, including potentially in-licensing other technologies and therapeutics;
- seek to discover and develop additional drug candidates;
- seek regulatory approvals for any drug candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale up external manufacturing capabilities to commercialize any products for which we may obtain regulatory approval; and
- maintain, expand and protect our intellectual property portfolio.

We believe we have developed a viable plan to continue as a going concern. However, the plan relies upon our ability to obtain additional sources of capital and financing. If the amount of capital we are able to raise from financing activities, together with our revenues from operations, is not sufficient to satisfy our capital needs, we may be required to cease operations.

To become and remain profitable, we must succeed in developing and commercializing products that generate significant income. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates, discovering additional drug candidates, obtaining regulatory approval for these drug candidates manufacturing, marketing and selling any products for which we may obtain regulatory approval, and establishing and managing our collaborations at various stages of each candidate's development. We are only in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate income that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical and dietary supplement product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration, or FDA, or the European Medicines Agency, or EMA, to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our drug candidates, our expenses could increase and revenue could be further delayed.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have a 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. Although we have made initial sales of our SUGARDOWN® product as a dietary supplement and, while we expect to continue selling or licensing that product, we have no other products currently available for sale, and none are expected to be commercially available before 2020, if at all. We may never obtain FDA or EMA 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 or become worthless.

We will require additional financing to implement our business plan, which may not be available on favorable terms or at all, and we may have to accept financing terms that would place restrictions on us.

We presently have an immediate need for capital, and if we do not raise capital, we may be forced to curtail operations and our business might fail. We anticipate that our cash resources will be sufficient to fund our planned operations on a month to month basis until revenue from Asia sales in 2019. Even if we are able to raise near term capital, we will need to continue to conduct significant research, development, testing and regulatory compliance activities for IPOXYN, BTI-410 and BTI-320 that, together with projected general and administrative expenses, we expect will result in operating losses for the foreseeable future. We may not generate sales or other revenue from SUGARDOWN® 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 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. If we are unable to raise additional funds, we may be forced to curtail or even abandon our business plan.

Until such time, if ever, as we can generate substantial product income, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. In addition, 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. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or making acquisitions or significant asset sales.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or drug candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock.

Our products are based on novel, unproven technologies.

Our drug candidates in development are based on novel, unproven technologies, including the use of proprietary carbohydrate compounds and proprietary peptides alone and in combination with FDA approved drugs currently used in the treatment of diabetes, ischemia, anemia and trauma and other diseases. Peptides are straightforward to synthesize but are challenging to obtain good pharmacokinetic levels without administering relatively high doses. Despite the strong safety profile of peptides, they are subject to injection site reactions and discomfort in administration leading to poor compliance. 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 and human studies that we believe were successful, pre-clinical results in animal studies are not necessarily predictive of outcomes in subsequent 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 or subsequent 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.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

All our drug candidates are unproven and their risk of failure is high. It is impossible to predict when or if our drug candidates will receive regulatory approval or, in the case of IPOXYN, prove effective and safe in humans. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must conduct extensive clinical trials and, in the case of IPOXYN, first complete preclinical development, to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failed clinical trial can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our drug candidates, including:

- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our drug candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate the trials; and
- regulators may revise the requirements for approving our drug candidates, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our drug candidates;
- not obtain marketing approval at all, which would seriously impair our viability;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as we intend or desire;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

We are planning to initiate Phase II clinical trials for BTI-410, to continue Phase II clinical trials and initiate Phase III clinical trials for BTI-320. In addition, subject to securing adequate funding, we could potentially initiate pre- clinical studies of IPOXYN. However, we cannot provide any assurance that we will successfully initiate or complete those planned trials and be able to initiate any other clinical trials for any of our drug candidates. The results of our clinical trials could yield negative or ambiguous results. Since BTI-320 and BTI-410 are our most advanced drug candidates, such results could adversely affect future development plans, collaborations and our stock price.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our drug candidates and harming our business and results of operations.

A fast track, breakthrough therapy or other designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We may seek fast track, breakthrough therapy or similar designation for some of our drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, and even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

Additionally, we may in the future seek a breakthrough therapy designation for some of our product candidates that reach the regulatory review process. A breakthrough therapy is a drug candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and that, as indicated by preliminary clinical evidence, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies by the FDA are eligible for accelerated approval and increased interaction and communication with the FDA designed to expedite the development and review process.

As with fast track designation, designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and may determine not to grant such a designation. Even if we receive a breakthrough therapy designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional FDA procedures. Further, obtaining a breakthrough therapy designation does not assure or increase the likelihood of the FDA's approval of the applicable product candidate. In addition, even if one or more of our product candidates qualifies as a breakthrough therapy, the FDA could later determine that those products no longer meet the conditions for the designation or determine not to shorten the time period for FDA review or approval.

In addition, we may seek to avail ourselves of the FDA's 505(b)(2) approval procedure where it is appropriate to do so. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act permits an applicant to file a new drug application (or NDA) with the FDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and the FDA's findings of safety and effectiveness based on certain preclinical testing or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. If this approval pathway is not available to us with respect to a particular formulation or product, or at all, the time and cost associated with developing and commercializing such formulations or products may be prohibitive and our business strategy would be materially and adversely affected.

We rely on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We currently use third-party clinical research organizations, or CROs, to conduct our planned clinical trials and do not plan to independently conduct clinical trials of our other drug candidates. We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials. These agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that would delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with regulatory standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials with which we must comply. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *ClinicalTrials.gov*, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our drug candidates.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our drug candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States, such as the EMA. In addition, some of our competitors have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' drug candidates.

Patient enrollment is affected by other factors including:

- the severity of the disease under investigation;
- the patient eligibility criteria for the study in question;
- the perceived risks and benefits of the drug candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- our payments for conducting clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

We are unable to forecast with precision our ability to enroll patients. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

If serious adverse or unacceptable side effects are identified during the development of our drug candidates or we observe limited efficacy, we may need to abandon or limit our development of some of our drug candidates.

If our drug candidates are associated with undesirable side effects in clinical trials, have limited efficacy or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. We believe our results to date suggest an acceptable safety profiles at their respective stages of development. However, many compounds that initially showed promise in early stage testing for treating diabetes and inflammatory diseases have later been found to cause side effects that prevented further development of the compound.

Even if any of our drug candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if any of our drug candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. For example, current diabetes treatments are well established in the medical community, and physicians may continue to rely on these treatments. In addition, many new drugs have been recently approved and many more are in the pipeline for the same diseases for which we are developing our drug candidates. If our drug candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our drug candidates, if approved for commercial sale, will depend on a number of factors, including:

- their efficacy, safety and other potential advantages compared to alternative treatments;
- our ability to offer them for sale at competitive prices;
- their convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our drug candidates;
- the prevalence and severity of their side effects;
- any restrictions on the use of our products together with other medications;
- interactions of our products with other medicines patients are taking; and
- inability of certain types of patients to take our products.

If we are unable to address and overcome these and similar concerns, our business and results of operations could be substantially harmed.

If we are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our drug candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have limited experience in the sale, marketing or distribution of our products. To achieve commercial success for any product for which we obtain marketing approval, we will need to successfully establish and maintain relationships with third parties to perform sales and marketing functions, such as Advance Pharmaceutical.

In the future, we may build a focused sales and marketing infrastructure to market or co-promote some of our drug candidates in the United States and potentially elsewhere. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a drug candidate or dietary supplement for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or educate physicians on the benefits of our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

Currently, we rely on third parties to sell, market and distribute our drug candidates. We may not be successful in entering into, or maintaining, arrangements with such third parties or may be unable to do so on terms that are favorable to us. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates.

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.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products, particularly in the diabetes sector, is highly competitive. We face competition with respect to our current drug candidates, and will face competition with respect to any drug candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the control of blood sugar and the treatment of diabetes generally. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

A substantial number of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products.

We may be unable to compete in our target marketplaces, which could impair our ability to generate revenues, thus causing a material adverse impact on our results of operations.

Our reliance on one product and a limited number of customers for a significant portion of our revenues could materially and adversely affect our results of operations and liquidity.

During the years ended December 31, 2018 and 2017, all of our revenue was generated by sales and royalties of our SUGARDOWN® product. Advance Pharmaceutical Company, Ltd., a related party, accounted for 0% and 25%, respectively for the years ended December 31, 2018 and 2017. If we are unable to expand our customer base through our new marketing efforts, and we are not able to secure additional business from our existing customer or our sales to this customer decline, our reliance on a limited number of customers may have a material adverse effect on our business, result of operations, financial condition or liquidity. Furthermore, if we are unable to commercialize any of our pharmaceutical drug candidates, our reliance on a single product may have a material adverse effect on our business, result of operations, financial condition or liquidity.

Our success depends upon our ability to retain key executives and to attract, retain, and motivate qualified personnel, and the loss of these persons could adversely affect our operations and results.

We are highly dependent on the principal members of our management, scientific and clinical team, including Carl Rausch, our Chief Executive Officer and Director. We have a consulting agreement with Mr. Rausch. We currently have no employees in our Company, we are otherwise entirely staffed by consultants, each of whom may terminate their employment with us at any time.

The loss of the services of our executive officers or other key employees/consultants or key members of our scientific or medical advisory boards, could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely and expect to continue to rely to a significant degree on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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 marketing and the selling of pharmaceutical products. Any growth 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. We currently have an agreement with Advance Pharmaceutical Co. Ltd. to develop markets in Hong Kong, China and Macau for SUGARDOWN®. In November 2014, we agreed to expand this marketing agreement to include 12 additional countries: Korea, Taiwan, Singapore, Thailand, Malaysia, Vietnam, Philippines, Myanmar, Indonesia, Laos, Brunei and Cambodia. In March 2015, we agreed to expand their marketing agreement to include Japan. In May 2014, we entered into a strategic marketing agreement a leading branding and marketing agency, aimed at driving brand awareness and growing sales of SUGARDOWN® among the large pre-diabetic population in North America. This agreement was terminated in July 2015. 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 for SUGARDOWN®. 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 other 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 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 have entered into agreements with commercial partners to engage in sales, marketing and distribution efforts around our products in development. We may be unable to maintain these third-party relationships, or establish new 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 or maintain relationships with third parties for the sales and marketing of our proposed products, we will need to develop our own sales and marketing capabilities. Furthermore, 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 could 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.

RISKS RELATED TO OUR INDUSTRY

We will need regulatory approvals to commercialize our products as drugs.

If we choose to offer BTI-320, BTI-410, 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 has been invented and/or developed or co-developed by our former 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 patents that may be issued to us, that we may acquire, or that we may license in the future, 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 RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to obtain and maintain patent protection for our products, or if the scope of the patent protection obtained is not sufficiently broad, competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be impaired.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our drug candidates.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office, or U.S. PTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party preissuance submission of prior art to the U.S. PTO, or become involved in opposition, derivation, reexamination, *inter partes* review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection of our products. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and ultimately unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect us.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our drug candidates without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our products or use of our products do not infringe third-party patents. It is also possible that we have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing, which is referred to as the priority date. Therefore, patent applications covering our products or technology could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including inter parties review, interference, or derivation proceedings before the U.S. PTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the U.S. PTO and foreign patent agencies in several stages over the lifetime of the patent. The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees or contractors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and drug candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

RISKS RELATING TO OUR COMMON STOCK

The market price of our common stock may be highly volatile, and you could lose all or part of your investment.

The trading price of our common stock is likely to be volatile. This volatility may prevent you from being able to sell your shares at or above the price you paid for your shares. Our stock price could be subject to wide fluctuations in response to a variety of factors, which include:

- any adverse results or delays in commencement or completion of our planned clinical trials for BTI-320, BTI-410 or IPOXYN;
- changes in laws or regulations applicable to SUGARDOWN®, BTI-320, BTI-410 or IPOXYN or any future product candidates, including but not limited to clinical trial requirements for approvals;
- unanticipated serious safety concerns related to the use of SUGARDOWN®, BTI-320, BTI-410 or IPOXYN or any future product candidates;
- a decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- our inability to obtain adequate product supply for SUGARDOWN®, BTI-320, BTI-410 or IPOXYN or any future product candidate, or the inability to do so at acceptable prices;
- adverse regulatory decisions;
- the introduction of new products or technologies offered by us or our competitors;
- the effectiveness of our or our potential partners' commercialization efforts;
- the inability to effectively manage our growth;
- actual or anticipated variations in quarterly operating results;
- our failure to meet or exceed the estimates and projections of the investment community;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- the overall performance of the U.S. equity markets and general political and economic conditions;
- developments concerning our sources of manufacturing supply and any commercialization partners;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- additions or departures of key scientific or other consultants or management personnel;
- adverse market reaction to any indebtedness we may incur or securities we may issue in the future;
- sales of our common stock by our stockholders in the future;
- significant lawsuits, including patent or stockholder litigation;

- changes in the market valuations of similar companies;
- the trading volume of our common stock;
- effects of natural or man-made catastrophic events or other business interruptions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the stock of biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

We have a limited market for our common stock, which makes our securities very speculative.

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

The financial and operational projections that we may make from time to time are subject to inherent risks.

The projections that we provide herein or our management may provide from time to time (including, but not limited to, those relating to potential peak sales amounts, clinical and regulatory timelines, production and supply matters, commercial launch dates, and other financial or operational matters) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, regulatory, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There may be differences between actual and projected results, and actual results may be materially different from than those contained in the projections. The inclusion of the projections in this prospectus should not be regarded as an indication that we, our management, or their representatives considered or consider the projections to be a guaranteed prediction of future events, and the projections should not be relied upon as such.

Our ability to use our net operating loss carry-forwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, referred to as the Internal Revenue Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change net operating loss carry-forwards and other pre- change tax attributes (such as research tax credits) to offset its post-change income may be limited. We believe that our private placements within a three-year period and other transactions that have occurred over the past three years, we may have triggered an "ownership change" limitation. We may also experience ownership changes in the future. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carry-forwards to offset U.S. federal taxable income may be subject to limitations, which potentially could result in increased future tax liability to us.

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 OTCQB under the symbol BTHE. Our common stock is subject to the requirements of Rule 15(g)-9 promulgated under the Securities Exchange Act, so long as the price of our common stock is below $5.00 per share and our common stock is not listed on a U.S. national securities exchange. 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. 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.

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.

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

As of March 15, 2019, we had issued and outstanding (i) 111,131,373 shares of common stock, (ii) warrants issued to the investors in our 2013 private placement collectively exercisable for 3,333,320 shares of common stock (the "Investor Warrants"), (iii) other warrants exercisable for 1,166,670 shares of common stock, (iv) warrants issued to the investors in our 2016 private placement collectively exercisable for 16,000,000 shares of common stock, (v) shares issuable in exchange for our 2016 private placement debt of 3,633,467 (vi) outstanding stock options exercisable for 9,594,000 shares of common stock (vii) shares issuable in exchange for our related party convertible debt of 32,773,900, (viii) shares issuable in exchange for our Series A preferred stock of 8,250,000 and (ix) warrants issued to the investors in our 2016 private placement collectively exercisable for 18,500,000 shares of common stock. These securities will be eligible for public sale only if registered under the Securities Act or if the stockholder qualifies for an exemption from registration under Rule 144 or other applicable exemption. We believe that our stockholders are currently entitled to sell our shares pursuant to Rule 144 to the extent they satisfy the conditions thereunder. An aggregate of 17,659,007 shares of outstanding common stock and 3,333,320 shares of common stock issuable upon exercise of outstanding Investor Warrants are registered for resale. The market price of our capital stock could drop significantly if the holders of the shares being registered hereunder sell them or are perceived by the market as intending to sell them. Moreover, to the extent that additional shares of our outstanding stock are registered, or otherwise become eligible for resale, and are sold, or the holders of such shares are perceived as intended to sell them, this could further depress the market price of our common stock. These factors could also make it more difficult for us to raise capital or make acquisitions through the issuance of additional shares of our common stock or other equity securities.

The right of the investors in our recent convertible debt financings to potentially receive additional shares of our common stock could have a negative impact on our common stock price and could impair our ability to raise capital.

Pursuant to the terms of our fixed price convertible note financings with a related party and significant stockholder, we may potentially be required to issue additional shares of common stock to such investor causing dilution to existing shareholders. Moreover, the existence of these rights could materially impair our ability to obtain financing, which would have a material adverse effect on our business and viability.

The right of the investors in certain of our recent convertible debt financings to participate in future financings of ours could impair our ability to raise capital.

Under the note purchase agreements with certain of the investors in our recent convertible debt financings, in the event that we seek to raise money through the offer and sale of debt or equity securities under specified circumstances, we must first offer such investors a right to participate in at least a portion of the securities we propose to offer in such funding. The existence of such right of participation, or the exercise of such rights, may in the deter potential investors from providing us needed financing, or may deter investment banks from working with, which would have a material adverse effect on our ability to finance our company.

Our Certificate of Incorporation permits "blank check" preferred stock, which can be designated by our Board of Directors without stockholder approval.

We have 5,000,000 authorized shares of preferred stock. The shares of our preferred stock may be issued from time to time in one or more series, each of which shall have a distinctive designation or title as is determined by our Board of Directors prior to the issuance of any shares thereof. The preferred stock may 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 our stockholders, stockholders will have no control over what designations and preferences our preferred stock will have. If preferred stock is designated and issued, then depending upon the designation and preferences, the holders of the preferred stock may exercise voting control over us. As a result, our stockholders will have no control over the designations and preferences of the preferred stock and as a result the operations of our company.

Our management and five significant stockholders collectively own a substantial majority of our common stock.

Collectively, our officers, our directors and five significant stockholders own or exercise voting and investment control of approximately 68.7% of our outstanding common stock on a fully diluted basis. As a result, investors may be prevented from affecting matters involving our 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.

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

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

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they change their recommendations regarding our common stock adversely, the price of our common stock and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock would likely decline. If any analyst who may cover us was to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our common stock or trading volume to decline.

Item 1B. Unresolved Staff Comments.

The Company presently does not have unresolved staff comments.

Item 2. Properties.

We do not own any real property. We do not lease any office space at this time. We did lease office space at 354 Merrimack Street, Lawrence, MA 01843 on a month to month basis. This concluded in September 2018, although we do maintain mail service there. With the acquisition of CureDM, we leased office space on a month-to-month basis at The BioScience Center 5901 Indian School Rd., Albuquerque, NM 87110. We believe our facilities are in good operating condition and that our facilities are adequate for all present and near term uses.

Item 3. Legal Proceedings.

During March 2019, subsequent to our year end, we were served with notification of litigation regarding our merger with CureDM Holdings. CureDM Holdings' former parent company, CureDM Inc. has filed a complaint regarding breach of contract and other matters relating to their desire to unwind the merger according to the original merger agreement. This matter has just recently been filed and we are still evaluating it with our legal counsel. At this time, we are unable to state with certainty and outcome either positive or negative. We do intend to vigorously defend against the claims.

In addition to the above matter, we are also in arbitration with another company, Level Brands, regarding a marketing contract between our companies. Both parties are claiming non performance under the contract. The matter is currently in arbitration but is very early into the process and we are unable to determine any outcome positive or negative at this time.

We may from time to time become a party to various legal or administrative proceedings arising in the ordinary course of our business.

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 ($)	
	High	Low
2018 Fiscal Year		
March 31, 2018	$ 0.11	$ 0.04
June 30, 2018	$ 0.09	$ 0.05
September 30, 2018	$ 0.08	$ 0.04
December 31, 2018	$ 0.05	$ 0.02
2017 Fiscal Year		
March 31, 2017	$ 0.08	$ 0.05
June 30, 2017	$ 0.07	$ 0.04
September 30, 2017	$ 0.08	$ 0.04
December 31, 2017	$ 0.05	$ 0.03

On April 12, 2019, the closing price for the common stock on the OTCBB was $0.03 per share.

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

Worldwide Stock Transfer, LLC
One University Plaza Suite 505
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 2018 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)	250,000	$ 0.60	7,250,000
Equity compensation plans not approved by security holders (2)	9,344,000	$ 0.36	8,156,000
Total	**9,594,000**		**15,406,000**

(1) Consists of our Amended and Restated 2010 Stock Plan (the "2010 Plan"). See Note 9 -"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 and an amendment to increase the number of shares of common stock issuable to 7,500,000 was approved in September 2013.

(2) Consists of our Amended and Restated 2011 Non-Qualified Stock Plan (the "2011 Plan"). See Note 9 -"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 as it does not provide for the issuance of incentive stock options. An amendment to increase the number of shares of common stock issuable to 17,500,000 was approved in March 2013.

Holders

As of April 12, 2019, there were approximately 1,912 holders 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

On February 2, 2018, the Company entered into Securities Purchase Agreements with four accredited investors. In connection with these agreements, the Company issued 27,500 shares of Series A Preferred Stock and warrants to acquire 5,500,000 shares of common stock in consideration of $275,000. The shares of Series A Preferred Stock are convertible, at any time at the option of the holder, into an aggregate of 2,750,000 shares of the Company's common stock. The Warrants shall be exercisable for a period of five years at an exercise price of $0.15 per share.

During the first nine months of 2018, 29 investors converted their Convertible Debenture totaling $1,225,000 plus accrued interest of $52,066, into 17,027,544 shares of the Company's common stock.

Unless otherwise stated, 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 recipients' 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 some shares were issued for services, we received no cash proceeds for the issuance of those 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

Boston Therapeutics, headquartered in Lawrence, MA, (OTCQB: BTHE) is a leader in the field of complex carbohydrate chemistry and peptide therapeutic drug discovery and development. The Company's initial product pipeline is focused on developing and commercializing therapeutic molecules for sugar control more specifically prediabetics and diabetes: investigative material BTI-320, a non- systemic, non-toxic, investigative therapeutic compound designed to reduce post-meal glucose elevation. In addition, under manufacturing control, SUGARDOWN®, a similar base material to BTI-320 has progressed into market testing as a dietary supplement designed to manage post-meal sugar spikes. Recently, with the acquisition of CureDM in the first quarter of 2018, a new investigative material BTI-410, an injectable peptide, may fulfill the medical need to replace injection of insulin by stimulating the beta cell maturation. And the adjunctive therapeutic material called IPOXYN, is an investigative intravenous fluid therapy for the prevention of necrosis and a treatment for ischemia, with an initial target indication of lower limb ischemic events often associated with diabetes. This covers a wider combined prevention and therapeutic option for the growing worldwide epidemic related to metabolic diseases with diabetes being the leader.

The Company has incurred recurring operating losses since inception as it has worked to bring its SUGARDOWN® product to market and develop BTI-320 and IPOXYN. Management expects such operating losses will continue until such time that substantial revenues are received from SUGARDOWN® or the regulatory and clinical development of BTI-320 or IPOXYN is completed. The Company has approximately $12,500 cash on hand at December 31, 2018. Management is currently seeking additional capital through private placements and public offerings of its common stock. In addition, the Company may seek to raise additional capital through public or private debt or equity financings as well as collaboration activities in order to fund our operations. We raised $275,000 in gross proceeds from private placements of our Series A Preferred Stock during the first quarter of 2018. During the second quarter of 2018, we issued a note payable to a related party for $100,000. At the end of the third quarter of 2018, we approved a Private Placement Memorandum in an effort to raise additional funds. Also, at the end of the third quarter, the Company issued a Note Payable to CJY Holdings, Ltd, a related party, for $305,937. Also, in the fourth quarter of 2018, we increased the amount of the note payable to the related party noted above to $174,500. An additional $50,000 was advanced to the Company during April 2019. Management anticipates that cash resources will be sufficient to fund our planned operations into the second quarter of 2019. The future of the Company is dependent upon its ability to obtain continued financing and upon future profitable operations from the partnering, development and clarity of its new business opportunities.

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 operations.

Results of Operations

Fiscal 2018 as compared to Fiscal 2017

Revenue

Revenue for fiscal 2018 was $31,723, an increase of $2,367 compared to revenue of $29,356 for fiscal 2017. The increase in 2018 is related to the Company's sales and marketing effort through radio and social media advertising that began late in 2017. The Company ceased that activity due to lack of funds. The Company increased the price of its Sugardown product during the second half of 2018 which also accounted for the increased revenue. Revenue in 2017 includes approximately $7,400 of royalty revenue from Advanced Pharmaceutical Company, Ltd, a related party.

Direct Expenses

Direct expenses for fiscal 2018 was $67,133 an increase of $17,372 as compared to $49,761 for fiscal 2017. The increase due to an increase in reserve for expired inventory of approximately $31,750 in 2018 as compared to an increase of approximately $13,000 in 2017.

Research and Development

Research and development expense for fiscal 2018 was $182,665, an increase of $5,019 as compared to $177,646 for fiscal 2017. Fiscal 2018 includes non cash expenses for the amortization of intangible assets of $158,000 compared to $64,000 for fiscal year 2017. In fiscal 2017, the Company recognized a fourth quarter expense of approximately $61,000 related to preparations for the trial which started in the second quarter of 2018. Also, in 2017, we spent $37,000 on stabilization studies at the University of GA, related to our Sugardown product. The Company has initiated clinical trials for its Sugardown product and its BTI320 in China (Hong Kong), starting in the second quarter of 2017. Both trials are being funded by the Asian license holder who is also a Director and significant stockholder.

Sales and Marketing

Sales and marketing expense for fiscal 2018 was $77,166, an increase of $53,260 as compared to $23,906 for fiscal 2017. The increase is related to the marketing agreement entered into with Level Brands, Inc. The Company is currently in arbitration with Level Brands, Inc., in an effort to end the contract which the Company believe is not beneficial. In late 2017, we initiated a different program concentrating on social media outlets with targeted radio advertisements in New England. This program continued through the second quarter of 2018 when it was discontinued due to lack of funds.

General and Administrative

General and administrative expense for fiscal 2018 was $1,738,168, an increase of $694,469 as compared to $1,043,699 for fiscal 2017. The 2018 numbers include a stock award to two consultants totaling $330,000. In addition, the increase costs in 2018 are from accrued payroll costs of $188,716 to our new COO hired as a result of our acquisition of CureDM. These fees will be paid upon adequate funds raised by the Company according to the CureDM purchase agreement. The Company also had increased costs for non-cash stock compensation of approximately $125,000 related to stock options issued to our new COO during Q1 2018 and also due to a revaluation of options issued to our CEO that were re-priced during the first quarter of 2018. These increases were offset set by lower costs for professional and other fees as the Company has been conserving its cash position pending additional financing.

Impairment of Goodwill

We recorded impairment of goodwill in the amount of $1,246,002 for the year ended December 31, 2018. There was no impairment recorded for the year ended December 31, 2017.

Other (Expenses) Income

Total other expense was ($321,806) for fiscal 2018 representing an increase expense of $2,589 as compared to ($319,217) for fiscal 2017. Interest expense decreased by approximately $928,000 for the year ended December 31, 2018. This was due to the significant number of debt conversions that took place during 2018. Amortization of deferred financing costs from our 2016 fund raising also decreased by approximately $47,000 as the costs fully amortized during the third quarter of 2018. Also, during 2018, the Company recognized gains of $2,374 due to the early extinguishment of its debt due to the conversions compared to a loss of ($81,541) during 2017. The Company also recognized gains of $400,225 and $83,287 from the change in the valuations of it warrant and derivative liabilities, respectively during 2018. For 2017, the Company had gains of $639,435 and $904,896 from the change in the valuations of it warrant and derivative liabilities, respectively.

Liquidity and Capital Resources

As of December 31, 2018, we had cash of $12,467 and accounts payable and accrued expenses of $1,670,461. For the year ended December 31, 2018 the Company used $883,841 of cash in operations.

The Company has incurred recurring operating losses since inception as it has worked to bring its SUGARDOWN® product to market and develop BTI-320 and IPOXYN. Management expects such operating losses will continue until such time that substantial revenues are received from SUGARDOWN® or the regulatory and clinical development of BTI-320 or IPOXYN is completed. The Company has approximately $12,500 cash on hand at December 31, 2018. Management is currently seeking additional capital through private placements and public offerings of its common stock. In addition, the Company may seek to raise additional capital through public or private debt or equity financings as well as collaboration activities in order to fund our operations. We raised $275,000 in gross proceeds from private placements of our Series A Preferred Stock during the first quarter of 2018. During the second quarter of 2018, we issued a note payable to a related party for $100,000. At the end of the third quarter of 2018, we approved a Private Placement Memorandum in an effort to raise additional funds. Also, at the end of the third quarter, the Company issued a Note Payable to CJY Holdings, Ltd, a related party, for $305,937. Also, in the fourth quarter of 2018, we increased the amount of the note payable to the related party noted above to $174,500. An additional $50,000 was advanced to the Company during April 2019. Management anticipates that cash resources will be sufficient to fund our planned operations into the second quarter of 2019. Our continuation as a going concern is dependent upon its ability to obtain continued financing and upon future profitable operations from the partnering, development and clarity of its new business opportunities.

The Company may seek to raise additional capital through public or private debt or public or private equity financings, and partnerships or licensing opportunities in order to fund our operations. 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.

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 F-1.

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

None

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, our disclosure controls and procedures were ineffective to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the required time periods specified in the Commission's rules and forms and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Our principal executive officer and principal financial officer, do not expect that our disclosure controls and procedures or our internal controls will prevent all error or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. During the fourth quarter ended December 31, 2018, we carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation and due to identified control deficiencies regarding the lack of segregation of duties and the need for a stronger internal control environment, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were ineffective as of the end of the period covered by this report.

To address the material weaknesses, we performed additional analysis and other post-closing procedures in an effort to ensure our financial statements included in this annual report have been prepared in accordance with generally accepted accounting principles. Accordingly, management believes that the financial statements included in this report fairly present in all material respects our financial condition, results of operations and cash flows for the periods presented.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control-Integrated Framework (2013). A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As disclosed in our previous filings, there are material weaknesses in the Company's internal control over financial reporting due to the fact that the Company does not have an adequate process established to ensure appropriate levels of review of accounting and financial reporting matters, which resulted in our closing process not identifying all required adjustments and disclosures in a timely fashion. The Company's CEO/CFO has identified control deficiencies regarding the lack of segregation of duties and the need for a stronger internal control environment. The small size of the Company's accounting staff may prevent adequate controls in the future, such as segregation of duties, due to the cost/benefit of such remediation.

Although the Company has hired a consultant 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.

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.

Because of the above material weakness, management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2018, based on the criteria established in "Internal Control-Integrated Framework" issued by the COSO.

Changes in Internal Control Over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

No Attestation Report by Independent Registered Accountant

The effectiveness of our internal control over financial reporting as of December 31, 2018 has not been audited by our independent registered public accounting firm by virtue of our exemption from such requirement as a smaller reporting company.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers 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
Carl Rausch	70	Director	August 2016 to Present
Conroy Chi-Heng Cheng	41	Director	December 2013 to Present
S. Colin Neill	72	Director	December 2013 to Present

Carl W. Rausch, is our Chief Executive Officer, Chief Financial Officer and Director since August 12, 2016. From 2008 until he joined our Company, Mr. Rausch served as an independent consultant for biopharmaceutical industrial clients, university based and early stage biopharmaceutical company facility development as well as contract research organizations (CRO's). For over 30 years he has been involved in preclinical and clinical strategic management of investigative biological materials for the clinical registration with the European Medicines Agency and the US Food and Drug Administration and with Asia development and registrations in the region. From 2006 to 2018, Mr. Rausch holds or has held investment, management, and technical advisory positions as a principal with sole proprietorship in Biotechnology Partners LLC, which does and has provided advisory and leadership services to biotechnology clients, World Technology East II, Ltd, Newainovation Ltd, Medical Technology Associates II, Advance Pharmaceitocal Company, Ltd., Clementi and Associates, Inc. Mr. Rausch served as the Vice Chairman and Chief Technical Officer of Biopure Corporation ("Biopure") from 2002 to 2005. Most notably, Mr. Rausch cofounded Biopure in 1984. From 1984 until 2002 the organization grew and went public on the Nasdaq exchange, Mr. Rausch served as its Chairman and Chief Executive Officer for 18 years. In 2002 Mr. Rausch turned over the management to a new team. Following Mr. Rausch's departure as Chief Executive Officer of Biopure in 2002, Mr. Rausch pursued independent strategic development for the global growth of the Company and the growth of the many facets of oxygen therapeutic technology. Post the 2002 new CEO and regulatory management placement in 2002, there was an early departure and subsequent removal in 2004, Mr. Rausch was recalled to act in a key advisory role during the transition to secure new management. In 2005 Mr. Rausch broaden the consulting business and terminated completely the advisory of Biopure Corporation by 2006. Prior to Biopure's founding, Mr. Rausch was Vice President, Preparative and Process Chromatography Division, at Millipore Corporation. He holds an M.S. degree in chemical engineering from the Massachusetts Institute of Technology and holds an M.S. degree in medical engineering and a B.S. degree in chemical engineering from Tufts University. He has been the inventor of many key patents and publications in his area of technical expertise. We believe that Mr. Rausch is well qualified to serve as a member of our Board of Directors due to his executive leadership experience and his extensive experience in the biotechnology industry and in commercialization.

S. Colin Neill, a Director of our company since December 2013, became President of Pharmos Corporation in January 2008, and has served as Chief Financial Officer, Secretary, and Treasurer of Pharmos since October 2006. He held these positions through November 2012. From September 2003 to October 2006, Mr. Neill served as Chief Financial Officer, Treasurer and Secretary of Axonyx Inc., a biopharmaceutical company that developed products and technologies to treat Alzheimer's disease and other central nervous system disorders, where he played an integral role in the merger between Axonyx and TorreyPines Therapeutics Inc., a privately-held biopharmaceutical company. Mr. Neill served as Senior Vice President, Chief Financial Officer, Secretary and Treasurer of ClinTrials Research Inc.; a $100 million publicly traded global contract research organization in the drug development business, from 1998 to its sale in 2001. Following that sale from April 2001 to September 2003 Mr. Neill served as an independent consultant assisting small start-up and development stage companies in raising capital. Earlier experience was gained as Vice President of Finance and Chief Financial Officer of BTR Inc., a $3.5 billion US subsidiary of BTR plc, a British diversified manufacturing company, and Vice President Financial Services of The BOC Group Inc., a $2.5 billion British owned industrial gas company with substantial operations in the health care field. Mr. Neill served four years with American Express Travel Related Services, first as chief internal auditor for worldwide operations and then as head of business planning and financial analysis. Mr. Neill began his career in public accounting with Arthur Andersen LLP in Ireland and later with Price Waterhouse LLP as a senior manager in New York City. He also served with Price Waterhouse for two years in Paris, France. Mr. Neill graduated from Trinity College, Dublin with a first class honors degree in Business/Economics and he holds a master's degree in Accounting and Finance from the London School of Economics. He is a Certified Public Accountant in New York State and a Chartered Accountant in Ireland. Mr. Neill served on the board of Galectin Therapeutics (formerly named Pro-Pharmaceuticals, Inc.) from May 2007 to October 2011 and from April 2004 to June 2008 on the board of OXIS International, Inc. We believe that Mr. Neill is well qualified to serve as a member of our Board of Directors due to his extensive executive leadership experience in our industry as well as his many years serving in senior financial management roles.

Conroy Chi-Heng Cheng, a Director of our company since December 2013. Mr. Cheng served as our interim Chief Executive Officer and Chief Financial Officer from March 2016 until August 12, 2016. He also serves as the Chief Executive Officer of Net Plus Company Limited. He serves as an Executive Director of Net Plus Company Limited. He has been an Executive Director of New World Development Co. Ltd. since June 2010. He serves as a Director of Chow Tai Fook Enterprises Limited. He served as an Independent Non-executive Director of Hong Kong Energy Holdings Limited (alternate name JIC Technology Co. Ltd. & China Renewable Energy Investment Limited) from July 2002 to May 2007. Mr. Cheng has a Bachelor of Arts degree majoring in Economics from the University of Western Ontario, Ontario, Canada in 1999. Mr. Cheng also serves as a director of Advance Pharmaceutical Company, Ltd., our marketing and distribution partner for sixteen countries in Asia. We believe that Mr. Cheng is well qualified to serve as a member of our Board of Directors due to his executive leadership experience and his extensive experience with business development.

Our Directors are elected annually and each holds office until the annual meeting of our stockholders 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, they may receive compensation as determined by our Board of Directors from time to time. Vacancies in the Board of Directors will be filled by majority vote of the remaining directors or in the event that our sole Director vacates his position, by our majority stockholders. Our Directors may be reimbursed by us 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 an officer
Carl W. Rausch	70	Chief Executive Officer, Chief Financial Officer and Director	July 2016 to the present

Biographical information with respect to Mr. Rausch is set forth above.

Scientific Advisory Board

We are evaluating a Scientific Advisory Board that will be comprised of Clinicians and Clinical Research professionals who are interested in the field of Diabetes or in other subjects related to our product pipeline. The board will provide leadership and expertise to assist us in designing, executing and implementing our clinically oriented activities in a safe, efficient and professional manner

Medical Advisory Board

We are evaluating a Medical Advisory Board that will be comprised of Clinicians and Clinical Research professionals who are interested in the field of Diabetes or in other subjects related to our product pipeline. The board will provide leadership and expertise to assist us in designing, executing and implementing our clinically oriented activities in a safe, efficient and professional manner

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 three members. We currently have five vacancies on our Board. 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. One of the three members of the Board of Directors, S. Colin Neill, is “independent” as defined in Section 4200(a)(15) of NASDAQ Stock Market Rules.

Audit Committee

Our Board of Directors has established an audit committee consisting of three independent directors. The committee currently consists of one current member of the board, S. Colin Neill and has two openings. Mr. Neill serves as the chairman of the audit committee. The Company is actively seeking additional board members for the committee. The audit committee is primarily responsible for reviewing the services performed by the independent registered public accounting firm and evaluating our accounting policies and our system of internal controls. Mr. Neill serves as our “audit committee financial expert.” We believe 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. Neill 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

Our Company's Board of Directors has established a nominating and corporate governance committee consisting of three independent directors. The committee currently has no members the board having three openings. The Company is actively seeking additional board members for the committee, including a committee chair. 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; and
- 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's Board of Directors has established a compensation committee consisting of three independent directors. The committee currently has no members of the board having three openings. The Company is actively seeking additional board members for the committee, including a committee chair. The compensation committee is primarily responsible for overseeing and administering our compensation plans and executive compensation matters.

Compensation Committee Interlocks And Insider Participation

The Compensation Committee of the Board has no members and has three current openings. All members of the committee are non-employee directors 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 Committee currently consists of one current member of the board, S. Colin Neil, and has two openings. 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, 2018 (the "Audited Financial Statements").

- The Audit Committee reviewed and discussed the Company's Audited Financial Statements with management;
- The Audit Committee discussed with Liggett & Webb, P.A. ("Liggett"), the Company's independent registered public accounting firm for fiscal 2018, the matters required to be discussed by the Public Company Accounting Oversight Board in Rule 3200T;
- The Audit Committee received from the independent registered public accounting firm the written disclosures regarding auditor independence, discussed with Liggett its independence from the Company and its management: 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, 2018, for filing with the U.S. Securities and Exchange Commission.

All members of the Audit Committee concur in this report.

Audit Committee: *S. Colin Neill (Chairman)*

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers and persons who own more than 10% of the issued and outstanding shares of our common stock to file reports of initial ownership of common stock and other equity securities and subsequent changes in that ownership with the SEC. Officers, directors and greater than ten percent stockholders are required by SEC regulation to furnish us with copies of all Section 16(a) forms they file. To our knowledge, based solely on a review of the copies of such reports furnished to us and written representations except for the Form 3 Initial Statement of Beneficial Ownership to be filed by Carl W. Rausch, that no other reports were required, during the fiscal year ended December 31, 2018 all Section 16(a) filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with.

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
Carl Rausch, Chief Executive Officer (3)	2018	$ 226,320	$ —	$ —	$ 226,320
	2017	$ 226,320	$ —	$ —	$ 226,320
Loraine Upham Former Chief Operating Officer (1)	2018	$ 188,716	$ —	$ —	$ 188,716

(1) Ms. Upham served as Chief Operating Officer until her resignation on November 30, 2018. These fees will be paid upon adequate funds raised by the Company according to the CureDM purchase agreement. Includes accrued vacation of $5,383.

(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 2018 and 2017" below.

(3) Includes $132,020 of paid compensation, the remainder remains unpaid and is included in current liabilities. All payments were suspended effective August 1, 2018

Grants of Plan-Based Awards

The following table shows for the fiscal years ended December 31, 2018 and 2017, certain information regarding grants of plan-based awards, or common stock options, to the named executive officers.

GRANTS OF PLAN-BASED AWARDS IN FISCAL 2018 and 2017

Name	Award Type	Grant Date	Approval Date	Estimated Possible Payouts Under Non-Equity Incentive Plan Awards Target ($)	All Other Option Awards: Number of Securities Underlying Options (3)(4)	Exercise or Base Price of Option Awards ($/Sh) (1)	Grant Date Fair Value of Stock and Option Awards ($)(2)
Loraine Upham	Non-Qualified Stock Option	02/12/18	02/12/18	—	4,000,000	$ 0.06 – 0.20	$ 193,875

(1) Stock options issued in 2018 were granted with an exercise price in excess of the fair market value on the date of grant.

(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 2018 and 2017. 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 accompanying Note 11 to Boston Therapeutics, Inc.'s audited financial statements for the year ended December 31, 2018 and 2017.

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

(4) The stock options were unvested at the time of Ms. Upham's resignation on November 30, 2018 and have been forfeited.

Outstanding Equity Awards at December 31, 2018

The following table sets forth, as of December 31, 2018, certain information regarding outstanding equity awards at fiscal year-end for the named executive officers.

OUTSTANDING EQUITY AWARDS AT 2018 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
Carl Rausch	1,500,000	—	$ 0.10	08/22/2021
Carl Rausch	500,000	—	$ 0.18	03/25/2025
Carl Rausch	2,000,000	—	$ 0.20	08/22/2021
Carl Rausch	—	2,000,000	$ 0.40	08/22/2021
Carl Rausch	—	2,000,000	$ 0.60	08/22/2021

(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 2010 and 2011 Plans including the potential for future vesting acceleration.

Option Exercises and Stock Vested in 2018

Our Named Executive Officers did not exercise any stock options during fiscal years 2018 and 2017.

Director Compensation

The following table sets forth all compensation awarded to, earned by or paid to the non-employee directors in 2018 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 ($)	Total ($)
Carl W. Rausch	$ —	$ —	$ —	$ —	$ —	$ —	$ —
S. Colin Neill (2)	$ 30,000	$ —	$ —	$ —	$ —	$ —	$ 30,000
Conroy Chi-Heng Cheng	$ —	$ —	$ —	$ —	$ —	$ —	$ —

(1) The "Option Awards" column reflects non-qualified options to purchase an aggregate of 7,500,000 shares of our common stock at an exercise price between $0.10 and $0.60. Of these shares, 1,500,000 have an exercise price of $0.10 for a period of 10 years granted effective August 22, 2016 and vested immediately; 2,000,000 have an exercise price of $0.20 for a period of five years shares granted August 22, 2016 and vested when the Company raised over $1 million in the 3rd quarter of 2016; 2,000,000 have an exercise price of $0.40 for a period of five years shares granted August 22, 2016 and vest upon the Company raising $5,000,000 in financing and 2,000,000 have an exercise price of $0.60 for a period of five years shares granted August 22, 2016 and vest upon the Company entering into a significant corporate alliance for substantial marketing and selling of the Company's product portfolio. On March 7, 2018, Dr. Rausch and the Company entered a letter agreement pursuant to which the First Option exercise prices was reduced to $0.10 per share and the Second Option and Third Option was reduced to $0.15 per share.

(2) Mr. Neill is due cash compensation of $2,500 per month in his position as the Chairman of the Audit Committee. Any unpaid amounts are included in accounts payable at December 31, 2018.

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. Assumptions used in the calculation of these amounts for the fiscal year ended December 31, 2018 are included in Note 11 "Stock Option Plan and Stock-Based Compensation" to the Company's audited financial statements for the year ended December 31, 2018 included herein.

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 2018 and 2017 and the cash compensation described in the table above and the consulting agreement described below, there are currently no other agreements in effect entitling the non-employee directors to compensation.

Employment Contracts

The Company entered into an Employment Agreement with Carl W. Rausch pursuant to which Mr. Rausch was engaged as the Chief Executive Officer of the Company for a period of three years. Mr. Rausch was initially required to relocate from Hong Kong to the United States. However, due to his continued efforts in Hong Kong, the Company and Mr. Rausch, in March 2017, have amended the employment agreement to remove the provision requiring Mr. Rausch to relocate to the United States. Mr. Rausch received a signing bonus of $60,000 and an annual salary of $224,000, which will be increased to $264,000 upon Mr. Rausch relocating to the United States. Further, upon the Company being listed on a national exchange, Mr. Rausch's salary will be increased by $20,000. The Company shall grant Mr. Rausch a Stock Option (the "Rausch Option") to acquire an aggregate of 6,000,000 shares of common stock of the Company, exercisable for five (5) years, subject to vesting. The Rausch Option shall be earned and vested in three equal tranches of 2,000,000 upon the Company raising $1,000,000 in financing, the Company raising $5,000,000 in financing and the Company entering into a significant corporate alliance for substantial marketing and selling of the Company's product portfolio. The initial tranche shall be exercisable at $0.20 per share, the second tranche will be $0.40 per share and the third tranche shall be $0.60 per share, which such vesting is subject to Mr. Rausch's continued employment as an executive with the Company as of the vesting date. In addition, as additional consideration for Mr. Rausch's commitment to the Company, the stock options previously granted to Mr. Rausch shall be amended to extend the expiration date to the ten year anniversary of signing date and such options shall be considered fully vested. Mr. Rausch shall be entitled to certain raises and milestones subject to the achievement of certain milestones to be agreed upon. In the event the Employment Agreement is terminated prior to the expiration of the term by the Company without cause or by Mr. Rausch with good reason, the Company shall pay Mr. Rausch an amount equal to Mr. Rausch's accrued but unpaid base salary and earned but unpaid bonus prior to the termination date, reimbursement for any reimbursable business expenses and Mr. Rausch's salary for a period of one year.

On February 12, 2018, with an effective date of January 1, 2018, Loraine Upham was appointed as Chief Operating Officer. Except for the CureDM Group ContributionMs. Upham has not had direct or indirect material interest in any transaction or proposed transaction, in which the Company was or is a proposed participant, exceeding $120,000. In addition, the Company and Ms. Upham entered into an Executive Retention Agreement pursuant to which Ms. Upham was engaged as Chief Operating Officer with an annual salary of $200,000. However, Ms. Upham's salary shall accrue until the Company has raised a minimum of $1,250,000. Ms. Upham is eligible for bonuses as determined by the Board of Directors. These include a bonus of $20,000 is to be paid upon the Company successfully raising $1,250,000 through the sale of equity; an annual performance bonus based on milestones related to clinical progress, partnering and fund raising success to be established by the Board of Directors or the Compensation Committee, if in existence on an annual basis. In addition, Ms. Upham received a stock option to purchase 4,000,000 shares of common stock under the Company's Amended and Restated 2011 Stock Incentive Plan, vesting over three (3) years, one third on the first anniversary of the effective date and the balance in equal quarterly installments. The exercise price of the initial tranche of options (1,333,334 shares) shall be $0.06 per share, the second tranche (1,333,333 shares) shall be $0.10 per share and the final tranche (1,333,333 shares) shall be $0.20 per share. The term of the options is five years. Ms. Upham resigned from the Company on November 30, 2018. As a result of her resignation all of her stock options were terminated and returned to the option pool. Her accrued salary and vacation of $188,716 will be paid once the funding is obtained.

There are no other employment or consulting contracts between us and our 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.

There are no arrangements between us 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

Prior to the formation of the Company's Compensation Committee compensation decisions were made by the full Board of Directors. In setting compensation, the Compensation Committee considers (and the Board of Directors 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 of Directors 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 2018 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)	250,000	$ 0.60	7,250,000
Equity compensation plans not approved by security holders (2)	9,344,000	$ 0.36	8,156,000
Total	**9,594,000**		**15,406,000**

(1) Consists of our Amended and Restated 2010 Stock Plan (the "2010 Plan"). See Note 11 —"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 and an amendment to increase the number of shares of common stock issuable to 7,500,000 was approved in September 2013.

(2) Consists of our Amended and Restated 2011 Non-Qualified Stock Plan (the "2011 Plan"). See Note 11 —"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 as it does not provide for the issuance of incentive stock options. An amendment to increase the number of shares of common stock issuable to 17,500,000 was approved by the Board of Directors in March 2013.

Security Ownership of Beneficial Owners and Management

The following table sets forth certain information concerning the ownership of the Company's common stock as of March 15, 2018, with respect to: (i) each person known to the Company to be the beneficial owner of more than five percent of the Company's common stock; (ii) all directors; and (iii) directors and executive officers of the Company as a group. The notes accompanying the information in the table below are necessary for a complete understanding of the figures provided below. As of March 15, 2019, Boston Therapeutics had 111,131,373 shares of common stock outstanding. In general, "beneficial ownership" includes those shares that a stockholder has the power to vote or the power to transfer, and stock options and other rights to acquire common stock that are exercisable currently or become exercisable within 60 days. Unless otherwise indicated, the address for each person is Boston Therapeutics, Inc., 354 Merrimack Street #4, Lawrence, MA 01843.

Name and Address of Beneficial Owner	Number of Shares	Percent of Class (1)
Carl W. Rausch (2)**	14,000,000(3)	11.4%(3)
David Platt 12 Appleton Circle Newton, MA 02459	8,151,600(4)	7.3%(4)
Harold Solomon Parnes 1525 Voorhies Avenue Brooklyn, NY 11235	26,126,342(5)	21.0%(5)
CJY Holdings Limited 7B Jonsim Place 288 Queens Road East Wanchai, Hong Kong	60,489,690(6)	40.5%(8)
CureDM, Inc.	12,997,488	11.7%
S. Colin Neill(2)**	130,100(7)	*%
Conroy Chi-Heng Cheng(2)**	2,058,600(8)	1.9%(8)
All Officers and Directors as a Group (4 persons)	16,188,700	13.4%

* Less than 1%

** Directors and Officers

(1) Except as expressly stated, the percentages in the table are based on 111,131,373 shares of common stock outstanding as of April 12, 2019.

(2) The business address for these individuals is 354 Merrimack Street, Lawrence, MA 01843.

(3) Includes (i) a stock option to acquire 6,000,000 shares of common stock (the "August 2016 Option"), (ii) a stock option to acquire 500,000 shares of common stock at $0.18 per share, which expires on August 12, 2026 and (iii) a stock option to acquire 1,500,000 shares of common stock at $0.10 per share, which expires on August 12, 2026. The August 2016 Option shall be earned and vested in three equal tranches of 2,000,000 upon the Company the Company raising $1,000,000 in financing, the Company raising $5,000,000 in financing and the Company entering into a significant corporate alliance for substantial marketing and selling of the Company's product portfolio. The initial tranche shall be exercisable at $0.20 per share, the second tranche will be $0.40 per share and the third tranche shall be $0.60 per share, which such vesting is subject to Mr. Rausch's continued employment as an executive with the Company as of the vesting date.

Also include 20,000 shares of the Company's Series A Preferred stock convertible into 2,000,000 shares of the Company's common stock along with warrants to purchase 4,000,000 shares of common stock held by World Technology East 2 (WTE2). WTE2 is majority owned by Mr. Rausch. Each warrant entitles the holder to purchase one share of the Company's common stock at a price of $0.10 per share. The warrants are good for 5 years with 2,000,000 expiring April 26, 2022 and 2,000,000 expiring February 20, 2023.

(4) Includes 520,000 shares owned by Dr. Platt's wife and 500,000 shares issuable pursuant to outstanding stock options currently exercisable. Excludes 20,000 shares held by Dr. Platt's daughter as to which Dr. Platt disclaims beneficial ownership. Excludes 20,000 shares held by Dr. Platt's son as to which Dr. Platt disclaims beneficial ownership.

(5) Dr. Parnes beneficially owns 7,524,156 shares of common stock held directly. In addition, Dr. Parnes owns common stock purchase warrants to acquire an aggregate of 2,100,000 shares of common stock at $0.10 per share. However, the convertible notes and the common stock purchase warrants prohibit the holder from converting or exercising such instruments if the investor's beneficial ownership were to exceed 4.99% of the Issuer's outstanding shares of common stock. Dr. Parnes also own warrants to purchase 9,000,000 shares of the Company's common stock. However, the convertible notes and the common stock purchase warrants prohibit the holder from converting or exercising such instruments if the investor's beneficial ownership were to exceed 4.99% of the Issuer's outstanding shares of common stock.

Includes 2,100,000 shares issuable pursuant to outstanding warrants to purchase common stock currently exercisable.

Also include 55,000 shares of the Company's Series A Preferred stock convertible into 5,500,000 shares of the Company's common stock along with warrants to purchase 11,000,000 shares of common stock

(6) Includes 5,333,320 shares issuable pursuant to outstanding warrants to purchase common stock currently exercisable and 32,773,900 shares issuable upon conversion of the Convertible Notes Payable plus accrued interest. Cheng Chi Him exercises voting and investment control over these securities.

(7) Includes 130,000 shares issuable pursuant to an outstanding stock option currently exercisable.

(8) Includes 1,998,600 shares owned by Sugardown Co., LTD., a wholly-owned subsidiary of Advance Pharmaceutical Company Ltd. Conroy Chi-Heng Cheng, a director of Boston Therapeutics, Inc., exercises voting and investment control over these securities. Includes 60,000 shares issuable pursuant to an outstanding stock option currently exercisable.

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

Except as otherwise set forth herein, 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:

Conroy Chi-Heng Cheng is a director of the Company and a director of Advance Pharmaceutical Company ("Advance Pharmaceutical"), a Hong Kong-based, privately-held company. On June 24, 2011, prior to his election to the Company's Board, the Company entered into a definitive Licensing and Manufacturing Agreement (the "Agreement") with Advance Pharmaceutical. Under terms of the Agreement, the Company manufactures and supplies product in bulk for Advance Pharmaceutical. Advance Pharmaceutical is responsible for the packaging, marketing and distribution of SUGARDOWN®, in in Hong Kong, China and Macau. In November 2014, we agreed to expand their marketing agreement to include 12 additional countries: Korea, Taiwan, Singapore, Thailand, Malaysia, Vietnam, Philippines, Myanmar, Indonesia, Laos, Brunei and Cambodia. In March 2015, we agreed to expand their marketing agreement to include Japan. Advance Pharmaceutical will also have rights to develop and manufacture SUGARDOWN®, for commercial sale in these countries, subject to establishment of quality assurance and quality control standards set forth by the Company. The Agreement provides that Advance Pharmaceutical will pay royalties to the Company for SUGARDOWN®,) and related products developed by the Company and a reduced royalty rate for products based on the Company's intellectual property and developed by Advance Pharmaceutical. Revenue generated through this agreement for the years ended December 31, 2018 and 2017 were royalties of $0 and sales of $7,380, respectively.

Advance Pharmaceutical, through a wholly owned subsidiary, has purchased an aggregate 1,998,000 shares of the common stock in conjunction with the Company's private placement offerings during the years 2013 and 2014. The shares were purchased on the same terms as the other participants acquiring shares in the respective offerings.

On March 14, 2013, the Company issued 500,000 shares of its common stock at a price per share of $0.50 and issued a warrant to purchase 250,000 additional shares for $1.00 per share for gross proceeds of $250,000 to CJY Holdings Limited, a company controlled by Conroy Chi-Heng Cheng's brother Cheng Chi Him. The warrant is exercisable immediately and has a five year term.

In July 2013, CJY Holdings purchased 6,666,660 shares of the Company's common stock and warrants to purchase an aggregate of 3,333,320 shares of the Company's common stock for an aggregate purchase price of $2,000,000 in the private placement conducted by the Company between July and September 2013. The warrants have an exercise price of $0.50 per share, are currently exercisable and have a five year term. During July 2018, the warrants were extended for an additional five years. In June 2015, the Company received $200,000 of cash proceeds from CJY Holdings Limited, in connection with a potential future exercise of its warrant. On November 12, 2015, the Company entered into a modification of a previously issued warrant agreement to CJY. The Board approved the reduction in the common stock warrant exercise prices from $0.50 to $1.00 per share to $0.17 per share. In connection with the June 2015 proceeds of $200,000 previously received by the Company and the reduction in the warrant exercise price, the Board approved the issuance of 1,194,440 shares of Common Stock to CJY in connection with the modified warrant agreement. On December 5, 2016, the common stock was issued. Prior to the issuance of common stock, the $200,000 was recorded in common stock subscribed.

Through December 31, 2011, Dr. Platt, the former Chairman and Chief Executive Officer, advanced $257,820 to the Company to fund start-up costs and operations. Advances by Dr. Platt carry an interest rate of 6.5% and were due on June 29, 2013. On May 7, 2012, Dr. Platt and the Company's former President entered into promissory notes to advance to the Company an aggregate of $40,000. The notes accrue interest at 6.5% per year and were due June 30, 2013. The outstanding notes of $297,820 have been amended each year to extend the maturity dates. Effective June 30, 2015, the outstanding notes for Dr. Platt were amended to extend the maturity dates to June 30, 2017 and are currently in default. This note has been classified as a current liability on the balance sheet. The maturity date for the Company's former President remained June 30, 2016. This note was paid in full during 2017.

In December 2013, the Board of Directors agreed to indemnify Dr. Platt for legal costs incurred in connection with an arbitration (now concluded) initiated before the American Arbitration Association by Galectin Therapeutics, Inc. (formerly named Pro-Pharmaceuticals, Inc.) for which Dr. Platt previously served as CEO and Chairman. Galectin sought to rescind or reform the Separation Agreement entered into with Dr. Platt upon his resignation from Galectin to remove a $1.0 million milestone payment which Dr. Platt asserted he was entitled to receive and to be repaid all separation benefits paid to Dr. Platt. The Company initially capped the amount for which it would indemnify Dr. Platt at $150,000 in December 2013 and Dr. Platt agreed to reimburse the indemnification amounts paid by the Company should he prevail in the arbitration. The Board decided to indemnify Dr. Platt after considering a number of factors, including the scope of the Company's existing indemnification obligations to officers and directors and the potential impact of the arbitration on the Company. In May 2014, the Board approved a $50,000 increase in indemnification support, solely for the payment of outside legal expenses. The Company recorded a total of $182,697 in costs associated with Dr. Platt's indemnification, of which $119,401 was recorded in the year ended December 31, 2013 and $63,296 was recorded in the year ended December 31, 2014. In July 2014, the arbitration was concluded in favor of Dr. Platt, confirming the effectiveness of the separation agreement and payment was made to Dr. Platt in July 2014. On March 2, 2015, the Board voted to rescind the requirement that Dr. Platt reimburse the Company the entire $182,697. The Board determined that interest should be charged to Dr. Platt from the time he received the funds in July 2014, to the date of the board meeting and that this amount would be offset against interest the Company owes Dr. Platt in conjunction with the note payable as referenced in Note 12 of the accompanying Notes to the Financial Statements. The remaining amount would be considered settled in full by the Company.

Item 14. Principal Accountant Fees and Services.

The table below shows the fees that we paid or accrued for the audit and other services provided by Liggett & Webb, P.A. ("LW") for the fiscal year ended December 31, 2018 and 2017.

Fee Category	2018	2017
Audit Fees – LW	$ 72,500	$ 72,500
Audit Related Fees	$ 27,750	$ —
Tax Fees	$ 2,500	$ 2,500
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 the acquisition audit of CureDM Group Holdings LLC.

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 registered public accounting firm. The Audit Committee approved the audit and audit-related services to be performed by the independent registered public accounting firms and tax professionals in 2018 and 2017.

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 Financial Statements commencing on Page F-1.

(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 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. 333-192344) filed with the SEC on November 14, 2013 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)
3.3	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)
4.1	Form of Securities Purchase Agreement by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on October 2, 2015 and incorporated herein by reference)
4.2	Form of 10% Convertible Promissory Note issued to CJY Holdings Limited (filed as Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on October 2, 2015 and incorporated herein by reference)
4.3	Letter Amendment by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on October 30, 2015 and incorporated herein by reference)
4.4	Letter Amendment by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 20, 2015 and incorporated herein by reference)
4.5	Letter Amendment by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the SEC on December 10, 2015 and incorporated herein by reference)
4.6	Letter Amendment by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.5 to the Company's Current Report on Form 8-K filed with the SEC on March 2, 2016 and incorporated herein by reference)
4.7	Letter Amendment by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.6 to the Company's Current Report on Form 8-K filed with the SEC on March 22, 2016 and incorporated herein by reference)
4.8	Letter Amendment by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.7 to the Company's Current Report on Form 8-K filed with the SEC on May 12, 2016 and incorporated herein by reference)
4.9	Letter Amendment by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.8 to the Company's Current Report on Form 8-K filed with the SEC on July 6, 2016 and incorporated herein by reference)
4.10	Form of Securities Purchase Agreement by and between Boston Therapeutics, Inc. and Investors (filed as Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 15, 2016 and incorporated herein by reference)
4.11	Form of 6% Senior Convertible Debenture Due 2018 issued to Investors (filed as Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 15, 2016 and incorporated herein by reference)
4.12	Form of Stock Purchase Warrant issued to Investors (filed as Exhibit 4.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 15, 2016 and incorporated herein by reference)
4.13	Letter Amendment by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.4 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 15, 2016 and incorporated herein by reference)
4.14	Form of Securities Purchase Agreement by and between Boston Therapeutics, Inc. and CJY Holdings Limited (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 26, 2017 and incorporated herein by reference)
4.15	Form of 6% Subordinated Convertible Debenture Due (filed as Exhibit 4.2 to the Current Report on Form 8-K filed with the SEC on April 26, 2017 and incorporated herein by reference)
4.16	Form of Stock Purchase Warrants (filed as Exhibit 4.3 to the Current Report on Form 8-K filed with the SEC on April 26, 2017 and incorporated herein by reference)
4.17	Form of Securities Purchase Agreement by and between Boston Therapeutics, Inc. and Investors (filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 14, 2017 and incorporated herein by reference)
4.18	Form of Certificate of Designation (filed as Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on August 14, 2017 and incorporated herein by reference)
4.19	Form of Common Stock Purchase Warrants (filed as Exhibit 4.3 to the Current Report on Form 8-K filed with the SEC on August 14, 2017 and incorporated herein by reference)
4.20	Form of 10% promissory note issued to World Technology East II Limited (filed as exhibit 4.1 to the Company's current Report on Form 8-K filed with the SEC on June 12, 2018 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	Amended and Restated Boston Therapeutics, Inc. 2010 Stock Plan (filed as Exhibit 10.1 to Amendment No. 1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2013 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	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)
10.6	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)
10.7	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)
10.8	Unit Purchase Agreement between Boston Therapeutics, Inc. and the investors named therein dated as of July 23, 2013, as amended (filed as Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 13, 2013 and incorporated herein by reference)
10.9	Registration Rights Agreement between Boston Therapeutics, Inc. and the investors named therein dated as of July 23, 2013, as amended (filed as Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the SEC on November 13, 2013 and incorporated herein by reference)
10.10	Warrant Repricing and Exercise Agreement entered by and between Boston Therapeutics, Inc. and CJY Holdings Limited dated November 12, 2015, effective June 15, 2015 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2015 and incorporated herein by reference)
10.11	Executive employment Agreement between Boston Therapeutics, Inc. and Carl W. Rausch dated as of August 12, 2016 (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on August 15, 2016 and incorporated herein by reference)
10.12	Letter Agreement dated March 27, 2017 entered between Boston Therapeutics, Inc. and Carl W. Rausch (filed as exhibit 10.24 to the Company's Annual Report on Form 10-K filed with the SEC on March 28, 2017 and incorporated herein by reference)
10.13	Contribution Agreement by and among Boston Therapeutics, Inc. and CureDM Group Holdings, LLC dated February 12, 2018, effective January 1, 2018, (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on February 12, 2018 and incorporated herein by reference)
10.14	Executive Retention Agreement by and between Boston Therapeutics, Inc. and Loraine Upham dated February 12, 2018, effective January 1, 2018, (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on February 12, 2018 and incorporated herein by reference)
10.15	License agreement between Boston Therapeutics, Inc. and Level Brands, Inc. (filed as exhibit 10.1 to the Company's current Report on Form 8-K filed with the SEC on July 2, 2018 and incorporated herein by reference)
23.1	Consent of Liggett & Webb P.A.*
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 years ended December 31, 2018 and December 31, 2017 formatted in XBRL: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statement of Changes in Stockholders' Equity (Deficit), (iv) Statements of Cash Flows, and (v) Notes to Financial Statements tagged as blocks of text.*

* 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 16, 2019

By: /s/ Carl W. Rausch
Carl W. Rausch
Chief Executive Officer and Chief Financial Officer
(Principle Executive Financial and Accounting 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/ Carl W. Rausch Carl Rausch	Director, Chief Executive Officer and Chief Financial Officer (Principal Executive Officer)	April 16, 2019
/s/ Conroy Chi-Heng Cheng Conroy Chi-Heng Cheng	Director	April 16, 2019
/s/ S. Colin Neill S. Colin Neill	Director	April 16, 2019

Boston Therapeutics, Inc.
FINANCIAL STATEMENTS

For the years ended December 31, 2018 and 2017

CONTENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Boston Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Boston Therapeutics, Inc. (“Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders’ deficit, and cash flows for each of the years in the two-year period ended December 31, 2018, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the results of its consolidated operations and its cash flows for each of the years in the two-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

The Company’s Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has limited cash resources, recurring cash used in operations and a history of operating losses. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are described in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Liggett & Webb, P.A.

We have served as the Company's auditor since 2015.

New York, New York
April 16, 2019

Boston Therapeutics, Inc.
Consolidated Balance Sheets
December 31, 2018 and 2017

	2018	2017
ASSETS		
Current assets:		
Cash	$ 12,467	$ 137,279
Accounts receivable	384	588
Prepaid expenses and other current assets	908,091	214,539
Inventory, net	1,013	38,541
Total current assets	921,955	390,947
Property and equipment, net	2,132	3,565
Intangible assets, net	515,212	439,286
Goodwill	—	69,782
Total assets	$ 1,439,299	$ 903,580
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 509,818	$ 299,257
Accrued expenses and other current liabilities	1,160,643	352,526
Deferred revenue	104,782	104,782
Convertible note payable – related party, net of discount, current portion	1,371,668	1,017,143
Convertible notes payable, net of discount, current portion	250,000	1,207,291
Notes payable – related parties, current portion	758,257	277,820
Note payable marketing agreement	450,000	—
Derivative liability, current portion	54,242	429,141
Total current liabilities	4,659,410	3,687,960
Warrant liability	925,806	1,099,200
Total liabilities	5,585,216	4,787,160
COMMITMENTS AND CONTINGENCIES (See Note 12)	—	—
Stockholders' deficit:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized:		
Series A Preferred stock, 150,000 shares designated, 82,500 and 55,000 shares issued and outstanding at December 31, 2018 and 2017, respectively	83	55
Common stock, $0.001 par value, 2,000,000,000 shares authorized, 110,131,373 and 64,437,163 shares issued and outstanding at December 31, 2018 and 2017, respectively	110,131	64,437
Additional paid-in capital	19,156,138	15,862,980
Accumulated deficit	(23,412,269)	(19,811,052)
Total stockholders' deficit	(4,145,917)	(3,883,580)
Total liabilities and stockholders' deficit	$ 1,439,299	$ 903,580

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

Boston Therapeutics, Inc.
Consolidated Statements of Operations
For the years Ended December 31, 2018 and 2017

	2018	2017
Revenue	$ 31,723	$ 29,356
Operating expenses:		
Direct expenses	67,133	49,761
Research and development	182,665	177,646
Sales and marketing	77,166	23,906
General and administrative	1,738,168	1,043,699
Impairment of goodwill	1,246,002	—
Total operating expenses	3,311,134	1,295,012
Operating loss	(3,279,411)	(1,265,656)
Other (expenses) income:		
Interest expense	(729,158)	(1,656,343)
Financing costs	(78,534)	(125,664)
Gain (loss) on extinguishment of debt	2,374	(81,541)
Change in fair value of derivative liability	83,287	904,896
Change in fair value of warrant liability	400,225	639,435
Total other (expenses) income	(321,806)	(319,217)
Loss before provision for income taxes	(3,601,217)	(1,584,873)
Provision for income taxes	—	—
Net loss	$ (3,601,217)	$ (1,584,873)
Net loss per share- basic and diluted	$ (0.04)	$ (0.03)
Weighted average shares outstanding basic and diluted	102,498,023	51,467,103

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

Boston Therapeutics, Inc.
Statement of Stockholders' Deficit
For the Years Ended December 31, 2018 and 2017

	Preferred Stock Shares	Preferred Stock Amount	Common Stock Shares	Common Stock Amount	Additional Paid-in Capital	Accumulated Deficit	Total
Balance at December 31, 2016	—	$ —	46,702,836	$ 46,703	$ 15,060,616	$ (18,226,179)	$ (3,118,860)
Conversion of convertible note payable and accrued interest into common stock	—	—	1,704,968	1,705	115,770	—	117,475
Conversion of related party accrued Interest into common stock	—	—	21,370	21	2,116	—	2,137
Conversion of accrued Interest into common stock	—	—	1,507,989	1,508	77,661	—	79,169
Conversion of related party convertible note and accrued interest into common stock	—	—	14,000,000	14,000	686,000	—	700,000
Issuance of Series A preferred stock for cash	55,000	55	—	—	549,945	—	550,000
Loss on extinguishment upon conversion of convertible note payable related party	—	—	—	—	(170,813)	—	(170,813)
Issuance of common stock in exchange for consulting services	—	—	500,000	500	26,900	—	27,400
Issuance of warrant to purchase common stock in exchange for consulting services	—	—	—	—	12,495	—	12,495
Stock based Compensation	—	—	—	—	49,756	—	49,756
Reclassification of derivative liability	—	—	—	—	(547,466)	—	(547,466)
Net Loss	—	—	—	—	—	(1,584,873)	(1,584,873)
Balance, December 31, 2017	55,000	55	64,437,163	64,437	15,862,980	(19,811,052)	(3,883,580)
Stock based compensation	—	—	—	—	175,076	—	175,076
Issuance of common stock in acquisition of CureDM Group Holdings LLC	—	—	25,000,000	25,000	1,225,000	—	1,250,000
Issuance of Series A Preferred stock for cash	27,500	28	—	—	274,972	—	275,000
Conversion of convertible note payable and accrued interest into common stock	—	—	17,027,544	17,027	1,260,039	—	1,277,066
Issuance of warrants to purchase capital stock in exchange for extension of note payable	—	—	—	—	21,121	—	21,121
Issuance of common stock in exchange for consulting services	—	—	3,666,666	3,667	326,333	—	330,000
Reclassification of derivative liability	—	—	—	—	10,617	—	10,617
Net loss	—	—	—	—	—	(3,601,217)	(3,601,217)
Balance, December 31, 2018	82,500	$ 83	110,131,373	$ 110,131	$ 19,156,138	$ (23,412,269)	$ (4,145,917)

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

Boston Therapeutics, Inc.
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2018 and 2017

	2018	2017
Cash flows from operating activities:		
Net Loss	$ (3,601,217)	$ (1,584,873)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	159,902	67,001
Impairment of goodwill	1,246,002	—
Stock-based compensation	175,076	49,756
Issuance of common stock and common stock warrants for consulting services	330,000	39,895
(Gain)/loss on extinguishment of debt	(2,374)	81,541
Change in fair value of warrant liabilities	(400,225)	(639,435)
Change in fair value of derivative liabilities	(83,287)	(904,896)
Provision for inventory obsolescence	31,752	12,997
Amortization of debt discount and deferred finance cost	624,608	1,510,782
Warrants issued for extension of debt	21,121	—
Changes in operating assets and liabilities		
Accounts receivable	204	4,423
Inventory	5,776	3,578
Prepaid expenses and other current assets	(243,552)	(131,829)
Accounts payable	46,354	(20,217)
Accrued expenses	806,019	243,455
Deferred revenue	—	(7,380)
Net cash used in operating activities	(883,841)	(1,275,202)
Cash flows from investing activities		
Cash acquired through CureDM purchase	3,592	—
Purchase of property and equipment	—	(4,704)
Net cash provided by (used in) investing activities	3,592	(4,704)
Cash flows from financing activities		
Proceeds from issuance of notes payable to related parties	480,437	—
Proceeds from issuance of convertible notes payable, related party	—	200,000
Repayment of notes payable, related party	—	(20,000)
Proceeds from issuance of preferred stock	275,000	550,000
Net cash provided by financing activities	755,437	730,000
Net decrease in cash	(124,812)	(549,906)
Cash, beginning of year	137,279	687,185
Cash, end of year	$ 12,467	$ 137,279
Supplemental disclosure of cash flow information		
Cash paid during the year for:		
Interest	$ —	$ —
Income taxes	$ —	$ —
Non-cash financing activities:		
Issuance of common stock for the acquisition of CureDM Groups Holdings LLC	$ 1,250,000	$ —
Issuance of note payable for marketing services	$ 450,000	$ —
Conversion of convertible notes payable plus accrued interest into common stock	$ 1,277,066	$ 198,781
Derivative liabilities associated with issuance of preferred stock	$ 226,833	$ 547,466
Conversion of convertible notes payable related party plus accrued interest into common stock	$ —	$ 700,000
Derivative liability associated with convertible note payable	$ 10,617	$ —
Loss on extinguishment of convertible note payable related party charged to additional paid in capital	$ —	$ 170,813

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. On February 12, 2018, the Company acquired CureDM Group Holdings LLC ("CureDM"), for 47,741,140 shares of common stock of which 25,000,000 were delivered at closing and 22,741,140 shall be delivered in four equal tranches of 5,685,285 each upon the achievement of specific milestones. See Notes 3 and 15.

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: BTI-320, a non-systemic, non-toxic, tablet for reduction of post-meal blood glucose in people living with diabetes that is fully developed, and IPOXYN, an injectable anti-necrosis, anti-hypoxia drug that we are currently developing. Due to the lack of adequate funding, the Company has not done any work with respect to IPOXYN to date.

Going Concern

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. The Company has limited cash resources, recurring cash used in operations and operating losses history. As shown in the accompanying financial statements, the Company has an accumulated deficit of approximately $23.4 million as of December 31, 2018 and used cash in operations of $883,841 during the year ended December 31, 2018. These factors among others, raise substantial doubt about the Company's ability to continue as a going concern.

The Company has incurred recurring operating losses since inception as it has worked to bring its SUGARDOWN® product to market and develop BTI-320 and IPOXYN. Management expects such operating losses will continue until such time that substantial revenues are received from SUGARDOWN® or the regulatory and clinical development of BTI-320 or IPOXYN is completed. The Company has approximately $12,500 cash on hand at December 31, 2018. Management is currently seeking additional capital through private placements and public offerings of its common stock. In addition, the Company may seek to raise additional capital through public or private debt or equity financings as well as collaboration activities in order to fund our operations. The Company raised $275,000 in gross proceeds from private placements of our Series A Preferred Stock during the first quarter of 2018. See Note 9. During the second quarter of 2018, the Company issued a note payable to a related party for $100,000. See Note 11. At the end of the third quarter of 2018, the Company approved a Private Placement Memorandum in an effort to raise additional funds. Also, at the end of the third quarter, the Company issued a Note Payable to CJY Holdings, Ltd, a related party, for $305,937. Also, in the fourth quarter of 2018, the Company has increased the amount of the note payable to the related party noted above to $174,500. An additional $339,144 was advanced to the Company during April 2019, from these related parties. Management anticipates that cash resources will be sufficient to fund our planned operations into the second quarter of 2019. The future of the Company is dependent upon its ability to obtain continued financing and upon future profitable operations from the partnering, development and clarity of its new business opportunities.

There can be no assurance that we will be successful in accomplishing our objectives. Without such additional capital, we may be required to cease operations. The accompanying financial statements do not include any adjustments that might result should the Company be unable to continue as a going concern.

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").

Principles of Consolidation

The consolidated financial statements include the Company and its wholly owned subsidiary, CureDM, from the date of acquisition. All significant intercompany transactions are eliminated in consolidation.

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.

Cash and Cash Equivalents

The Company considers 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. The Company had no cash equivalents at December 31, 2018 and 2017.

Revenue Recognition

For revenue from product sales, the Company recognizes revenue in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 606 ("ASC 606"). A five-step analysis must be met as outlined in ASC 606: (i) identify the contract with the customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations, and (v) recognize revenue when (or as) performance obligations are satisfied. Provisions for discounts and rebates to customers, estimated returns and allowances, and other adjustments are provided for in the same period the related sales are recorded. The Company defers any revenue for which the product has not been delivered or is subject to refund until such time that the Company and the customer jointly determine that the product has been delivered or no refund will be required.

The Company generates revenues from sales of SUGARDOWN®. In practice, the Company has not experienced or granted significant returns of product. Shipping fees charged to customers are included in revenue and shipping costs are included in costs of sales.

The Company generates revenue from royalties pursuant to a licensing and manufacturing agreement, whereby the licensee sells and distributes territory licensed products, excluding those manufactured and supplied by the Company in the territory. During the years ended December 31, 2018 and 2017, the Company recognized royalties revenue from APC of $0 and $7,380, respectively.

As disclosed in Note 10, Advance Pharmaceutical Company Ltd. ("APC"), a related party, accounted for 0% and 25% of total revenue, during the years ended December 31, 2018 and 2017, respectively.

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. There were no allowances for doubtful accounts as of December 31, 2018 and 2017.

Inventory

Inventory consists of raw materials, work-in-process and finished goods of SUGARDOWN®. Inventories are stated at the lower of cost (weighted average cost method) or market, not in excess of net realizable value. The Company adjusts the carrying value of its inventory for excess and obsolete inventory. The Company continues to monitor the valuation of its inventory.

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, 2018 and 2017, the Company recorded depreciation expense of $1,706 and $2,716, respectively.

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.

As the Company operates its business in one operating segment and one reporting unit, the Company's goodwill is assessed at the Company level for impairment in the fourth quarter of each year or more frequently if events or changes in circumstances indicate that impairment may exist. The Company has the option to first assess qualitative factors to determine whether it is necessary to perform the two-step impairment test. If the Company's qualitative assessment reveals that goodwill impairment is more likely than not, the Company performs the two-step impairment test. Alternatively, the Company may bypass the qualitative test and initiate goodwill impairment testing with the first step of the two-step goodwill impairment test.

During the first step of the goodwill impairment test, the Company compares the fair value of the reporting unit to its carrying value, including goodwill. If the fair value of a reporting unit exceeds its carrying value, then the Company concludes that no goodwill impairment has occurred. If the carrying value of the reporting unit exceeds its fair value, the Company performs the second step of the goodwill impairment test to measure possible goodwill impairment loss. If the carrying value of the reporting unit's goodwill exceeds its implied fair value, then we would record an impairment loss equal to the difference.

The Company performed its impairment review of goodwill for the years ended December 31, 2018 and 2017 and concluded that goodwill was impaired at December 31, 2018. The company recorded impairment of goodwill in the amount of $1,246,002 for the year ended December 31, 2018.

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, 2018 did not include 9,594,000, 38,999,990, 36,407,367 and 8,250,000 for options, warrants and shares to be issued upon conversion of notes payable and Series A Preferred Stock, respectively, because of their anti-dilutive effect. The weighted average number of common shares for the year ended December 31, 2017 did not include 9,594,000, 41,029,669, 50,419,670 and 5,500,000 for options, warrants and shares to be issued upon conversion of notes payable and Series A Preferred Stock, respectively, 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, 2018 and 2017.

On December 22, 2017, the Tax Cuts and Jobs Act (TCJA) was signed into law by the President of the United States. TCJA is a tax reform act that among other things, reduced corporate tax rates to 21 percent effective January 1, 2018. FASB ASC 740, Income Taxes, requires deferred tax assets and liabilities to be adjusted for the effect of a change in tax laws or rates in the year of enactment, which is the year in which the change was signed into law. Accordingly, the Company adjusted its deferred tax assets and liabilities at December 31, 2017, using the new corporate tax rate of 21 percent. See Note 12.

Advertising Costs

Advertising costs are expensed as incurred and are reported as a component of operating expenses in the selling and marketing expenses in the statements of operations. The Company did not incur any advertising costs for either year ended December 31, 2018 and 2017, respectively.

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

Fair values determined by Level 1 inputs utilize observable data such as quoted prices in active markets. Fair values determined by Level 2 inputs utilize data points other than quoted prices in active markets that are observable either directly or indirectly. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the reporting entity to develop its own assumptions. The Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and notes payable. The carrying value of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses approximates fair value due to their short-term nature using level 3 inputs as defined above. The carrying value of the notes payable as of December 31, 2018 and 2017, evaluated using level 3 inputs defined above based on quoted market prices on rates available to the Company for debt with similar terms and maturities, approximates the fair value.

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.

Convertible Instruments

U.S. GAAP requires companies to bifurcate conversion options from their host instruments and account for them as free standing derivative financial instruments according to certain criteria. The criteria include circumstances in which (a) the economic characteristics and risks of the embedded derivative instrument are not clearly and closely related to the economic characteristics and risks of the host contract, (b) the hybrid instrument that embodies both the embedded derivative instrument and the host contract is not re-measured at fair value under otherwise applicable generally accepted accounting principles with changes in fair value reported in earnings as they occur and (c) a separate instrument with the same terms as the embedded derivative instrument would be considered a derivative instrument. An exception to this rule is when the host instrument is deemed to be conventional, as that term is described under applicable ASC 480-10.

When the Company has determined that the embedded conversion options should not be bifurcated from their host instruments, the Company records, when necessary, discounts to convertible notes for the intrinsic value of conversion options embedded in debt instruments based upon the differences between the fair value of the underlying common stock at the commitment date of the note transaction and the effective conversion price embedded in the note. Debt discounts under these arrangements are amortized over the term of the related debt to their stated date of redemption.

Common Stock Purchase Warrants and Other Derivative Financial Instruments

The Company classifies as equity any contracts that (i) require physical settlement or net-share settlement or (ii) provide the Company with a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement) providing that such contracts are indexed to the Company's own stock. The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the Company's control) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement). The Company assesses classification of its common stock purchase warrants and other free standing derivatives at each reporting date to determine whether a change in classification between assets and liabilities is required.

The Company's free standing derivatives consisted of warrants to purchase common stock that were issued in connection with the issuance of debt and of embedded conversion options with senior convertible debentures. The Company evaluated these derivatives to assess their proper classification in the balance sheet as of December 31, 2018 using the applicable classification criteria enumerated under ASC 815-Derivatives and Hedging. The Company determined that certain embedded conversion and/or exercise features do not contain fixed settlement provisions. The convertible debentures contain a conversion feature such that the Company could not ensure it would have adequate authorized shares to meet all possible conversion demands.

As such, the Company was required to record the debt and warrant derivatives which do not have fixed settlement provisions as liabilities and mark to market all such derivatives to fair value at the end of each reporting period.

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 recognizes the compensation cost of share-based awards on a straight-line basis over the requisite service period, which is generally 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 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 requisite service 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.

Recent Accounting Pronouncements

There are various updates recently issued, most of which represented technical corrections to the accounting literature or application to specific industries and are not expected to have a material impact on the Company's financial position, results of operations or cash flows.

Reclassification

Certain amounts in the December 31, 2017 financial statements have been reclassified to conform to the presentation used at December 31, 2018.

3. ACQUISITION OF CUREDM

On February 12, 2018, the Company entered into a Contribution Agreement with the members of CureDM Group Holdings, LLC, a limited liability company ("CureDM Group"), all of which except five are accredited investors ("CureDM Group Members") pursuant to which the CureDM Group Members agreed to contribute 100% of the outstanding securities of CureDM Group in exchange for an aggregate of 47,741,140 shares of common stock of the Company (the "BTHE Contribution Shares") of which 25,000,000 BTHE Contribution Shares were delivered at closing and 22,741,140 BTHE Contribution Shares (the "Milestone BTHE Shares") shall be delivered in four equal tranches of 5,685,285 BTHE Contribution Shares each upon the achievement of specific milestone s (the "CureDM Group Contribution"). The closing of the CureDM Group Contribution occurred on February 12, 2018.

A summary of consideration is as follows:

25,000,000 shares of the Company's common stock	$	1,250,000
22,741,140 contingency shares of the Company's common stock		—
Total consideration	$	1,250,000

The following summarizes the current estimates of fair value of assets acquired and liabilities assumed:

Assets acquired:		
Cash	$	3,592
Property and equipment		273
Goodwill		1,176,220
Intangibles		234,122
Liabilities assumed:		
Accounts payable and accrued expenses		(164,207)
Net assets acquired	$	1,250,000

As of December 31, 2018, the Company expects the probability of the milestones for issuance of the contingent shares to be remote and therefore has placed no value on the shares as of December 31, 2018. See Note 15.

The purchase price allocation for the above acquisition is subject to further refinement as management completes its assessment of the valuation of certain assets and liabilities.

The Company accounts for acquisitions in accordance with the provisions of ASC 805-10. The Company assigns to all identifiable assets acquired a portion of the cost of the acquired net assets equal to the estimated fair value of such assets at the date of acquisition. The Company records the excess of the cost of the acquired net assets over the sum of the amounts assigned to identifiable assets acquired as goodwill.

The Company accounts for and reports acquired goodwill under Accounting Standards Codification subtopic 350-10, Intangibles-Goodwill and Other ("ASC 350-10"). In accordance with ASC 350-10, at least annually, the Company tests its intangible assets for impairment or more often if events and circumstances warrant. Any write-downs will be included in results from operations.

Pro forma results

The following table sets forth the unaudited pro forma results of the Company as if the acquisition of CureDM had taken place on the first day of the period presented. These combined results are not necessarily indicative of the results that may have been achieved had the companies been combined as of the first day of the period presented. This pro forma financial information is based on historical results of operations, adjusted for the allocation of the purchase price and other acquisition accounting adjustments, and is not indicative of the results that may have been achieved had the companies been combined as of the first day of the period presented.

	For the year ended December 31,	
	2018	2017
Total revenues	$ 31,273	$ 31,263
Net loss	(3,601,217)	(2,086,490)
Basic and diluted net earnings per common share	$ (0.04)	$ (0.03)

4. INVENTORY

Inventory 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 inventory at December 31, 2018 and 2017 net of inventory reserves, were as follows:

	2018	2017
Raw materials	$ —	$ 33,055
Finished goods	1,013	5,486
Total	$ 1,013	$ 38,541

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. The Company recorded a charge to the provision for inventory obsolescence in the amount of $31,752 and $12,997 for the years ended December 31, 2018 and 2017, respectively.

5. INTANGIBLE ASSETS

The SUGARDOWN® technology and patent applications, 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 as of December 31:

	2018	2017
SUGARDOWN® technology and patent applications	$ 1,134,122	$ 900,000
Less accumulated amortization	(618,910)	(460,714)
Intangible assets, net	$ 515,212	$ 439,286

Amortization expense for each of the years ended December 31, 2018 and 2017 was $158,196 and $64,285, respectively.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

The following table represents the major components of accrued expenses and other current liabilities at December 31, 2018 and 2017:

	2018	2017
Accrued payroll	$ 188,716	$ —
Professional fees	95,018	60,000
Accrued consulting fees	202,000	—
Interest	668,183	292,526
Accrued expense reimbursement	6,726	—
Total	$ 1,160,643	$ 352,526

7. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company measures the fair value of financial assets and liabilities based on the guidance of ASC 820 "Fair Value Measurements and Disclosures" which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 - quoted prices in active markets for identical assets or liabilities
Level 2 - quoted prices for similar assets and liabilities in active markets or inputs that are observable
Level 3 - inputs that are unobservable based on an entity's own assumptions, as there is little, if any, related market activity (for example, cash flow modeling inputs based on assumptions)

Financial liabilities as of December 31, 2018 and 2017 measured at fair value on a recurring basis are summarized below:

	December 31, 2018	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Derivative liability	$ 54,242	$ —	$ —	$ 54,242
Warrant liability	925,806	—	—	925,806
Total	$ 980,048	$ —	$ —	$ 980,048

	December 31, 2017	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Derivative liability	$ 429,141	$ —	$ —	$ 429,141
Warrant liability	1,099,200	—	—	1,099,200
Total	$ 1,528,341	$ —	$ —	$ 1,528,341

The Company determined that certain conversion/exercise option related to a convertible note and issued warrants did not have fixed settlement provisions and are deemed to be derivative financial instruments, since the conversion/exercise prices was subject to reset adjustment should the Company issue any option to acquire the Company's common stock lower than the conversion /exercise price. Accordingly, the Company was required to record such conversion/exercise options as a liability and mark such derivative to fair value each reporting period. Such instrument was classified within Level 3 of the valuation hierarchy.

The fair value of the conversion/exercise options were calculated using a binomial lattice formula with the following weighted average assumptions during the years ended December 31, 2018 and 2017:

Conversion option:

	December 31, 2018	December 31, 2017
Common Stock Closing Price	$ 0.03	$ 0.04 to 0.07
Conversion Price per Share	$ 0.075 to 0.10	$ 0.075 to 0.10
Conversion Shares	5,333,333	21,666,667
Call Option Value	0.013 to 0.055	0.0188 to 0.0568
Dividend Yield	0.00%	0.00%
Volatility	221.92%	208.82% to 214.34%
Risk-free Interest Rate	2.46% to 2.51%	1.03% to 1.76%
Term	0.32 to .625 years	0.62 to 2 years

Exercise option:

	December 31, 2018	December 31, 2016
Common Stock Closing Price	$ 0.03	$ 0.04 to 0.075
Conversion Price per Share	$ 0.10 to 0.15	$ 0.10 to 0.15
Conversion Shares	34,000,000	29,000,000
Call Option Value	0.026 to 0.028	0.0375 to 0.0723
Dividend Yield	0.00%	0.00%
Volatility	221.92%	208.82 to 214.34%
Risk-free Interest Rate	2.46 to 2.51%	1.62 to 2.2%
Term	2.62 to 4 years	3.62 to 5 years

The risk-free interest rate is the United States Treasury rate on the measurement date having a term equal to the remaining contractual life of the instrument. The volatility is a measure of the amount by which the Company's share price has fluctuated or is expected to fluctuate. The dividend yield is 0% as the Company has not made any dividend payment and has no plans to pay dividends in the foreseeable future. Level 3 liabilities are valued using unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of the derivative liabilities. For fair value measurements categorized within Level 3 of the fair value hierarchy, the Company's Chief Financial Officer, who reports to the Chief Executive Officer, determine its valuation policies and procedures. The development and determination of the unobservable inputs for Level 3 fair value measurements and fair value calculations are the responsibility of the Company's Chief Financial Officer and are approved by the Chief Executive Officer. Level 3 financial liabilities consist of the derivative liabilities for which there is no current market for these securities such that the determination of fair value requires significant judgment or estimation. Changes in fair value measurements categorized within Level 3 of the fair value hierarchy are analyzed each period based on changes in estimates or assumptions and recorded as appropriate. Significant observable and unobservable inputs include stock price, exercise price, annual risk free rate, term, and expected volatility, and are classified within Level 3 of the valuation hierarchy. An increase or decrease in volatility or interest free rate, in isolation, can significantly increase or decrease the fair value of the derivative liabilities. Changes in the values of the derivative liabilities are recorded as a component of other income (expense) on the Company's statements of operations.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial liabilities that are measured at fair value on a recurring basis using significant unobservable input for the years ended December 31, 2017 and 2016:

	Debt Derivative	Warrant Liability
Balance December 31, 2016	$ 1,234,106	$ 1,093,765
Aggregate amount of derivative instruments issued	85,381	644,870
Transferred in due to conversions	14,551	—
Change in fair value of derivative liabilities	(904,897)	(639,435)
Balance, December 31, 2017	429,141	1,099,200
Aggregate amount of derivative instruments issued	—	226,831
Transferred in due to conversions	(291,612)	—
Change in fair value of derivative liabilities	(83,287)	(400,225)
Balance, December 31, 2018	$ 54,242	$ 925,806

8. CONVERTIBLE NOTES PAYABLE

In August and September 2016, the Company issued senior convertible debentures for an aggregate of $1,600,000 (the "Convertible Debentures") in exchange for an aggregate net cash proceeds of $1,327,300, net of financing costs. The Convertible Debentures have a stated interest rate of 6% per annum payable quarterly beginning June 30, 2017 and were due two years from the date of issuance, the latest due September 15, 2018 and are convertible into shares of the Company's common stock at the option of the holder at a conversion price of $0.075 with certain anti-dilutive (reset) provisions and are subject to forced conversion if either i) the volume weighted average common stock price for each of any 10 consecutive trading days equals or exceeds $0.50, or (ii) the Company's elects to lists a class of securities on a national securities exchange.

As long as the convertible notes remain outstanding, the Company is restricted from incurring any indebtedness or liens, except as permitted (as defined), amend its charter in any matter that materially effects rights of noteholders, repay or repurchase more than de minimis number of shares of common stock other than conversion or warrant shares, repay or repurchase all or any portion of any indebtedness or pay cash dividends.

In connection with the issuance of the Convertible Debentures, the Company issued an aggregate of 16,000,000 warrants to purchase the Company's common stock at $0.10 per share, expiring five years from the date of issuance, the latest being September 15, 2021. These warrants contain a cashless exercise and certain anti-dilutive (reset) provisions.

The Company determined that certain conversion/exercise option related to a convertible note and issued warrants did not have fixed settlement provisions and are deemed to be derivative financial instruments due to price protection features present in the conversion/ exercise price that are not consistent with a fixed for fixed model.

The accounting treatment of derivative financial instruments requires that the Company record the fair value of the derivative as of the issuance date of the debenture and warrants and to re-measure the derivatives at fair value as of each subsequent reporting date.

The Company recognized the value attributable to the conversion feature of the convertible debenture and issued warrants of $2,203,336 and together with financing costs of $272,700 (aggregate of $2,476,036) as a discount against the notes up to $1,600,000 with the excess of $876,036 charged to current period interest. The Company valued the conversion option and the warrants using the Binomial Lattice pricing model as described in Note 6. The debt discount was amortized over the note's maturity period as interest expense.

On April 11, 2017, one investor converted his Convertible Debenture of $75,000 plus accrued interest of $2,873, into 1,038,301 shares of the Company's common stock. Upon conversion, a loss on extinguishment was recorded in the amount of $51,267.

On July 14, 2017, one investor converted his Convertible Debenture of $50,000 plus accrued interest of $2,482, into 711,755 shares of the Company's common stock. Upon conversion, a loss on extinguishment was recorded in the amount of $30,274.

In August 2018, two investors entered in agreements to extend the due date of convertible debentures held in the amount of $250,000 until August 31, 2019. One of the investors was issued warrants to acquire 375,000 shares of common stock for $0.075 per share. The warrants expire in five years. The fair value of the warrants on the date of issuance was $21,121 which is included in interest expense for the year ended December 31, 2018.

During 2018, 29 investors converted their Convertible Debentures totaling $1,225,000 plus accrued interest of $52,066, into 17,027,544 shares of the Company's common stock. Upon conversion, a loss on extinguishment was recorded in the amount of $2,374.

For the year ended December 31, 2018 and 2017, the Company amortized $543,347 and $760,082, respectively, debt discount to operations as interest expense.

Convertible notes payable consist of the following at December 31, 2018 and December 31, 2017:

	2018	2017
Principal balance	$ 250,000	$ 1,475,000
Debt discount	—	(189,175)
Deferred finance costs	—	(78,534)
Outstanding, net of debt discount	$ 250,000	$ 1,207,291

9. MARKETING AGREEMENT

On June 26, 2018, the Company entered into a License Agreement with Level Brands, Inc. (NYSE: LEVB), an innovative licensing, marketing and brand management company with a focus on lifestyle-based products which includes an exclusive license to the *kathy ireland*® Health & Wellness™ brand. Under the terms of the License Agreement, the Company received a non-exclusive, non-transferrable license to use the *kathy ireland* Health & Wellness™ trademark in the marketing, development, manufacture, sale and distribution of the Sugardown® product domestically and internationally. The initial term of the License Agreement is seven years, with an automatic two-year extension unless either party notifies the other of non-renewal at least 90 days prior to the end of the then current term. Level Brands has agreed to use its commercially reasonable efforts to perform certain promotional obligations, including: (i) producing four branded videos to promote the licensed product and/or the Company; (ii) creation of an electronic press kit; (iii) making their media and marketing teams available for use in creating the video content for which the Company will separately compensate; and (iv) curate social media posts in multiple social media channels.

As compensation, the Company will provide Level Brands with the following:

- A marketing fee of $850,000, for development of video content and an electronic press kit which will be used ongoing to support product marketing. This fee is paid with a promissory note of $450,000 and a number of shares of stock of the Company valued at $400,000, based on the closing price on the day prior to the effective date;
- Quarterly fees for the first two years of up to $100,000 and issuance of 100,000 shares each quarter, based on sales volumes. The Company has the right to make all the stock payments in cash; and
- a royalty of 5% of the gross licensed marks sales up to $10,000,000, 7.5% royalty on sales from $10,000,000 to $50,000,0000 and 10% on sales over $50,000,000, payable monthly as well as a 1% of all revenue for all Company products as of the date hereof.

The Note Payable of $450,000 bears interest at 8% and matures December 31, 2019, unless the Company raises $750,000 through Level Brands prior to that date in which case the Note is to be repaid in full including accrued interest. Accrued interest at December 31, 2018 totaled $18,493.

As of December 31, 2018, the Company has not issued the $400,000 of common stock (See Note 15)

10. 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 2,000,000,000 shares of its $0.001 par value common stock. During the year ended December 31, 2013, the Company amended its certificate of incorporation to increase the number of common shares from 100,000,000 to 200,000,000. The amendment went into effect September 7, 2013.

On January 9, 2018, the Company's Board of Directors voted to approve an increase in authorized common stock shares outstanding from 200 million shares to 2 billion shares of the Company's common stock. This increase was approved by the shareholders in the first quarter of 2018.

Series A Preferred Stock

The Company has designated 150,000 shares of its preferred stock as Series A Preferred Stock. Each share of Series A Preferred Stock has a stated value of $10. The Series A Preferred Stock is convertible into shares of the Company's common stock by dividing the stated value by a conversion price of $0.10 per share. The Series A Preferred Stock shall have voting rights on an as converted basis (subject to limitations) and liquidation preference for each share of Series A Preferred Stock at an amount equal to the stated value per share. As of December 31, 2018, and 2017, the Company has 82,500 and 55,000 shares of Series A Preferred Stock outstanding, respectively.

On August 14, 2017, the Company entered into Securities Purchase Agreements with two accredited investors. In connection with these agreements, the Company issued 45,000 shares of Series A Preferred Stock and warrants to acquire 9,000,000 shares of common stock. The shares of Series A Preferred Stock are convertible, at any time at the option of the holder, into an aggregate of 4,500,000 shares of the Company's common stock. The Warrants shall be exercisable for a period of five years at an exercise price of $0.15 per share.

The Company recognized the value attributable to the conversion feature of the issued warrants of $650,421 as a charge against additional paid in capital up to $450,000 with the excess of $200,421 charged to change in fair value of warrant liability during the year ended December 31, 2017. The Company valued the warrants using the Binomial Lattice pricing model as described in Note 6.

On October 24, 2017, the Company entered into Securities Purchase Agreements with an accredited investor. In connection with the agreement, the Company issued 10,000 shares of Series A Preferred Stock and warrants to acquire 2,000,000 shares of common stock. The shares of Series A Preferred Stock are convertible, at any time at the option of the holder, into an aggregate of 1,000,000 shares of the Company's common stock. The Warrants shall be exercisable for a period of five years at an exercise price of $0.15 per share.

The Company recognized the value attributable to the conversion feature of the issued warrants of $93,312 as a charge against additional paid in capital. The Company valued the warrants using the Binomial Lattice pricing model as described in Note 6.

On February 2, 2018, the Company entered into Securities Purchase Agreements with four accredited investors. In connection with these agreements, the Company issued 27,500 shares of Series A Preferred Stock and warrants to acquire 5,500,000 shares of common stock in consideration of $275,000. The shares of Series A Preferred Stock are convertible, at any time at the option of the holder, into an aggregate of 2,750,000 shares of the Company's common stock. The Warrants shall be exercisable for a period of five years at an exercise price of $0.15 per share.

The Company recognized the value attributable to the conversion feature of the issued warrants of $226,833 as a charge against additional paid in capital. The Company valued the warrants using the Binomial Lattice pricing model as described in Note 6

Common Stock

On April 11, 2017, the Company issued a total of 1,038,301 shares of its common stock in conjunction with the conversion of one of the 6% Convertible Debentures plus accrued interest. Of the total amount of shares issued, 1,000,000 were for the conversion of a Note for $75,000 and 38,301 shares were issued for the conversion of accrued interest of $2,873.

On July 14, 2017, in accordance with the terms of a Securities Purchase Agreement, the Company issued 666,667 shares to an investor upon conversion of a note payable held by the investor for $50,000. The cost basis for the shares issued was $0.075.

On July 31, 2017, in accordance with the terms of a Securities Purchase Agreement, the Company issued 21,370 shares to a related party in lieu of cash for payment of accrued interest of $2,130. The cost basis for the shares issued was $0.10.

On September 29, 2017, in accordance with the terms of a Securities Purchase Agreement, the Company issued 1,507,989 shares to investors in lieu of cash for payment of accrued interest of $79,169. The cost basis for the shares issued was $0.0525.

On October 4, 2017, the Company issued 500,000 shares of its common stock with a fair value of $27,400 to a vendor in exchange for consulting services.

On October 6, 2017 the Company issued a total of 10,000,000 shares of its common stock in conjunction with the conversion of $500,000 of its Related Party Convertible Notes Payable.

On October 16, 2017 the Company issued a total of 4,000,000 shares of its common stock in conjunction with the conversion of $200,000 of its Related Party Convertible Notes Payable plus accrued interest. Of the total amount of shares issued, 1,000,000 were for the conversion of the Notes Payable for $50,000 and 3,000,000 shares were issued for the conversion of accrued interest of $150,000.

On February 16, 2018, the Company's Board of Directors approved the issuance of 3,666,666 shares of the Company's common stock to two consultants for services rendered amounting to $330,000.

During 2018, 29 investors converted their Convertible Debenture totaling $1,225,000 plus accrued interest of $52,066, into 17,027,544 shares of the Company's common stock.

Common Stock Warrants

The Company accounts for warrants as either equity instruments or liabilities depending on the specific terms of the warrant agreement. As of December 31, 2018, the Company had 38,999,990 warrants outstanding which are all classified as equity instruments and are fully exercisable.

The following table summarizes the Company's common stock warrants activity for the years ended December 31, 2018 and 2017:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding as of December 31, 2016	28,424,669	$ 0.29	$ —
Granted	13,250,000	0.14	
Exercised	—	—	
Forfeited/Canceled	(645,000)	1.00	
Outstanding as of December 31, 2017	41,029,669	0.23	$ —
Granted	5,875,000	0.15	
Exercised	—	—	
Forfeited/Canceled	(7,904,679)	0.43	
Outstanding as of December 31, 2018	38,999,990	$ 0.17	$ —

The aggregate intrinsic value represents the pretax intrinsic value, based on the warrants with an exercise price less than the Company's stock price of $0.03 at December 31, 2018, which would have been received by the warrant holders had those warrant holders exercised their warrants as of that date.

11. 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. On September 7, 2013, the 2010 plan was amended to increase the number of shares of common stock issuable under the 2010 Plan to 7,500,000. As of December 31, 2018 and 2017, there were 250,000 and 250,000 options outstanding under the 2010 Plan, respectively.

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 to increase the number of shares of common stock issuable under the 2011 Plan to 12,000,000 shares. During the period ended March 31, 2013, the 2011 Plan was amended to increase the number of shares of common stock issuable under the 2011 Plan to 17,500,000. As of December 31, 2018 and 2017, there were 9,344,000 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 typically expire in five to ten years.

On February 12, 2018, Loraine Upham was appointed as Chief Operating Officer. Ms. Upham received a stock option to purchase 4,000,000 shares of common stock under the Company's Amended and Restated 2011 Stock Incentive Plan, vesting over three (3) years, one third on the first anniversary of the effective date and the balance in equal quarterly installments. The exercise price of the initial tranche of options (1,333,334 shares) shall be $0.06 per share, the second tranche (1,333,333 shares) shall be $0.10 per share and the final tranche (1,333,333 shares) shall be $0.20 per share. The term of the options is five years. Ms. Upham resigned from the Company on November 30, 2018. As a result of her resignation all of her stock options were terminated and returned to the option pool.

On March 1, 2018 the Board of Directors approved a reduction in the exercise price of 6,000,000 stock options issued to the Company's CEO on August 22, 2016. The First tranche of 2,000,000 will be exercisable at $0.10 per share and the second and third tranches of 2,000,000 will be exercisable at $0.15 per share. The remainder of the terms remain unchanged. On August 22, 2016, the Company granted 6,000,000 options to purchase its common shares to its new CEO as a part of his employment agreement. The options consist of 3 separate tranches with different exercise prices and vest upon reaching certain milestones. All 6 million options have a five year life. The first 2,000,000 shares have an exercise price of $0.20 per share and vest upon the Company raising at least $1 million in financing. The second 2,000,000 shares carry an exercise price of $0.40 per share and vest upon the Company raising $5 million in financing. The third 2,000,000 shares carry an exercise price of $0.60 per share and vest upon the Company entering into a significant corporate alliance for substantial marketing and selling of the Company's product portfolio.

In addition, the Company amended 1,500,000 stock options previously granted to the new CEO to extend the expiration date to August 22, 2026. These options were all previously vested.

No stock options were issued under either plan during the year ended December 31, 2017.

The fair value of stock options granted and revaluation of non-employee consultant options for year ended December 31, 2018 was calculated with the following assumptions:

	2018
Risk-free interest rate	2.22 - 2.3%
Expected dividend yield	0%
Volatility factor	217.6% - 219.04%
Expected life of option	1.71 - 5 years

The weighted-average fair value of stock options granted during the year ended December 31, 2016 under the Black-Scholes option pricing model was $0.12. For the years ended December 31, 2018 and 2017, the Company recorded stock-based compensation expense of $175,076 and $49,756, respectively, in connection with share-based payment awards. As of December 31, 2018 and 2017, there was $144,991 and $182,439, respectively of unrecognized compensation expense related to non-vested stock option awards.

The following table summarizes the Company's stock option activity during the years ended December 31, 2018 and 2017:

	Shares	Exercise Price per Share	Weighted Average Exercise Price per Share	Aggregate Intrinsic Value
Outstanding as of December 31, 2016	12,289,000	$ 0.10 – 1.21	$ 0.39	$ —
Granted	—	—	—	
Exercised	—	—	—	
Options forfeited/cancelled	(2,695,000)	0.10 – 0.50	0.47	
Outstanding as of December 31, 2017	9,594,000	$ 0.10 – 1.21	$ 0.36	$ —
Granted	4,000,000	0.06 – 0.20	0.12	
Exercised	—	—	—	
Options forfeited/cancelled	4,000,000	0.06 – 0.20	0.12	
Outstanding as of December 31, 2018	9,594,000	$ 0.10 – 1.21	$ 0.29	$ —

The following table summarizes information about stock options that are vested or expected to vest at December 31, 2018:

	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	1,600,000	0.10	5.75	$ —	1,600,000	$ 0.10	5.75	$ —
0.18	934,000	0.18	4.50	—	934,000	0.18	4.50	—
0.20	2,150,000	0.20	3.37	—	2,150,000	0.20	3.37	—
0.37	58,000	0.37	3.67	—	58,000	0.37	3.67	—
0.40	2,000,000	0.40	2.67	—	—	0.40	2.67	—
0.42	63,000	0.42	2.00	—	63,000	0.42	2.00	—
0.50	310,000	0.50	0.83	—	310,000	0.50	0.83	—
0.60	2,000,000	0.60	2.67	—	—	0.60	2.67	—
0.69	100,000	0.69	5.25	—	100,000	0.69	5.25	—
1.21	379,000	1.21	5.03	—	379,000	1.21	5.03	—
$ 0.10-1.21	9,594,000	$ 0.29	3.70	$ —	5,594,000	$ 0.27	4.47	$ —

The following table sets forth the status of the Company's non-vested stock options as of December 31, 2018 and 2017:

	Number of Options	Weighted-Average Grant-Date Fair Value
Non-vested as of December 31, 2016	4,000,000	$ 0.50
Granted	—	—
Forfeited	—	—
Vested	—	—
Non-vested as of December 31, 2017	4,000,000	$ 0.50
Granted	4,000,000	0.12
Forfeited	—	—
Vested	(4,000,000)	0.12
Non-vested as of December 31, 2018	4,000,000	$ 0.50

The weighted-average remaining contractual life for options exercisable at December 31, 2018 is 3.70 years. At December 31, 2018 the Company has 8,156,000 and 7,250,000 options available for grant under the 2011 Plan and 2010 Plan, respectively.

The aggregate intrinsic value for fully vested, exercisable options was $0 at both December 31, 2018 and 2017, respectively. The aggregate intrinsic value of options exercised during the years ended December 31, 2018 and 2017 was $0 for both years as no options were exercised. The actual tax benefit realized from stock option exercises during the years ended December 31, 2018 and 2017 were $0 for both years as no options were exercised in either year.

12. RELATED PARTY TRANSACTIONS

Through December 31, 2011, a founder of the company and significant shareholder, Dr. David Platt advanced $257,820 to the Company to fund start-up costs and operations. Advances by Dr. Platt carry an interest rate of 6.5% and were due on June 29, 2013. On May 7, 2012, Dr. Platt and the Company's former President and also a significant shareholder entered into promissory notes to advance to the Company an aggregate of $40,000. The notes accrue interest at 6.5% per year and were due June 30, 2013. The outstanding notes of $297,820 were amended each year to extend the maturity dates. Effective June 30, 2015, the outstanding notes for Dr. Platt were amended to extend the maturity dates to June 30, 2017. During 2017, the Company made principal payments totaling $20,000 to the former President of the Company, reducing the total balance of the outstanding notes to $277,820. As of December 31, 2018, the remaining notes to Dr. Platt are in default and are classified as current liabilities.

On June 24, 2011, the Company entered into a definitive Licensing and Manufacturing Agreement (the "Agreement") with Advance Pharmaceutical Company Ltd. ("Advance Pharmaceutical"), a Hong Kong-based privately-held company. Under terms of the Agreement, the Company manufactures and supplies product in bulk for Advance Pharmaceutical. Advance Pharmaceutical is responsible for the packaging, marketing and distribution of SUGARDOWN® in certain territories within Asia. In addition, APC is able to purchase the SUGARDOWN product directly from the US manufacturer and sell it within APC's distribution area. In these situations, the Company is entitled to royalty payments from APC of 10% of the total sales price paid upon shipment of the product. Advance Pharmaceutical, through a wholly owned subsidiary, has purchased an aggregate 1,799,800 shares of the Company's common stock in conjunction with the Company's private placement offerings during the years ended December 31, 2012 and 2011. The shares were purchased on the same terms as the other participants acquiring shares in the respective offerings. Conroy Chi-Heng Cheng is a director of Advance Pharmaceutical and joined the Company's Board in December 2013. Revenue generated pursuant to the Agreement for years ended December 31, 2018 or 2017 was $0 and $7,380, respectively.

In December 2013, the Board of Directors agreed to indemnify Dr. Platt for legal costs incurred in connection with an arbitration (now concluded) initiated before the American Arbitration Association by Galectin Therapeutics, Inc. (formerly named Pro-Pharmaceuticals, Inc.) for which Dr. Platt previously served as CEO and Chairman. Galectin sought to rescind or reform the Separation Agreement entered into with Dr. Platt upon his resignation from Galectin to remove a $1.0 million milestone payment which Dr. Platt asserted he was entitled to receive and to be repaid all separation benefits paid to Dr. Platt. The Company initially capped the amount for which it would indemnify Dr. Platt at $150,000 in December 2013 and Dr. Platt agreed to reimburse the indemnification amounts paid by the Company should he prevail in the arbitration. The Board decided to indemnify Dr. Platt after considering a number of factors, including the scope of the Company's existing indemnification obligations to officers and directors and the potential impact of the arbitration on the Company. In May 2014, the Board approved a $50,000 increase in indemnification support, solely for the payment of outside legal expenses. The Company recorded a total of $182,697 in costs associated with Dr. Platt's indemnification, of which $119,401 was expensed in the year ended December 31, 2013 and of which $63,296 was expensed in the year ended December 31, 2014. In July 2014, the arbitration was concluded in favor of Dr. Platt, confirming the effectiveness of the separation agreement and payment was made to Dr. Platt in July 2014.

On March 2, 2015, the Board of Directors voted to reduce the amount that Dr. Platt was required to reimburse the Company to $82,355 and to offset this amount against interest accrued in respect of the outstanding note payable to Dr. Platt. In addition, the Board determined that Dr. Platt would be charged interest related to the $182,697 indemnification payment since funds were received by Dr. Platt in July 2014. The Board of Directors concluded the foregoing constituted complete satisfaction of Dr. Platt's indemnification by the Company. Accordingly, the Company recorded the reduction in accrued interest through equity during the year ended December 31, 2015. As of December 31, 2018 and 2017, $59,650 and $38,979, respectively, of accrued interest in connection with the related party promissory notes, had been included in accrued expenses and other current liabilities on the accompanying balance sheet.

During September 2015, the Company entered into a securities purchase agreement with CJY. Pursuant to this agreement, the Company issued to CJY a convertible promissory note in the principal amount of $750,000. The Note was amended during the fourth quarter of 2015 to $1,200,000. During 2016, the Note was amended to $1,752,000. This Note provided necessary bridge financing to the Company prior to a financing of $1,600,000 completed in the third quarter of 2016. Interest accrues at the rate of 10% per annum and is due upon maturity of the note in August 2018. The Company may prepay this Note and any accrued interest at any time. At any time amounts outstanding under the CJY Note are convertible into the Company's common stock, in whole or in part, at the option of the lender, at a conversion price of $0.05 per share. A beneficial conversion feature of $1,642,000 was calculated and capped at the value of the note pursuant to ASC 470 - 20. The Company recorded amortization of the beneficial conversion feature as interest expense in the amount of $261,656 and $565,062 during the years ended December 31, 2018 and 2017, respectively.

On October 6, 2017, in accordance with the terms of the Securities Purchase Agreement, CJY Holdings converted $500,000 of Notes in exchange for 10,000,000 shares of the Company's common stock. The cost basis for the shares issued was $0.05. Upon conversion, a loss on extinguishment of $15,354 was charged to additional paid in capital.

On October 16, 2017, CJY holdings converted an additional $50,000 of the Notes along with $150,000 of accrued interest into 4,000,000 shares of the Company's common stock. The cost basis for the shares issued was $0.05. Upon conversion, a loss on extinguishment of $155,459 was charged to additional paid in capital.

During August 2018, CJY Holdings agreed to extend the maturity of the Notes payable for one year through August 2019.

On April 26, 2017, Boston Therapeutics, Inc. (the "Company") entered into Securities Purchase Agreement with CJY Holdings Limited ("CJY") providing for the sale by the Company to CJY of 6% Subordinated Convertible Debenture in an amount of up to $1,000,000 (the "Debentures"). In addition to the Debentures, CJY will also receive stock purchase warrants (the "Warrants") to acquire 500,000 shares of common stock of the Company for every $50,000 in Debentures purchased. The Warrants are exercisable for five years at an exercise price of $0.10 and may be exercised on a cashless basis. The Company may only use the proceeds for the payment of services or materials associated with clinical trials. The Company closed on $200,000 in financing and issued the related Debentures and Warrants under this agreement on April 26, 2017.

The Debentures bear interest at 6% per annum and mature two years from issuance. CJY may elect to convert all or part of the Debentures, plus accrued interest, at any time into shares of common stock of the Company at a conversion price of $0.10 per share. Interest on the Debentures is payable in cash or shares of common stock at $0.10 per share quarterly commencing June 30, 2017. The conversion price is subject to adjustment for stock dividends and stock splits. In addition, if after the original issue date of the Debentures, either (i) the volume weighted average price equals or exceeds $0.50 for 10 consecutive trading days or (ii) the Company elects to list a class of securities on a national securities exchange, the Company may cause CJY to convert all or part of the then outstanding principal amount of the Debentures plus, accrued but unpaid interest, liquidated damages and other amounts owed.

CJY agreed to restrict its ability to convert the Debentures and exercise the Warrants and receive shares of common stock such that the number of shares of common stock held by CJY after such conversion or exercise does not exceed 4.99% of the then issued and outstanding shares of common stock.

A beneficial conversion feature of $186,939 was calculated and capped at the value of the note pursuant to ASC 470 - 20. The Company recorded amortization of the beneficial conversion feature as interest expense in the amount of $92,842 and $63,765 during the years ended December 31, 2018 and 2017, respectively. In connection with this borrowing, the Company also issued warrants to purchase 2,000,000 shares of the Company's common stock at $0.10 per share.

Convertible notes payable – related party consist of the following at December 31:

	2018	2017
Principal balance	$ 1,402,000	$ 1,402,000
Debt discount	(30,332)	(384,857)
Outstanding, net of debt discount	$ 1,371,668	$ 1,017,143

On June 12, 2018, the Company issued a note payable for $100,000 to World Technology East II Limited ("WTE2"). WTE2 is a Hong Kong company owned equally by Carl W. Rausch, the Company's CEO and a director, and Conroy Chi-Heng Cheng, a director of the Company. The WTE2 Note is an unsecured obligation of the Company. Principal and interest under the WTE2 Note is due and payable June 12, 2019, however, in the event that the Company raises in excess of $1,000,000 in equity financing, then the Company will use part of its proceeds to pay off the WTE2 Note. During the fourth quarter of 2018, the Company increased the amount of the note payable to $174,500 with borrowings of $44,500 on October 4, $15,000 on November 5 and $15,000 on December 7. Interest accrues on the WTE2 Note at the rate of 10.0% per annum. Accrued interest at December 31, 2018 totaled $6,843.

Included in accounts payable at December 31, 2018 and December 31, 2017, are amounts due shareholders, officers and directors of the Company in the amounts of $121,453 and $80,982, respectively.

Included in accrued expenses at December 31, 2018 and 2017 are amounts due shareholders, officers and directors of the Company in the amounts of $590,829 and $247,912, respectively.

13. PROVISION FOR INCOME TAXES

During the years ended December 31, 2018 and 2017, no provision for income taxes was recorded as the Company generated net operating losses.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	2018	2017
Net operating loss carryforwards	23.9%	23.9%
State taxes, net of federal benefit	5.0%	5.0%
Federal research and development tax credit	0.3%	0.3%
Other	4.5%	4.5%
Change in deferred tax asset valuation allowance	(33.7)	(33.7)%
Effective income tax rate	0.0%	0.0%

Net deferred tax assets as of December 31, 2018 and 2017 consisted of the following:

	2018	2017
Net operating loss carryforwards	$ 4,964,400	$ 4,175,600
Tax credit carryforwards	112,200	103,100
Non-qualified stock options	832,000	790,100
Gross deferred tax assets	5,908,600	5,068,800
Valuation allowance	(5,908,600)	(5,068,800)
Net deferred tax assets	$ —	$ —

As of December 31, 2018, the Company had net operating loss carryforwards for federal and state income tax purposes of $20.8 million, which begin to expire in years 2035 and 2019, respectively. The Company also has estimated available research and development tax credit carryforwards for federal income tax purposes of $112,200, which begin to expire in year 2032.

Pursuant to the Internal Revenue Code Section 382 ("Section 382"), certain ownership changes may subject the net operating loss carryforwards ("carryforwards") and research and development tax credit carryforwards to annual limitations which could reduce or defer the carryforwards. Section 382 imposes limitations on a corporation's ability to utilize carryforwards if it experiences an ownership change. An ownership change may result from transactions increasing the ownership of certain stockholders in the stock of a corporation by more than 50 percentage points over a three-year period. In the event of an ownership change, utilization of the carryforwards would be subject to an annual limitation under Section 382 determined by multiplying the value of its stock at the time of the ownership change by the applicable long-term tax-exempt rate. Any unused annual limitation may be carried over to later years. The imposition of this limitation on its ability to use the carryforwards to offset future taxable income could cause the Company to pay U.S. federal income taxes earlier than if such limitation were not in effect and could cause such carryforwards to expire unused, reducing or eliminating the benefit of such carryforwards. The Company has not completed a Section 382 study to determine if there have been one or more ownership changes due to the costs associated with such a study. Until a study is completed and the extent of the limitations, if any, is able to be determined, no additional amounts have been written off or are being presented as an uncertain tax position.

The Company provided a full valuation allowance for deferred tax assets generated since, based on the weight of available evidence; it is more likely than not that these benefits will not be realized. During the year ended December 31, 2018, the Company increased its valuation allowance by $839,800 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, 2018. Management reevaluates the positive and negative evidence at each reporting period.

On December 22, 2017, the U.S. government enacted comprehensive tax legislation commonly referred to as the Tax Cut and Jobs Act (the "Tax Act"). The Tax Act establishes new tax laws that affects 2018 and future years, including a reduction in the U.S. federal corporate income tax rate to 21%, effective January 1, 2018. For certain deferred tax assets and deferred tax liabilities, we have recorded a provisional decrease of $3,321,700, with a corresponding adjustment to valuation allowance of $3,321,700 as of December 31, 2017.

The Company applies the provisions of ASC 740-10, *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.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's tax years are still open under statute from 2013 to the present. Earlier years may be examined to the extent that tax credit or net operating loss carryforwards are used in future periods. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision.

14. COMMITMENTS AND CONTINGENCIES

Leases

The Company leased office space at 354 Merrimack Street, Lawrence, MA 01843 on a month to month basis. The Company discontinued leasing the space on September 30, 2018. The Company recognized rent expense of $2,700 and $3,600 for the years ended December 31, 2018 and 2017, respectively.

The Company also leases office space on a month-to-month basis at The BioScience Center 5901 Indian School Rd., Albuquerque, NM 87110. The Company recognized rent expense of $7,296 during the year ended December 31, 2018.

Contingent share liability

On February 12, 2018, the Company entered into a Contribution Agreement with the members of CureDM Group Holdings, LLC, a limited liability company ("CureDM Group"), all of which except five are accredited investors ("CureDM Group Members") pursuant to which the CureDM Group Members agreed to contribute 100% of the outstanding securities of CureDM Group in exchange for an aggregate of 47,741,140 shares of common stock of the Company (the "BTHE Contribution Shares") of which 25,000,000 BTHE Contribution Shares were delivered at closing and 22,741,140 BTHE Contribution Shares (the "Milestone BTHE Shares") shall be delivered in four equal tranches of 5,685,285 BTHE Contribution Shares each upon the achievement of specific milestones (the "CureDM Group Contribution"). The closing of the CureDM Group Contribution occurred on February 12, 2018.

Under the agreement, BTI was to use its best efforts to secure a binding commitment to close an equity financing with net proceeds of at least $1,000,000 within 180 days after the closing date. The use of the equity financing proceeds would be designated as working capital for at least, but not limited to the synthesis of HIP2B clinical material. In the event the equity financing is not closed by the required date, then, if both BTI and CureDM, Inc. mutually agree, (i) this Acquisition Agreement will then be null and void and have no further force and effect and all other rights and liabilities of the parties will terminate without any liability of any party to any other party and (ii) each party shall have released the other party. Further, if such event occurs, the CureDM Members will return all shares to BTI for cancellation.

Subsequent to June 30, 2018, the 180 day time period elapsed and the Company did not raise the required funding. The two Companies have agreed to keep working toward a successful closing and are negotiating a new expiration date.

The Company believes the milestones noted above will not be achieved and that the Milestone BTHE Shares will not be issued. Therefore, the Company has not established a contingent liability to recognize the milestone shares obligations.

Employment Agreement

The Company entered into an Employment Agreement with Carl W. Rausch pursuant to which Mr. Rausch was engaged as the Chief Executive Officer of the Company for a period of three years. Mr. Rausch was initially required to relocate from Hong Kong to the United States. However, due to his continued efforts in Hong Kong, the Company and Mr. Rausch, in March 2017, have amended the employment agreement to remove the provision requiring Mr. Rausch to relocate to the United States. Mr. Rausch received a signing bonus of $60,000 and an annual salary of $224,000, which will be increased to $264,000 upon Mr. Rausch relocating to the United States. Further, upon the Company being listed on a national exchange, Mr. Rausch's salary will be increased by $20,000. The Company granted Mr. Rausch a Stock Option (the "Rausch Option") to acquire an aggregate of 6,000,000 shares of common stock of the Company, exercisable for five (5) years, subject to vesting. The Rausch Option shall be earned and vested in three equal tranches of 2,000,000 upon the Company raising $1,000,000 in financing, the Company raising $5,000,000 in financing and the Company entering into a significant corporate alliance for substantial marketing and selling of the Company's product portfolio. The initial tranche shall be exercisable at $0.20 per share, the second tranche will be $0.40 per share and the third tranche shall be $0.60 per share, which such vesting is subject to Mr. Rausch's continued employment as an executive with the Company as of the vesting date. In addition, as additional consideration for Mr. Rausch's commitment to the Company, the stock options previously granted to Mr. Rausch shall be amended to extend the expiration date to the ten year anniversary of signing date and such options shall be considered fully vested. Mr. Rausch shall be entitled to certain raises and milestones subject to the achievement of certain milestones to be agreed upon. In the event the Employment Agreement is terminated prior to the expiration of the term by the Company without cause or by Mr. Rausch with good reason, the Company shall pay Mr. Rausch an amount equal to Mr. Rausch's accrued but unpaid base salary and earned but unpaid bonus prior to the termination date, reimbursement for any reimbursable business expenses and Mr. Rausch's salary for a period of one year.

On March 1, 2018 the Board of Directors approved a reduction in the exercise price of 6,000,000 stock options issued to the Company's CEO on August 22, 2016. The First tranche of 2,000,000 will be exercisable at $0.10 per share and the second and third tranches of 2,000,000 will be exercisable at $0.15 per share. The remainder of the terms remain unchanged.

On February 12, 2018, Loraine Upham was appointed as Chief Operating Officer. The Company and Ms. Upham entered into an Executive Retention Agreement pursuant to which Ms. Upham was engaged as Chief Operating Officer with an annual salary of $200,000. However, Ms. Upham's salary shall accrue until the Company has raised a minimum of $1,250,000. Ms. Upham is eligible for bonuses as determined by the Board of Directors. These include a bonus of $20,000 is to be paid upon the Company successfully raising $1,250,000 through the sale of equity; an annual performance bonus based on milestones related to clinical progress, partnering and fund raising success to be established by the Board of Directors or the Compensation Committee, if in existence on an annual basis. In addition, Ms. Upham received a stock option to purchase 4,000,000 shares of common stock under the Company's Amended and Restated 2011 Stock Incentive Plan, vesting over three (3) years, one third on the first anniversary of the effective date and the balance in equal quarterly installments. The exercise price of the initial tranche of options (1,333,334 shares) shall be $0.06 per share, the second tranche (1,333,333 shares) shall be $0.10 per share and the final tranche (1,333,333 shares) shall be $0.20 per share. The term of the options is five years. Ms. Upham resigned from the Company on November 30, 2018. As a result of her resignation all of her stock options were terminated and returned to the option pool. Her accrued salary and vacation of $188,716 will be paid once the funding is obtained. (See Note 15)

Consulting Agreement

On April 1, 2018, the Company entered into a Corporate Advisory Agreement with a consultant. Services commenced May 1, 2018 for a term of one year with an option to renew for an additional six months. Compensation pursuant to the agreement is as follows: (1) a monthly fee of $6,500 paid in cash, and (2) 3,000,000 shares of restricted common stock of which 1,400,000 shares were deliverable upon execution of the agreement and the remaining 1,600,000 delivered in monthly installments of 400,000 shares as long as the agreement has not been terminated. Included in accrued expenses is the monthly fee totaling$52,000 and the fair value of the shares of common stock totaling $211,600, as the shares have not been issued as of December 31, 2018.

15. SUBSEQUENT EVENTS

The Company has evaluated events and transactions that occurred from December 31, 2018 through the date of the filing for possible disclosure and recognition in the financial statements.

On January 10, 2019, the company's Board of Directors approved the issuance of 1,000,000 shares of the company's common stock to a consultant for services.

During March 2019 we were served with notification of litigation regarding our merger with CureDM Holdings. CureDM Holdings' former parent company, CureDM Inc. has filed a complaint regarding breach of contract and other matters relating to their desire to unwind the merger according to the original merger agreement. This matter has just recently been filed and we are still evaluating it with our legal counsel. At this time, we are unable to state with certainty and outcome either positive or negative. We do intend to vigorously defend against the claims.

In addition to the above matter, we are also in arbitration with another company, Level Brands, regarding a marketing contract between our companies. Both parties are claiming non performance under the contract. The matter is currently in arbitration but is very early into the process and we are unable to determine any outcome positive or negative at this time.

On April 4, 2019, the company borrowed $50,000 from a related party. The Note bears interest at 10% and is due in twelve months.

On April 12, 2019, the Company borrowed $289,144 from a related party to continue its clinical trials in the U.S. The Note bears interest at 10% and is due in twelve months.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (SEC File No. 333-185355, 333-177171 and 333-195341) of our report, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, dated April 16, 2019, relating to the consolidated financial statements of Boston Therapeutics, Inc. (the "Company") which appears in this annual report on Form 10-K of the Company as of and for the years ended December 31, 2018 and 2017.

/s/ Liggett & Webb, P.A.

New York, New York
April 16, 2019

Exhibit 31.1

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

I, Carl Rausch, 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 16, 2019

By: /s/ Carl W. Rausch
Carl W. Rausch
Chief Executive Officer

Exhibit 31.2

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

I, Carl Rausch, 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 16, 2019

By: /s/ Carl W. Rausch
Carl W. Rausch
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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Carl W. Rausch, 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 16, 2019

By: /s/ Carl W. Rausch
Carl W. Rausch
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, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Carl W. Rausch, 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 16, 2019

By: /s/ Carl W. Rausch
Carl W. Rausch
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.