Beta Bionics

A Massachusetts Public Benefit Corporation

Certified B Corporation

ANNUAL REPORT
8 Saint Mary's Street
Boston, MA 02215-2421
www.betabionics.org

This Annual Report is dated April 30, 2018.

BACKGROUND INFORMATION

The Company[1], having sold shares of its Class C Common Stock pursuant to Regulation CF under the Securities Act of 1933, is filing this Annual Report pursuant to Rule 202 of Regulation Crowdfunding (§227.202) for the fiscal year ended December 31, 2017. A copy of this Report may be found on our website at www.betabionics.org/about-us.

This Report contains forward-looking statements and information relating to, among other things, the Company, our business plan and strategy, and our industry. These forward-looking statements are based on our beliefs, assumptions we made, and information currently available to us. When used in the Report, the words "anticipate," "believe," "could," "estimate," "expect," "intend," "project," "should" and similar expressions are intended to identify forward-looking statements and constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Our forward-looking statements are based on our current expectations and assumptions regarding our business and performance, the economy, future conditions and forecasts of future events, circumstances and results. As with any projection or forecast, forward-looking statements are inherently susceptible to uncertainty and changes in circumstances. Our actual results may vary materially from those expressed or implied in our forward-looking statements. Important factors that could cause actual results to differ materially from those in our forward-looking statements include government regulation, our ability to raise additional capital, results of clinical trials, our ability to achieve regulatory approval, competitive developments, economic, strategic, political and social conditions and the risk factors set forth herein.

[1] Throughout this report, Beta Bionics, Inc. is referred to as "the Company", "we," "us," or

Any forward-looking statement we make speaks only as of the date on which it is made. We are under no obligation to, and expressly disclaim any obligation to, update or alter our forward-looking statements, whether as a result of new information, subsequent events or otherwise.

Name of issuer: Beta Bionics, Inc.
Legal status of issuer:
Form: Public Benefit Corporation
Jurisdiction of Incorporation/Organization: Massachusetts
Date of organization: October 21, 2015
Physical address of issuer:
Business Innovation Center – Photonics Center, Mail Stop 936 / Office: Suite 614,
8 Saint Mary's Street, Boston, MA 02215-2421
Website of issuer: www.betabionics.org

DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES

The members of our board of directors and our officers at December 31, 2017, are identified in the following tables.

Directors

Director	Principal Occupation	Main Employer(s)	Year Joined as Director
Edward R. Damiano	Founder, Chief Executive Officer and President; Professor of Biomechanical Engineering	Beta Bionics, Inc. and Boston University	2015
Edward B. Raskin	Attorney and VP, Public Benefit Development & Corporate Strategy	Beta Bionics, Inc.	2015
Jeff Hitchcock	President, Children with Diabetes	Children With Diabetes	2016
Deirdre Ibsen	Global Brand Development Leader, Lilly Diabetes	Eli Lilly and Company	2016

Martin Holst Lange, M.D., PhD	Corporate Project Vice President, Insulin & Devices, Global Development, Novo Nordisk	Novo Nordisk A/S	2017

Officers

Name	Principal Occupation	Hire date	Term of Office
Edward R. Damiano	Founder, Chief Executive Officer and President; Professor of Biomechanical Engineering	January 1, 2016	Indefinite
Gilbert Clarke	VP, Chief Financial Officer & Treasurer	January 1, 2016	Indefinite
Firas El-Khatib	VP, Autonomous Systems	January 1, 2016	Indefinite
Edward B. Raskin	VP, Public Benefit Development & Corporate Strategy	January 1, 2016	Indefinite
Serafina Raskin	VP, General Counsel and Corporate Secretary	January 1, 2016	Indefinite
Michael Rosinko	VP, Research & Development	January 3, 2017	Indefinite

Edward R. Damiano, PhD, President, CEO & Director

Ed Damiano is a Professor of Biomedical Engineering at Boston University, or BU, and has held that role since 2004. His expertise and training are in the areas of mechanical and biomedical engineering and applied mechanics. Ever since his son was diagnosed with type 1 diabetes at 11 months of age, he has been committed to creating and integrating closed-loop control technologies with a vision of building a bionic pancreas. This endeavor began with the design and development of mathematical algorithms to control blood glucose, which he and his team began testing in his laboratory at Boston University in 2005. These efforts led to the development of the iLet™ bionic pancreas system. In 2015, Ed and Firas El-Khatib founded Beta Bionics, Inc. as a Massachusetts public benefit corporation with the goal of bringing the iLet through clinical trials, regulatory approval and into the hands of people with type 1 diabetes or T1D.

Edward Raskin, JD, VP Public Benefit Development & Corporate Strategy, Director
In addition to his role as a Vice President and director of Beta Bionics, Ed Raskin is a partner in Kassinove & Raskin LLP, a law firm he founded with Dr. Andrew Kassinove, MD/JD in 2009, to defend and advise healthcare companies. At Beta Bionics, Ed is responsible for developing and aligning the company's business goals and objectives with its public benefit structure, social mission and B Corp certification through B Lab. In addition, he helps implement strategies for collaboration and relationships with strategic business partners and investors around the world. Ed's son was diagnosed with type 1 diabetes at the age of 7. Ed and Serafina Raskin are husband and wife.

Jeff Hitchcock, Director
Jeff Hitchcock is the Founder and President of Children with Diabetes, an Ohio-based 501(c)(3) non-profit that provides education and support to families living with type 1 diabetes through its web site (www.childrenwithdiabetes.com) and conferences throughout the United States and in Canada and the United Kingdom. Since founding Children with Diabetes in 1995, Jeff and Children with Diabetes have hosted conferences and educational events focused on improving the lives of families living with diabetes.

Deirdre Ibsen, Director
Deirdre Ibsen has been an employee of Eli Lilly and Company for over 25 years. Since 2011, she has served as the Global Brand Development Leader for Insulin and Devices in the Diabetes Business Unit based in Indianapolis, Indiana.

Martin Holst Lange, M.D., PhD, Director
Martin Lange is a long-term employee of Novo Nordisk A/S. Since 2013, he has worked as Corporate Project Vice President for Insulin & Devices. Martin brings a wealth of knowledge in the diabetes market to the Board.

Gilbert Clarke, MBA, VP, Chief Financial Officer and Treasurer
Gibb Clarke is a serial entrepreneur who has launched several successful medical device companies and is intimately familiar with the many challenges we face. At Beta Bionics, Gibb has applied his 15 years of leadership experience in the medical device field to help us by streamlining operations, managing suppliers and our finances. In addition to his role at Beta Bionics, Gibb is the Chief Executive Officer of Three Rivers Medical — a position he has held since 2015. From 2011 to 2014, Gibb was the Chief Executive Officer of Blockade Medical LLC. Gibb holds a Master's in Business Administration degree from Duke University.

Firas El-Khatib, PhD, VP, Autonomous Systems
In addition to his role at Beta Bionics, Firas El-Khatib is a co-investigator and a senior research scientist in the Department of Biomedical Engineering at Boston University, a role he has held since 2006. Firas created the control algorithms that run the insulin-only, glucagon-only and bi-hormonal configurations of the iLet bionic pancreas. At Beta Bionics, Firas directs and supports algorithm implementation and clinical research efforts with clinical partners to develop data necessary to seek regulatory approval of the iLet.

Serafina Raskin, JD, VP, General Counsel and Corporate Secretary

In addition to her role as General Counsel and Corporate Secretary for Beta Bionics, Serafina Raskin is a partner with Kassinove & Raskin LLP where she has worked since 2011. In her private practice, Serafina leads a team of attorneys who serve hospital systems, physicians' groups, long-term care organizations and other healthcare providers and payers. She works with clients on regulatory and compliance matters, medical staff and licensing issues, contract negotiations, litigation and general corporate law. She brings extensive experience in the management of legal affairs and compliance in the health-care field. She is admitted to practice law in California and registered as general counsel with the Massachusetts Bar. Her son was diagnosed with T1D in 2013 and is the impetus for her work at Beta Bionics and community service for type 1 diabetes organizations like the American Diabetes Association or ADA. Serafina and Ed Raskin are husband and wife.

Michael Rosinko, VP of Research and Development

Mike Rosinko joined Beta Bionics from Tandem Diabetes Care, where he was Vice President of Research & Development since 2008. Mike led the t:Slim and other Tandem products from inception to commercialization. At Tandem he was responsible for Project Management, Product Development, Engineering Management, Design Controls and Risk analysis. Not only does Mike bring over 25 years of experience in the medical device field to Beta Bionics, he also brings the specialized knowledge necessary to gain regulatory approval and commercialize a novel device. Mike holds a Master of Business Administration from Claremont Graduate University, a Master of Science in Electrical Engineering from the University of Southern California, and a Bachelor of Science in Electrical Engineering from University of Pittsburgh, where he graduated cum laude. In addition, he holds more than 20 patents in medical systems and devices.

CAPITAL STRUCTURE

The Company's securities

The total number of shares of all classes of stock which we have authority to issue is:

(i) 1,000,000 shares of Class A Common Stock;
(ii) 1,000,000 shares of Class B Common Stock;
(iii) 500,000 shares of Class C Common Stock;
(iv) 99,000 shares of Series A-1 Preferred Stock;
(v) 99,000 shares of Series A-2 Preferred Stock;
(vi) 166,445 shares of Series B Preferred Stock; and
(vii) 134,555 shares of undesignated Preferred Stock.

The respective rights of each class of stock, as provided in our Fourth Amended and Restated Articles of Organization are outlined in the following table:

Class of Security	Securities (or Amount) Authorized	Securities (or Amount) Outstanding	Voting Rights	Other Rights
Preferred Stock (in order of preference):				
Series A and Series A-2	99,000 99,000	50,000 50,000	One vote per share on an as converted basis	• Dividend rights senior to Series B Preferred and to Common • Liquidation preference • Convertible into Class B Common • Anti-dilution protection • Registration rights • Information rights, including access to clinical trial results and form factor testing data • Access to prototype and working models of the product • Pre-emptive rights on future capital stock offerings • Right of first refusal (Series A); Right of second refusal (Series A-2) for sale of Beta Bionics • Co-sale on sales by other shareholders • No redemption rights

Series B Preferred	166,445	16,331	One vote per share on an as converted basis	• Dividend rights senior to Common • Liquidation preference • Convertible into Class B Common • Registration rights • Information rights, including access to clinical trial results and form factor testing data • No redemption rights • Holders of record of the shares of Series B Preferred Stock, exclusively and as a separate class, are entitled to elect one director of the Corporation if, and only if, the we sell at least 49,933 shares of shares of Series B Preferred Stock to any single shareholder
Common Stock				
Class A	1,000,000	600,000	Ten votes per share	None
Class B	1,000,000	250,000	One vote per share	None
Class C	500,000	9,691	No voting rights	None
Other	None	None	None	None

Class of Security	Securities Reserved for Issuance upon Exercise or Conversion
Warrants	None
Options	100,000 Class B Common Stock (Employee Incentive Option Pool)
Antidilution	4,663 shares reserved for antidilution rights of Series A and A-1
Other rights:	None

As indicated in the table above, the rights of Class C Common Stock are materially limited by the rights held by the Series A Preferred, Series A-2 Preferred, Series B Preferred, Class A Common, and Class B Common Stock. Unlike other classes of our stock, Class C Common Stock has no special rights or preferences, no priority to dividends, no voting rights, no rights to a seat on our Board of Directors or other scientific, technical or advisory committees, no right to purchase additional shares to preserve proportionate ownership in our Company in the event that we later conduct other rounds of equity financing, no special informational rights, no special ability to exercise control over management decisions and no liquidity preference to mitigate downside risks.

Additionally, no holder of Class C Common Stock may sell, transfer, assign, pledge or otherwise dispose of or encumber any Class C Common Stock without our prior written consent. We may withhold consent for any legitimate corporate purpose including to generally limit incremental costs associated with administering such transfers.

Stock Plan

On February 5, 2016, we adopted our 2016 Equity Incentive Plan or the Plan. The Plan authorized us to issue options to purchase up to 10,000 shares of Class B Common Stock. On May 12, 2016, we amended the Plan to increase the total shares available to purchase Class B Common Stock to 100,000 shares reflecting a 10-for-1 split of our stock effective May 12, 2016.

As of December 31, 2017, we had issued all 100,000 options under the Plan at exercise prices of $16.22 per share, which was fair market value at the date of grant. These options all vest over four years from the grant date with a one-year "cliff period." The options expire 10 years after the date of grant. As of December 31, 2017, options to purchase 22,455 shares had vested.

Principal Security Holders

The following table lists as of December 31, 2017, owners of our voting securities holding more than 20% of the total votes eligible to be cast.

	Number and Class of Securities Held			
Shareholder	**Class A Common Stock**	**Class B Common Stock**	**Class C Common Stock**	**% of Voting Power**
Edward Damiano and Toby Milgrome (husband and wife)	600,000	-	-	92.58%

The above calculation is based on the number of shares of voting securities owned as of December 31, 2017. Each share of Class A Common Stock has 10 votes per share. Class C Common Stock is non-voting. Series A, A-2 and B Preferred Stock vote on an as converted basis.

Risks associated with being a minority shareholder

As holders of a majority-in-interest of voting rights in our Company, Edward R. Damiano and Toby Milgrome may make decisions with which other investors disagree or that negatively affect the value of other investors' securities. Our other investors will not have sufficient votes to change these decisions. Other investors' interests may conflict with those of the majority shareholders and there is no guarantee that we will develop in a way that is optimal for or advantageous to our minority shareholders.

For example, Edward R. Damiano and Toby Milgrome may change our management; vote to engage in new securities offerings and/or to register certain of our securities in a way that dilutes or negatively affects the value of the securities owned by minority investors; or even force out minority holders of securities.

Certain holders of our securities have access to more information than other investors, which may leave these other investors at a disadvantage with respect to any decisions regarding their securities. For example, as part of the investor agreements with Eli Lilly and Company and Novo Nordisk A/S, a representative of each has a seat on our Board of Directors and has rights to review certain Company records. Zealand Pharma A/S and the Trustees of Boston University hold similar rights to review certain Company records and their respective representatives have the right to observe all Board meetings.

Risks associated with additional issuances of securities; dilution

We expect to sell additional equity or equity-related securities in the future to meet our funding requirements. Sales of these securities would dilute the percentage ownership of our Company and the economic interest of any shareholder who does not purchase their *pro rata* portion of these new securities. There is no guarantee that any shareholder not holding preemptive rights will have the opportunity to increase their investment in the Company in future transactions.

In cases where holders of existing or future options or warrants exercise their rights to purchase our stock, the interests of our shareholders may also be diluted.

Based on the risks described above and elsewhere in this Report, shareholders could lose all or part of their investment.

Risks related to the valuation of our securities

Unlike companies with actively traded securities in public markets, there is no trading market for Beta Bionics securities, which makes valuing our securities difficult. Further, as a development-stage company, we do not have product revenues or profits, which may be used to assess the value of our securities.

The assessments of the value of our securities we obtain from independent appraisers in connection with issuances of options under our equity incentive plans or for accounting purposes may not reflect the value of our securities that any shareholder might obtain or that might be observed if our securities were traded publicly. These assessments are based on, among other things, our projections and forward-looking statements, which involve risks as previously described.

There is no assurance that any of our investors will not lose some or all of their investment in our securities.

Limited transferability and liquidity

An investment in our securities is likely to be illiquid and transfers of our securities are limited. Conditions imposed by federal and state securities laws and regulations must be satisfied prior to any sale, transfer, conversion or other disposition of our securities. There is no established public trading market in which our securities can be resold and such resales would be subject to federal and state laws and regulations as well as rules and standards of trading market platforms. As a result, our investors should not expect to be able to liquidate their investment at any time, if ever.

Risks associated with a sale of the Company or of its assets

Voting control of our Company is held by two individuals. As a result, other shareholders have no ability to influence a potential sale of our Company or of any substantial portion of our assets even in the event that such a transaction would benefit our other shareholders.

Further, even if our Board of Directors authorizes a sale of all or a part of our Company, or a disposition of a substantial portion of our assets, there is no assurance that the value our shareholders will receive, together with any value remaining in our Company after such transaction, will equal or exceed the amount value of shareholders' investment in our Company.

Transfer agent and registrar

eShares, Inc. (www.carta.com) (formerly www.eshares.com)195 Page Mill Road, Suite 101, Palo Alto, CA 94306 is the transfer agent and registrar for our stock.

DESCRIPTION OF BUSINESS AND BUSINESS PLAN

A. Overview

Beta Bionics is a development stage biotechnology company developing a bionic pancreas system called the iLet™, a revolutionary, fully-integrated, wearable bionic pancreas medical device platform. The iLet automatically and autonomously manages blood sugar levels in people with type 1 insulin-dependent diabetes (T1D) 24 hours per day, thus reducing the burden and cost of diabetes care. Good, consistent management of blood sugar levels in people with T1D is essential to preventing and minimizing potentially serious health complications. However, consistent management is challenging, requiring the kind of vigilance that is often unsustainable for many patients. What makes the iLet different from all other known diabetes medical devices that have come before it is that the iLet offers a comprehensive, fully automated systems approach to glycemic control rather than addressing only one part of the glycemic control challenge (e.g., insulin infusion, glucose sensing, therapeutic dosing decisions, etc.).

The iLet integrates:

(1) a glucose-sensing device that automatically and frequently estimates blood sugar levels;
(2) decision software that automatically determines therapeutic dosing requirements; and
(3) a single-hormone and dual-hormone configuration that automatically delivers insulin to lower blood sugar levels and glucagon (in the case of the dual-hormone system) to raise blood sugar levels.

The iLet is designed to solve the four greatest concerns of T1D management:

(1) reducing mean glycemia in nearly everyone to levels that would meet or exceed the American Diabetes Association's goal for therapy, and, if implemented at the time of diagnosis, could virtually eradicate long-term microvascular and neurological complications;
(2) profoundly curtailing **mild** hypoglycemia in everyone and, we believe, dramatically reducing the risk of **severe** hypoglycemia;
(3) automating glycemic management, thus relieving people with T1D from the relentless need to comply with therapy (because our bionic pancreas is the first technology designed to be entirely compliant with the patient's needs rather than the other way around); and
(4) relieving people with T1D – and their families – from the emotional hardship that is, for now, part of everyday life, including the constant fear of hypoglycemia and the worry and dread of long-term complications.

A device that solves any one of these concerns would be groundbreaking; a device that simultaneously solves all four is, we believe, without precedent and truly game changing.

No Basal. No Bolus. Just Go … Go Bionic!©

Not only is our technology innovative, but so too is our corporate structure. We formed our Company on October 21, 2015, as a Massachusetts public benefit corporation. The public benefit form of organization is a relatively new corporate structure. This structure allows, and, in fact, obliges, private companies to consider general and specific public benefits in management decisions, in addition to considering the traditional corporate goals of maximizing profit for shareholders.

Our bylaws establish the following four principles to guide us in the specific public benefit of improving human health for the T1D community:

1. To provide and to protect our turnkey solutions for safe and effective autonomous glycemic control;
2. To bring our technology to as many people with T1D as possible in an expeditious and responsible manner;
3. To continue to innovate and to offer the latest advances as expeditiously and responsibly as possible; and
4. To act in the best possible interest of the T1D community in connection with fulfilling our functions.

Since our incorporation, our primary activities have been the development of the iLet and our business plan, negotiating strategic alliances and other agreements, and raising capital. In the first three months of our existence, we successfully licensed the intellectual property related to the bionic pancreas technology from Boston University.

These foundational steps position the Company to ultimately seek regulatory approval and, if achieved, commercialize the iLet. Information related to the iLet is preliminary and investigative. The iLet is not yet approved by the U.S. Food and Drug Administration (FDA) or by any other regulatory body in any other country. Regulatory approval of the iLet is critical to our success and to ensuring that we meet our public benefit mission. To date, we have not generated any revenues from product sales and do not expect to do so in the near future.

B. Labor of Love

Dr. Edward R. Damiano, a Boston University professor of biomedical engineering, and senior research scientist Firas El-Khatib (at that time a student working with Ed in his lab), began their quest to develop a portable bionic pancreas not long after Ed's wife, Toby – a pediatrician, diagnosed their son, David, with T1D when he was an infant. Managing David's blood sugar perfectly proved impossible, and the consequences of not being perfect can be extremely dangerous, and even life threatening. Despite meticulous attention to detail, it was clear that David, himself, changed from day to day and even hour to hour, so that decisions made under

seemingly identical circumstances the day before would have different outcomes the next day. A child grows, becomes sick, feels content or anxious, eats all of his food or doesn't, has a different mix of carbs, fats, and proteins in one meal compared to another, plays hard that day or doesn't, or the dose of insulin given is off by just a little bit. The result is a child who is fine, or hypoglycemic, combative or helpless, or hyperglycemic and facing a lifetime of potential disability, including blindness, organ failure, and amputations. Furthermore, there is a tremendous amount of biological activity and hormonal variability from one night to the next, making blood sugar control a 24-hour-a-day, seven-day-a-week task.

Convinced that there should be a better solution to the management of insulin-dependent diabetes, Ed and his team at BU embarked upon a journey to improve the lives of his son and so many parents, children and adults living with the burden of diabetes.

Ultimately, the team at Beta Bionics is deeply motivated to bring the iLet to someone they love and for whom they may be providing care. It is a labor of love for all of us. We are building this technology for the T1D community – a community to which many of us belong.

C. Market

Diabetes is a chronic, life-threatening disease for which there is no known cure. Diabetes is caused by the body's inability to produce or effectively utilize insulin, a life-sustaining hormone that regulates glucose levels.

There are two main types of diabetes: type 1 (T1D) and type 2 (T2D).

- T1D is caused by an autoimmune response in which the body attacks and destroys insulin-producing cells in the pancreas called beta cells — hence the "Beta" in our name. As a result, the pancreas' ability to produce insulin is almost entirely destroyed. T1D is most commonly diagnosed during childhood or adolescence, but adults may also develop T1D. According to estimates, between 1.5 and as many as 3 million Americans may have type 1 diabetes.

- T2D is caused by increasing resistance to the insulin produced by beta cells. T2D has been most commonly thought of as a disease of middle and advanced age, but it is increasingly prevalent in children and adolescents. Over 29 million Americans are estimated to have T2D (9.3% of the population) and 14% of those individuals need insulin.

In people with T1D and T2D, blood glucose levels fluctuate from extremely high levels, a condition known as hyperglycemia, which is caused by too little insulin, to extremely low levels, a condition called hypoglycemia, which is caused by too much insulin.

Hyperglycemia may cause the individual to feel thirsty or confused, but it can also be insidious and not be noticed at all. In either case, it is not benign. Over time, hyperglycemia can result in damage to small blood vessels which leads to blindness, nerve damage and kidney failure. It can also damage larger blood vessels, which leads to coronary artery disease, stroke, heart attack,

poor wound healing and amputation of the distal extremities. In its most severe form, and without intervention, hyperglycemia with ketosis (diabetic ketoacidosis or DKA) will cause death in a matter of hours to days. Medical management of acute DKA is itself risky – death can occur from acute shifts in electrolytes and fluids.

The normal-glycemic range is 70–120 milligrams per deciliter (or mg/dl). Maintaining blood glucose near the normal range through conventional intensive insulin therapy is a challenging, yet critically important, task for people with type 1 diabetes but can significantly reduce long-term complications. A major problem with insulin therapy is that too much insulin can lead to a different problem, hypoglycemia. Hypoglycemia causes confusion, combative irrational behavior, shakiness, feeling of extreme stress due to catecholamine release, loss of mental acuity, unconsciousness, seizure, coma and even death. Thus, the required vigilance and diligence renders the management process challenging, aggravating and potentially daunting.

Current practices in diabetes management have not proven adequate to balancing the dangers of hyper- and hypoglycemia, although millions of people are compelled to try, day in and day out, with varying degrees of success.

We are profoundly grateful for the existing tools we do have, because without them our loved ones might not be alive today. However, our goal is that — with the iLet — we will all be able to do much better with less intensive oversight and constant worry.

D. Current Treatment Options

Currently, there is no system that autonomously makes all therapeutic decisions to administer insulin (or glucagon) in response to a near-continuous signal from a continuous glucose monitor (or CGM). Various CGMs have been FDA-approved and are commercially available. All of the systems competitive to our bionic pancreas technology share several commonalities:

(1) all require the patient to count carbohydrates and bolus for meals;
(2) all require a physician, virtually always an endocrinologist, to set and optimize one or more of the following pump settings: total daily insulin dose, insulin-to-carbohydrate ratios, basal infusion rates, and correction factors;
(3) none are initialized by body weight alone;
(4) none appear to have any capability of incorporating glucagon into their systems; and
(5) none have published clinical trial data that meet or beat our clinical outcomes in the dual-hormone configuration and most cannot match our insulin-only performance.

More specifically, the current state-of-the-art in the management of T1D includes:

- The regular use of hand-held, *in vitro* blood glucose meters (or BGM's). These meters are capable of measuring the glucose concentration of small blood samples (~ 0.3-5 microliters or μl) in 5-30 seconds; the capillary blood sample is obtained by pricking the skin with a lancet,

- The use of rapid-acting human insulin analogs that can be adjusted to compensate for meals rather than making meal adjustments to match the insulin taken hours earlier,

- Insulin pumps that can continuously deliver subcutaneous insulin at an infusion rate to suit metabolic insulin requirements, with microbursts of insulin infused to cover carbohydrates consumed through user-commanded dosing, and

- An insulin pump paired with a continuous glucose monitor that operates in a "hybrid closed loop" configuration. The only known system with these features is known as the Minimed 670G, which was approved by the FDA on September 29, 2016. The 670G has an "Auto Mode" option that, under certain circumstances, automatically adjusts basal insulin delivery every five minutes based on blood glucose levels.

Although the key to managing diabetes is to maintain tight control of blood glucose levels, in practice, the management of T1D is extremely challenging, requiring perpetual vigilance and intervention with insulin or carbohydrates. We believe that the iLet's automated insulin and glucagon administration has the potential to materially reduce the burden associated with day-to-day management of diabetes.

E. More About the iLet

The iLet is designed as a wearable, stand-alone, Class III medical device intended to provide ambulatory autonomous care for insulin-dependent diabetes. The iLet consists of:

1. an integrated dual-chamber pump capable of delivering insulin alone or insulin and glucagon at extremely precise doses;
2. an integrated CGM (produced by other companies);
3. a clinically-tested suite of mathematical control algorithms that autonomously determine and command doses of insulin or glucagon based on CGM glucose data;
4. a custom dual-cannula infusion set; and
5. an integrated touchscreen user interface.

The iLet requires only the patient's weight for initialization after which it autonomously adapts in real-time to changes in an individual's basal metabolic insulin need, and hormonal changes whether they are acute (e.g., circadian hormonal fluctuations, illness, physical activity, or emotional state) or gradual (e.g., those that occur during puberty or menopause). Our adaptive meal dose controller eliminates the need for the user to set or know their "carbohydrate-to-insulin ratios," as the iLet makes automatic adjustments based on dosing history for similar past meal announcements, customizing its dosing to the individual and the time of day. The bihormonal configuration of our iLet goes beyond the capability of insulin-only delivery with its proportional-derivative algorithm (based on the glucose level and rate of descent) that governs delivery of subcutaneous micro-doses of glucagon to help prevent or reduce hypoglycemia.

Taken together, these algorithms should provide a universal framework for glycemic control that requires no quantitative input from, or participation by, the user (besides entering body weight to initialize the iLet), but which automatically adapts insulin and glucagon dosing to meet each individual's needs. Another unique feature of iLet is that it can continue to manage insulin and glucagon delivery autonomously even when the CGM is offline by: (1) invoking the latest high-resolution "basal rate profile" it had converged upon when the CGM was online, (2) responding to meal announcements the same way, and (3) automatically responding to user-entered blood glucose, or BG, values by issuing a correction dose of insulin (or glucagon) based on its latest determination of user needs. Thus, our iLet never relies on, nor burdens the user, with determining subjective dosing decisions, which inevitably vary in quality and reliability over time or among different users. Indeed, our iLet is designed to provide a turnkey solution for people with T1D that comprehensively manages glycemia across a broad range of individual needs and a large spectrum of circumstances and challenges.

We believe that iLet is a technology that could forever change the way in which T1D is managed and the effectiveness with which care can be delivered. We also believe that iLet could be used to treat other conditions of glycemic impairment such as type 2 diabetes, post-bariatric surgery induced hypoglycemia, congenital hyperinsulinism, cystic-fibrosis-related diabetes and insulinoma induced chronic hypoglycemia.

In summary, we believe that the iLet's technology is pioneering because it:

- is initialized with only the patient's body mass and comes online immediately with no run-in period or physician optimization of insulin dosing settings;
- provides a truly turnkey solution for both children and adults with T1D and is able to cope with a wide range of insulin needs across all age groups;
- uses no more insulin than under usual care, but distributes insulin doses more efficiently and optimally than under usual care, thus dramatically improving mean glycemia and reducing hypoglycemia;
- is designed to specifically refrain from stacking or overdosing insulin;
- is completely autonomous in determining all dose deliveries, sparing the user from having to determine or set their so-called "basal-rate profiles," "correction factors," or "insulin-to-carbohydrate ratios;"
- continuously updates and stores a high-resolution "basal-rate" profile for insulin delivery (288 basal rate segments per day), which it dynamically adapts when the CGM is online and automatically invokes when the CGM is offline;
- autonomously doses insulin or glucagon for high or low glucose levels when the CGM is online and automatically corrects as necessary by dosing insulin or glucagon in response to user-entered BG values when the CGM is offline;
- allows optional user-initiated (but system-calculated) meal-priming insulin doses, which adapt autonomously to user requirements and time of day (separately for "breakfast", "lunch", and "dinner" meals);
- automatically shuts off insulin dosing, based on the glucose level and trend, to prevent hypoglycemia;

- allows the user to run a system-optimized dynamic glucose target, or to set a permanent glucose target, or to temporarily raise the glucose target for added safety during activities such as exercising, driving, etc.;
- allows the user to trigger a system-calculated glucagon microburst dose as an added safety measure prior to temporarily disconnecting from the bionic pancreas, such as for showering, swimming, etc.
- has been tested in C-peptide-negative as well as C-peptide-positive subjects in the outpatient setting; and
- has been tested under free-living conditions and without restrictions on exercise or other activities.

F. Licenses, Patents and Proprietary Rights

We have exclusive, worldwide sublicensable licenses from the Trustees of Boston University to a portfolio of U.S. and international patents (both issued and pending) and a trademark that relate to iLet.

Under the terms of the licensing agreements, we are responsible for specified milestone and maintenance payments as well as royalty payments on net sales if iLet is commercialized. We also have the right to sublicense our rights under the license agreements but are required to pay BU a percentage of any sublicense income.

Additionally, under the terms of the licensing agreements, we must develop, manufacture, sell and market the technology pursuant to specified milestones and time schedule. In the event we fail to meet the milestones, BU is entitled to terminate the licensing agreements with prior written notice unless we cure the breach. Upon termination, the intellectual property rights under the licenses would revert to BU.

We believe that proprietary protection of our technologies is critical to the development of our business. Our intellectual property strategy includes protecting existing, and further developing, proprietary technology for the sourcing, scale-up, and manufacturing of the iLet. This strategy includes expanding on technologies we have in-licensed as well as in-licensing additional technologies through collaborations with universities and other companies.

We rely upon trade-secret protection for certain confidential and proprietary information and take active measures to control access to that information. There is also substantial proprietary know-how surrounding the iLet development and manufacturing processes that remains a trade secret. We currently have confidentiality and non-disclosure agreements with all of our employees, consultants, vendors, advisory board members and contract research organizations.

There is no assurance that we will not breach our agreements with BU or that any of our measures will adequately protect our intellectual property from appropriation.

G. Our Commitment to Good Business Practices and Our Public Benefit Mission

We strive to benefit the public by providing education, support and eventually the bionic pancreas technology to alleviate the burdens of T1D management. We believe our status as a public benefit corporation, commitment to our public benefit mission, and focus on transparency, makes a difference in the way we conduct business. We believe this will result in a healthier and happier T1D community and that it will benefit our shareholders although there is no assurance that this will be the case.

Where other companies may focus only on return on investment, we are committed to both our shareholders and to the T1D community and work diligently to ensure that the bionic pancreas technology is protected and available for the benefit of diabetes patients. Beta Bionics is actively involved in the T1D community and is partnering with like-minded educational institutions, not-for-profit entities and socially minded companies to educate the public about T1D management and our bionic pancreas technology.

Our leadership strives to be ever mindful that we were founded by parents deeply affected by T1D to help not only their own children, but all children and adults struggling to live with T1D and the loved ones who support them.

H. Performance of the Bionic Pancreas System in Clinical Trials

Both the insulin-only and bihormonal configurations of our bionic pancreas technology have been rigorously tested in inpatient and real-world, outpatient and home-use studies in subjects with T1D. The technology has evolved over the years from a laptop-driven system, to a wearable iPhone-driven platform, to our current highly compact, fully-integrated, mobile iLet.

A ten-year collaboration between Boston University and the Massachusetts General Hospital (or MGH) resulted in three inpatient studies testing a laptop version of the bihormonal bionic pancreas in adults and adolescents with T1D.

The iPhone version of the bihormonal bionic pancreas has also been tested in four outpatient studies. Although still somewhat cumbersome, the iPhone system was a mobile platform that could be tested in home-use environments, afforded unrestricted subject activity, and allowed for longer-duration experiments than previously possible.

In 2013, the iPhone system was tested in five-day experiments in 20 adults with T1D in downtown Boston (our Beacon Hill Study). Studies in the summers of 2013 and 2014 compared the iPhone system with insulin pump therapy in 5-day experiments in 51 children ages 6 to 20 years old with T1D. These studies were conducted at Camp Joslin and the Clara Barton Camp in central Massachusetts (our 2013 and 2014 Summer Camp Studies).

A collaboration between MGH, the University of Massachusetts Medical Center, Stanford University, and the University of North Carolina, Chapel Hill, resulted in our Bionic Pancreas Multicenter Study conducted between 2014 and 2015. This study compared the iPhone system

with insulin pump therapy in a home-use study in 39 adults with T1D who used the device for 11 days at work and at home.

The mean CGM glucose levels obtained by the bihormonal bionic pancreas in our 2013 and 2014 Summer Camp Studies and our Bionic Pancreas Multicenter Study were 141 (standard deviation or ± of 10 mg/dl) in adults, 142 ± 12 mg/dl in adolescents, and 137 ± 11 mg/dl in pre-adolescents. Based on these mean CGM glucose levels, we believe the bionic pancreas is capable of achieving HbA1c of approximately 6.5 ± 0.4% in these three populations. (HbA1c is a key indicator of blood glucose control over an approximate 3-month period.) This level is below the mean CGM glucose level standard set forth by the ADA for all three populations. Positive results were observed in nearly all subjects tested while simultaneously eliminating almost all hypoglycemia. On the bionic pancreas, CGM glucose levels fell below 60 mg/dl only 0.6% of the time in adults and 1.2–1.3% of the time in adolescents and pre-adolescents in a summer camp setting.

Our clinical collaborators at Stanford and MGH have also conducted two home-use outpatient studies testing the iPhone-based bionic pancreas system in the insulin-only configuration targeting different glycemic set-points. In the Stanford Insulin-only study, 16 adults with T1D compared the bionic pancreas in the insulin-only configuration with insulin pump therapy in one-week experiments at work and at home (with a glucose target of 130 mg/dl). In the MGH Set-Point Study, 20 adults with T1D compared our bionic pancreas in the insulin-only configuration at a set-point of 130 mg/dl (i) with our bionic pancreas in the bihormonal configuration at glucose set-points of 100, 115, and 130 mg/dl, and (ii) with insulin pump therapy in three-day experiments at work and at home.

The mean CGM glucose levels obtained by the insulin-only bionic pancreas with a glycemic set-point of 130 mg/dl was 161 ± 9 mg/dl in the Stanford Insulin-only Study and 160 ± 17 mg/dl in our MGH Set-Point Study, with CGM glucose levels falling below 60 mg/dl only 0.9% and 0.8% of the time, respectively. Based on these mean CGM glucose levels, we believe that our insulin-only bionic pancreas would achieve an HbA1c in adults of 7.2 ± 0.5%, while simultaneously limiting CGM glucose levels below 60 mg/dl to occurring less than 1% of the time.

Based on these results, we believe that the insulin-only configuration of our bionic pancreas would result in HbA1c levels of ~ 7.3%. The bionic pancreas in the bihormonal configuration would obtain HbA1c of ~ 6.5%, which we believe would effectively eradicate nearly all long-term complications attributable directly to T1D.

The BU academic team has also tested the first generation of our fully-integrated iLet bionic pancreas in diabetic swine. Notably, results of the swine study showed no difference in the performance of our previous-generation iPhone-based bionic pancreas platform relative to our iLet platform.

Despite challenging conditions and with no restrictions on diet, exercise or other activity, the previous generations of our bionic pancreas technology have simultaneously lowered mean glucose and reduced hypoglycemia relative to comparator groups and demonstrated that the current iteration of the technology should be ready for its pivotal clinical trial. There is no

assurance that the results in a pivotal clinical trial will compare favorably to prior trials, or that pivotal trial results will meet requirements for regulatory approval in any jurisdiction.

I. Published Clinical Data Related to our Bionic Pancreas Technology

For purposes of non-scientific summary, the following clinical data have been published in the following peer-reviewed journals:

- The Lancet, 2016:
    - Background: The safety and effectiveness of a continuous, day-and-night automated glycemic control system using insulin and glucagon has not been shown in a free-living, home-use setting. We aimed to assess whether a bihormonal bionic pancreas initialized only with body mass can safely reduce mean glycemia and hypoglycemia in adults with type 1 diabetes who were living at home and participating in their normal daily routines without restrictions on diet or physical activity.
    - Methods: We conducted a random-order crossover study in volunteers at least 18 years old who had type 1 diabetes and lived within a 30-minute drive of four clinical sites in the U.S. Participants were randomly assigned (a 1:1 ratio) in blocks of two using sequentially numbered sealed envelopes first to a group to use the bihormonal bionic pancreas or a group that would follow usual care (conventional or sensor-augmented insulin pump therapy). After 11 days, each group would then crossover to the opposite intervention. During both study periods, participants continued all normal activities, including athletics and driving. The bionic pancreas was initialized with only the participant's body mass. Autonomously adaptive dosing algorithms used data from a continuous glucose monitor to control subcutaneous delivery of insulin and glucagon. Co-primary outcomes were the mean glucose concentration and time with continuous glucose monitoring (CGM) glucose concentration less than 3.3 millimols per liter, or mmol/L, analyzed over days 2–11 in participants who completed both periods of the study. This trial is registered with ClinicalTrials.gov, number NCT02092220.
    - Results: We randomly assigned 43 participants between May 6, 2014, and July 3, 2015, 39 of whom completed the study: 20 were assigned to bionic pancreas first and 19 were assigned to the comparator first. The mean CGM glucose concentration was 7.8 mmol/L (standard deviation, or SD, of 0.6) during the bionic pancreas period versus 9.0 mmol/L (SD 1.6) during the comparator period (difference 1.1 mmol/L, 95% confidence interval, or CI, 0.7–1.6; $p<0.0001$), and the mean time with CGM glucose concentration < 3.3 mmol/L was 0.6% (SD 0.6) during the bionic pancreas period versus 1.9% (SD 1.7) during the comparator period (difference 1.3%, 95% CI 0.8–1.8; $p<0.0001$). The mean nausea score on the Visual Analogue Scale (score 0–10) was greater during the bionic pancreas period (0.52 [SD 0.83]) than during the comparator period (0.05 [SD

0.17]; difference 0.47, 95% CI 0.21–0.73; p=0.0024). Body mass and laboratory parameters did not differ between periods. There were no serious or unexpected adverse events during the bionic pancreas period of the study.

- The Lancet Diabetes and Endocrinology, 2016:
    - Background: The safety and efficacy of continuous, multiday, automated glycemic management has not been tested in outpatient studies of pre-adolescent children with type 1 diabetes. We aimed to compare the safety and efficacy of a bihormonal bionic pancreas versus conventional insulin pump therapy in this population of patients in an outpatient setting.
    - Methods: In this randomized, open-label, crossover study, we enrolled pre-adolescent children (aged 6–11 years) with type 1 diabetes (diagnosed for ≥1 year) who were on insulin pump therapy, from two diabetes camps in the U.S. With the use of sealed envelopes, participants were randomly assigned in blocks of two to either five days with the bionic pancreas or conventional insulin pump therapy (control) as the first intervention, followed by a three-day washout period and then five days with the other intervention. Study allocation was not masked. The autonomously adaptive algorithm of the bionic pancreas received data from a continuous glucose monitoring (CGM) device to control subcutaneous delivery of insulin and glucagon. Conventional insulin pump therapy was administered by camp physicians and other clinical staff in accordance with their established protocols; participants also wore a CGM device during the control period. The co-primary outcomes, analyzed by intention to treat, were mean CGM-measured glucose concentration and the proportion of time with a CGM-measured glucose concentration below 3.3 mmol/L, on days 2–5. This study is registered with ClinicalTrials.gov, number NCT02105324.
    - Results: Between July 20, and August 19, 2014, 19 children with a mean age of 9.8 years (SD 1.6) participated in and completed the study. The bionic pancreas period was associated with a lower mean CGM-measured glucose concentration on days 2–5 than was the control period (7.6 mmol/L [SD 0.6] *vs* 9.3 mmol/L [SD 1.7]; p=0.00037) and a lower proportion of time with a CGM-measured glucose concentration below 3.3 mmol/L on days 2–5 (1.2% [SD 1.1] *vs* 2.8% [SD 1.2]; p<0.0001). The median number of carbohydrate interventions given per participant for hypoglycemia on days 1–5 (i.e.,, glucose <3.9 mmol/L) was lower during the bionic pancreas period than during the control period (three [range 0–8] *vs* five [0–14]; p=0.037). No episodes of severe hypoglycemia were recorded. Medium-to-large concentrations of ketones (range 0.6–3.6 mmol/dL) were reported on seven occasions in five participants during the control period and on no occasion during the bionic pancreas period (p=0.063).

- The New England Journal of Medicine, 2014:

    - Background: The safety and effectiveness of automated glycemic management have not been tested in multiday studies under unrestricted outpatient conditions.
    - Methods: In two random-order, crossover studies with similar but distinct designs, we compared glycemic control with a wearable, bihormonal, automated, "bionic" pancreas (bionic-pancreas period) with glycemic control with an insulin pump (control period) for five days in 20 adults and 32 adolescents with type 1 diabetes mellitus. The automatically adaptive algorithm of the bionic pancreas received data from a continuous glucose monitor to control subcutaneous delivery of insulin and glucagon.
    - Results: Among the adults, the mean plasma glucose level over the five-day bionic-pancreas period was 138 mg per deciliter (7.7 mmol per liter), and the mean percentage of time with a low glucose level (<70 mg per deciliter [3.9 mmol per liter]) was 4.8%. After one day of automatic adaptation by the bionic pancreas, the mean (±SD) glucose level on continuous monitoring was lower than the mean level during the control period (133 ±13 vs. 159 ±30 mg per deciliter [7.4 ±0.7 vs. 8.8 ±1.7 mmol per liter], p<0.001) and the percentage of time with a low glucose reading was lower (4.1% vs. 7.3%, p=0.01). Among the adolescents, the mean plasma glucose level was also lower during the bionic-pancreas period than during the control period (138 ±18 vs. 157 ±27 mg per deciliter [7.7 ±1.0 vs. 8.7 ±1.5 mmol per liter], p=0.004), but the percentage of time with a low plasma glucose reading was similar during the two periods (6.1% and 7.6%, respectively; p=0.23). The mean frequency of interventions for hypoglycemia among the adolescents was lower during the bionic-pancreas period than during the control period (one per 1.6 days vs. one per 0.8 days, p<0.001).

- Journal of Clinical Endocrinology and Metabolism, 2014:

    - Background**:** The objectives of the study were to test the ability of a third-generation bihormonal bionic pancreas algorithm, initialized with only subject weight, to adapt automatically to the different insulin needs of adults and adolescents, and to evaluate the impact of optional, automatically adaptive meal-priming boluses.
    - Methods: This was a randomized controlled trial, conducted at an inpatient clinical research center with 12 adults and 12 adolescents with T1D. Subjects in each age group were randomized to automated glycemic control for 48 hours with or without automatically adaptive meal-priming boluses.
    - Results: The 48-hour mean plasma glucose, or PG, values with and without adaptive meal-priming boluses were 132.9 vs 146.9 mg/dL (*p* .03) in adults and 162.6 vs 175.9 mg/dL (*p* .01) in adolescents. Adaptive meal-priming boluses improved mean PG without increasing time spent with

PG less than 60 mg/dL: 1.4% vs 2.3% (*p* .6) in adults and 0.1% vs 0.1% (*p* 1.0) in adolescents. Large increases in adaptive meal-priming boluses and shifts in the timing and size of automatic insulin doses occurred in adolescents. Much less adaptation occurred in adults. There was nearly a four-fold variation in the total daily insulin dose across all cohorts (0.36 – 1.41 U/kg/d).

- Diabetes Care, 2012:

    - Background: To test whether safe and effective glycemic control could be achieved in type 1 diabetes using a bihormonal bionic endocrine pancreas driven by a continuous glucose monitor in experiments lasting more than two days and including six high-carbohydrate meals and exercise as challenges to glycemic control.
    - Methods: Six subjects with type 1 diabetes and no endogenous insulin secretion participated in two 51-hour experiments. Blood glucose was managed with a bionic endocrine pancreas controlling subcutaneous delivery of insulin and glucagon with insulin pumps. A partial meal-priming bolus of insulin (0.035 units/kg/meal, then 0.05 units/kg/meal in repeat experiments) was administered at the beginning of each meal (on average 78 ± 12 grams of carbohydrates per meal were consumed). Plasma glucose control was evaluated with a reference quality measurement on venous blood every 15 min.
    - Results: The overall mean PG was 158 mg/dL, with 68% of PG values in the range of 70–180 mg/dL. There were no significant differences in mean PG between larger and smaller meal-priming bolus experiments. Hypoglycemia (PG 70 mg/dL) was rare, with eight incidents during 576-h of closed-loop control (0.7% of total time). During 192-h of nighttime control, mean PG was 123 mg/dL, with 93% of PG values in the range of 70–180 mg/dL and only one episode of mild hypoglycemia (minimum PG 62 mg/dL).

- Science Translational Medicine, 2010

    - Background: Automated control of blood glucose (BG) concentration is a long-sought goal for type 1 diabetes therapy. We have developed a closed-loop control system that uses frequent measurements of BG concentration along with subcutaneous delivery of both the fast-acting insulin analog lispro and glucagon (to imitate normal physiology) as directed by a computer algorithm. The algorithm responded only to BG concentrations and incorporated a pharmacokinetic model for lispro.
    - Methods: 11 subjects with type 1 diabetes and no endogenous insulin secretion were studied in 27-hour experiments, which included three carbohydrate-rich meals.
    - Results: In six subjects, the closed- loop system achieved a mean BG concentration of 140 mg/dl, which is below the mean BG concentration

target of <_154 mg/dl recommended by the American Diabetes Association. There were no instances of treatment-requiring hypoglycemia. Five other subjects exhibited hypoglycemia that required treatment; however, these individuals had slower lispro absorption kinetics than the six subjects that did not become hypoglycemic. The time-to-peak plasma lispro concentrations of subjects that exhibited hypoglycemia ranged from 71 to 191 minutes (mean, 117 ± 48 min) versus 56 to 72 minutes (mean, 64 ± 6 min) in the group that did not become hypoglycemic (aggregate mean of 84 min versus 31 min longer than the algorithm's assumption of 33 min, p = 0.07). In an additional set of experiments, adjustment of the algorithm's pharmacokinetic parameters (time-to-peak plasma lispro concentration set to 65 min) prevented hypoglycemia in both groups while achieving an aggregate mean BG concentration of 164 mg/dl. These results demonstrate the feasibility of safe BG control by a bihormonal artificial endocrine pancreas.

In addition to the above, the BU academic bionic pancreas team has published multiple additional manuscripts on their pre-clinical studies, commentaries and other manuscripts related to blood glucose control and continuous glucose monitoring studies. Clinical data related to bionic pancreas multi-center studies, during which subjects wore the system from 11 days to three weeks, has been collected but not yet formally published. The data collected from those studies continues to show that the bionic pancreas system effectively lowers mean average blood glucose while simultaneously reducing hypoglycemia and substantially eases the psychological burdens of managing T1D.

All prior published clinical data is available online at:
http://sites.bu.edu/bionicpancreas/publications-2/.

J. Pivotal Trial and Development Status

The final clinical study used to collect data for submission to regulatory authorities for approval of a medical product is generally referred to as a pivotal trial.

Our goal is to work with our clinical teams to initiate our Insulin-Only Bionic Pancreas Pivotal Trial in 2019, assuming successful completion of an insulin-only bridging study scheduled to begin in mid-2018. Separately, we aim to continue working with our clinical teams to initiate our Bihormonal Bionic Pancreas Pivotal Trial in 2019, assuming successful completion of a Phase IIb bihormonal bridging study estimated to begin in late 2018.

Our two pivotal trials have been designed to provide the essential clinical data necessary for a regulatory submission to the FDA for commercialization of the iLet. All design protocols for clinical trials are subject to change. There is no assurance that we will be successful in any trial or that, even if successful, that regulators will approve any of our product-candidates.

We propose to achieve our objective with the following two aims:

1. to conduct our Insulin-Only Bionic Pancreas Pivotal Trial (which we expect will take approximately six months to complete) to test the safety and efficacy of the iLet in controlling glycemia in the insulin-only configuration and to evaluate the behavioral and psychosocial impact of the insulin-only configuration of the iLet relative to usual care, and
2. to conduct our Bihormonal Bionic Pancreas Pivotal Trial (which we expect to take at least 12 months or more to complete), to test the safety and efficacy of the iLet in controlling glycemia in the bihormonal configuration, to evaluate the behavioral and psychosocial impact of the bihormonal configuration of the iLet relative to usual care, and to provide all safety data necessary and sufficient for a new chronic use indication for glucagon in our device.

Our ability to commence these pivotal trials depends on securing FDA and institutional review board, or IRB, approvals to conduct these trials, securing the funding necessary to conduct these trials, and to completing shorter bridging studies to demonstrate feasibility of the fully integrated iLet to autonomously control blood glucose.

As of December 31, 2017, existing resources are not adequate to permit us to conduct either trial. We are continuing to explore potential funding opportunities and alternatives to obtain the resources necessary to complete these trials and to support our operations during the periods in which they are being conducted. These funding opportunities and alternatives may include partnering arrangements with medical technology or pharmaceutical companies. There is no assurance that we will secure funding, or that partnering arrangements can be consummated, on acceptable terms, if at all.

K. Manufacturing of the iLet

Through December 31, 2017, we did not have our own manufacturing facilities adequate to manufacture the iLet in-house. Instead, we have relied on FDA-registered ISO 13485 third-party contract manufacturing facilities to build iLet units for testing. Similarly, infusion sets used with the iLet have been manufactured by a third-party facility that is fully compliant with relevant manufacturing protocols and standards.

Our longer-term manufacturing strategy is to develop our own in-house manufacturing capabilities. As opposed to others in the industry who produce their products outside the U. S., our plan is to manufacture and assemble iLets and associated disposables at our facility in Southern California. Manufacturing facility space and associated clean room space has been secured. It still needs to be validated and certified to ISO standards.

L. Sales and Marketing

Our marketing plan has been developed in an attempt to (1) avoid problems experienced by existing suppliers of T1D treatments and (2) reduce the capital required for sales and marketing activities in the immediate timeframe after regulatory approval if regulatory approval is received. Other T1D suppliers have expended significant capital by overspending on sales and marketing to support nationwide launches. We, on the other-hand, plan to penetrate the market by

leveraging a "patient pull" and "practitioner push" model primarily at our 16 adult and pediatric clinical sites. If we achieve reasonable penetration at each clinical site, we expect to bring in early revenues and gain experience with third-party payers.

We also intend to market beyond endocrinologists, reaching out to primary care physicians. Primary care physicians are estimated to manage the vast majority of people with type 1 diabetes but have previously resisted prescribing therapy devices due to the complexity of such systems – especially during the start-up process, which is complex and time-consuming.

Initial launch at our clinical trial sites should permit us to gain experience with payers in various U.S. regions as well as gain experience supporting patients in various geographies and from different socio-economic backgrounds. As we gain experience, we plan to expand market coverage, with the goal of eventually distributing throughout the U.S. Outside the U.S., we expect to proceed in a similar fashion with controlled launches in regional jurisdictions, then expanding outwards to other national health care systems, including in Europe, the Middle East, Asia, South America and Africa.

Our ability to demonstrate clinical effectiveness should permit us to focus on markets that are not currently penetrated by traditional diabetes product companies many of which have substantially greater resources than we have. We may also choose to partner with other biotech or pharmaceutical companies for sales and marketing, if and when applicable, or develop our own sales force to market the iLet both inside and outside the U.S.

There is no assurance that any of our plans or efforts will prove effective or profitable.

M. Collaboration Arrangements

From time to time we may enter into collaborative research agreements with academic and research institutions, including BU, to enhance our research and development capabilities. Such agreements often provide the industry partner with rights to license the intellectual property created through such collaborations. We may also enter into collaborative research agreements with other pharmaceutical companies when we believe such collaboration will support the development or commercialization of our technology.

N. Sublicenses to Third Parties

We currently do not have any sublicenses with third-parties but we may decide to grant sublicenses for certain applications of our technologies or in certain geographic regions.

O. Future Products/Indications for Use

Eventually, we may decide to seek indications for use in type 2 diabetes as well as other conditions of glycemic dysregulation. We are also exploring in-hospital use of our technology.

P. Facilities

We currently occupy office and laboratory space in Boston that we lease from BU. We also have leased office and manufacturing facilities in Irvine, California.

NUMBER OF CURRENT EMPLOYEES

As of December 31, 2017, we employed 18 people. Additionally, we engage a number of independent contractors to perform various services. Contractors we employ include regulatory consultants, contract manufacturers, engineering and design consultants, attorneys and accountants. As we expand our operations, we anticipate hiring additional personnel and engaging additional contractors.

ADDITIONAL RISK FACTORS

Risks Related to our Intellectual Property and Potential Litigation

We do not own the intellectual property underlying the iLet.

We rely on licenses from the Trustees of Boston University to use the various technologies that are material to operation of the iLet. We do not own the patents that underlie these licenses. The first license grants us exclusive worldwide rights under the five patents and one copyright related to the control algorithm run by the iLet. The second license grants us exclusive worldwide rights related to five patents relating to the infusion sets which deliver subcutaneously the glucagon and insulin hormones. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to our abiding by the terms of the licenses and meeting certain milestones set forth in the applicable license agreements. In addition, while we have significant input and participation into the strategy for the enforcement of the patent and trademark rights, the Trustees of Boston University have ultimate control over the prosecution and enforcement strategies relating to the patents and trademarks subject to these licenses. As a result, we are largely dependent upon the Trustees of Boston University to determine the appropriate strategy for prosecuting and enforcing the rights to the intellectual property under the license agreements.

Our ability to protect our intellectual property and proprietary technology is uncertain.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved in a timely manner or at all. Third-parties also may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual

property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information.

If any party infringes any of the patents on which we rely, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult, costly and time consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third-parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results.

The medical device industry is characterized by patent litigation, and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, or require us to pay damages.

Our success will depend in part on our not infringing the patents or violating the other proprietary rights of third-parties. Significant litigation regarding patent rights occurs in our industry. Our competitors in both the U. S. and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained, or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

In the future, we could receive communications from various industry participants alleging our infringement of their intellectual property rights. Any potential intellectual property litigation could force us to do one or more of the following:

- stop selling our products or using technology that contains the allegedly infringing intellectual property;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing;
- redesign those products that contain the allegedly infringing intellectual property which may be costly or not feasible; or
- attempt to obtain a license to the relevant intellectual property from third-parties,

which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the diabetes market increases, the possibility of intellectual property infringement claims against us increases.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of others or we are in breach of non-competition or non-solicitation agreements.

We may be subject to claims that we, or our employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or others. In addition, we have been and may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we successfully defend against these claims, litigation could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to having to pay monetary damages, we may lose valuable intellectual property rights or personnel. We cannot guarantee that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize proposed products, which could have a material adverse effect on our business, financial condition and operating results.

FDA regulations generally have counterparts in countries outside the U.S., many of which have comparable regulatory bodies and regulatory schemes. In addition, many states within the U.S. have their own regulations that apply to us and our business. The disclosures below are intended to apply to our business in individual states and outside the U.S. as well.

Risks Related to Our Legal and Regulatory Environment

If we or our third-party suppliers violate applicable regulations, our ability to market our product in a cost-effective and timely manner will be impaired.

If we should obtain marketing approval for our product, such product, along with the manufacturing processes, post-approval clinical data and promotional activities for the product, will be subject to continual review and inspections by the FDA and other regulatory agencies. Under the FDA's medical device reporting or MDR regulations, we must report to the FDA any incident in which our product may have caused or contributed to a death or serious injury. Further, under the MDR regulations, we must report any incident in which our product malfunctioned in such a manner that, if the malfunction were to recur, it would likely cause or contribute to a death or serious injury. Finally, we and our third-party suppliers must comply with the FDA's Quality System Regulation or QSR and other regulations, which address the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA enforces

compliance with the QSR through announced and unannounced inspections of manufacturing and other facilities, conducted at periodic intervals.

We will seek FDA's approval of our manufacturing facilities for medical device manufacturing facilities. We cannot assure you that we will obtain FDA or other regulatory approval of our facilities.

If our suppliers or we fail to comply with the applicable regulatory requirements in any material respect, if problems with our product are later discovered, including software bugs, the occurrence of unanticipated adverse events, manufacturing problems, or if, in response to any observed deficiencies, we propose a corrective action plan that is deemed insufficient, the FDA could take enforcement actions against us. Enforcement actions could include any of the following measures: warning letters; fines and civil penalties; restrictions on the product or manufacturing processes; unanticipated expenditures; delays in approving or refusal to approve our products; withdrawal of the product from the market; withdrawal of approvals by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; fines; civil penalties; and criminal prosecution. Any such actions could have a material adverse effect on our reputation, business, financial condition and operating results.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

Recall of our product, or the discovery of safety issues with our product, could have a significant negative impact on us.

If the FDA determines that our product shows material deficiencies or defects in design or manufacture, or poses an unacceptable risk to health, the FDA has the authority to require the recall of our product. Manufacturers may also voluntarily recall a product if they find any material deficiency in the product. In the event our product is associated with an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies, a government-mandated or voluntary recall by us, or one of our distributors, could occur. If our product were recalled, such recall would divert managerial and financial resources and could have a material adverse effect on our reputation, business, financial condition and operating results.

If we fail to comply with the extensive government regulations affecting us, our business will suffer.

Governmental authorities – principally the FDA and various state regulatory agencies – regulate the medical device industry extensively. The regulations are complex and are subject to rapid evolution and varying interpretations. Regulatory restrictions or changes could limit our ability to conduct or expand our operations, or could result in higher than anticipated costs or lower than anticipated sales. The FDA and other U.S. governmental agencies regulate numerous elements of our business, including product design and development; pre-clinical and clinical testing and trials; product safety; establishment registration and product listing; labeling and storage; marketing, speech/statements regarding the iLet, manufacturing, sales and distribution; pre-

market clearance or approval; servicing and post-market surveillance; advertising and promotion; and recalls and field safety corrective actions.

Before we can market or sell a new regulated product, or an existing product to which we have made a significant modification, in the U. S., we must obtain either approval under Section 510(k) of the Federal Food, Drug, and Cosmetic Act or approval of a pre-market application or PMA from the FDA. Because iLet is deemed a Class III medical device, we must comply with the PMA approval process and demonstrate the safety and effectiveness of the product on the basis of extensive data. The PMA process is customarily required for products that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. If a product is approved through a PMA application process, modifications to the product generally need FDA approval before the modified product can be sold. The process of obtaining regulatory approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these approvals on a timely basis, or at all.

If the FDA requires us to conduct a more rigorous examination for future products or modifications to our existing product than we had expected, we could be delayed in, or prevented from, introducing our product or modifications. A delay or cancellation could cause our sales to decline or to not meet our forecasts. In addition, the FDA may determine that future iterations of our product will require the more costly, lengthy and uncertain PMA process.

The FDA can delay, limit or deny approval of a product for many reasons, including our inability to demonstrate that our product is safe and effective for its intended use; the insufficiency of our clinical trial data to support approval; or the failure of our manufacturing process or facilities to meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations, revise existing regulations, or take other actions, which may prevent or delay approval of our product. Such actions by the FDA could also impact our ability to modify any then approved product on a timely basis.

Delays in obtaining approval for our product, or our failure to maintain approval for our product, could prevent us from generating revenue from the product or achieving profitability. In addition, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could cause customers not to use our product and could negatively impact our reputation and the perceived safety and efficacy of our product.

If we fail to comply with applicable regulations, such failure could jeopardize our ability to sell our product and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. If any of these sanctions were to be imposed on us, we could experience higher than anticipated costs or lower than anticipated sales. As a result, imposition of sanctions could have a material adverse effect on our reputation, business, financial condition and operating results.

Further, we may consider international expansion opportunities in the future. If we expand our operations outside of the U. S., we will be subject to various additional regulatory and legal requirements under the applicable laws and regulations of the international markets. These additional regulatory requirements may involve significant costs and, if we are not able to comply with any such requirements, our international expansion and business could be significantly harmed.

The healthcare industry is subject to extensive federal, state and local laws and regulations relating to billing for services; financial relationships with physicians and other referral sources; inducements and courtesies given to medical practitioners and patients; quality of medical equipment and services; confidentiality, maintenance and security issues associated with medical records and individually identifiable health information; medical device reporting; false claims; professional licensure; and product labeling. These laws and regulations are complex and, in many cases, still evolving. In many instances, these laws and regulations have not received significant regulatory or judicial interpretation. If our operations are found to violate any of the federal, state or local laws and regulations, which govern our activities, we may be subject to penalties including civil and criminal penalties, damages, fines or curtailment of our operations. Since many of these laws and regulations have not been fully interpreted by the regulatory authorities or the courts, we face an increased risk that we could be found in violation of such laws and regulations. Even if we successfully defend an action against us for violation of these laws or regulations, the defense could cause us to incur significant legal expenses and divert our management's time and attention from the operation of our business.

In addition, healthcare laws and regulations may change significantly in the future. Any such change may adversely affect our business. A court's or regulatory agency's review of our business may result in a determination that could materially and adversely affect our operations. Also, the healthcare regulatory environment may change in a manner that materially and adversely affects our operations.

We are not aware of any governmental healthcare investigations of us or our executives. However, if our executives or managers were to be subject to such investigations, we could incur significant liabilities or penalties, as well as adverse publicity.

If we undertake to modify to our product, we may be required to obtain new regulatory approvals, or to cease marketing or recall the modified product until approvals are obtained.

If we were to modify our product after PMA approval, and such modification could significantly affect the product's safety or effectiveness, or constitute a major change in its intended use, design, or manufacture, we would be required to obtain a modification to the PMA. The FDA requires every manufacturer to make the determination as to whether to seek modification of a PMA; however, the FDA may review any manufacturer's decision. The FDA may not agree with our decision regarding whether new approvals are necessary. If we determine that a modification to a PMA approval is unnecessary, and the FDA disagrees with our determination and requires us to submit new PMAs for modifications to our previously-approved product, we may be required to cease marketing or to recall the modified product until we obtain approval. In that event, we may be subject to significant regulatory fines or penalties.

Further, the FDA's ongoing review of the PMA process may make it more difficult for us to modify our previously approved product, either by imposing stricter requirements as to when to initiate a new PMA submission for a modification to a previously approved product, or by imposing more strenuous review criteria to such submissions.

If we violate applicable fraud and abuse laws, including anti-kickback laws and anti-referral laws, our business could suffer.

Numerous federal and state laws pertain to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Under these laws, our relationships with healthcare providers and other third-parties are subject to review. Violations of these laws are punishable by criminal and civil sanctions, including imprisonment and exclusion from participation in federal and state healthcare programs such as the Medicare, Medicaid and Veterans Administration health programs.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections; and

- foreign and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, collectively, the PPACA, amend the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. As such, a person or entity can now be found guilty under the PPACA even if he, she or it lacks actual knowledge of the statute or specific intent to violate it. In addition, under the PPACA, the government may assert that a claim resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Sanctions for violation of these

anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of those prohibitions. Any violations of these laws, or any action against us for violation of these laws, regardless of the outcome, could create a material adverse effect on our reputation, business, financial condition and operating results.

Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in the applicable laws, whether or not retroactive.

Our business is highly dependent on reimbursements by third-parties.

The sales of our product depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the U. S. continue to pass new legislation and regulations designed to contain the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further create industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales, which could have a material adverse effect on our business, financial condition and operating results.

Legislative or regulatory reforms may make it more difficult and costly for us to obtain regulatory approval of our product.

FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly and adversely affect our business and our products. Any new regulations or revisions, or reinterpretations of existing regulations, may impose additional costs or lengthen the time for the review of our product. Delays in the receipt of regulatory approvals for our proposed product, or even the possible denial of regulatory approval, could have a material adverse effect on our business, financial condition and operating results.

We may be liable if we engage in the off-label promotion of our product.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including those prohibiting promotion of off-label use of our products. Healthcare providers may use our products off-label, since the FDA does not regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional or training materials constitute promotion of an off-label use, we could be subject to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. In addition, other federal, state or foreign enforcement authorities might act if they consider our promotional or training materials to constitute promotion of an unapproved use. Such action could result in significant fines or penalties. Although we intend to refrain from statements that could be considered off-label promotion of our products, the FDA could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

We face the risk of product liability claims and may not be able to maintain or obtain appropriate insurance.

The testing, manufacturing and marketing of medical devices inherently involves the risk of product liability claims. Such claims may also arise from the misuse or malfunction of, or design flaws in, our product. We may be subject to product liability claims if our products cause, or merely appear to have caused, injury. Claims may be made by patients, healthcare providers or others selling our products. Although we intend to purchase product liability and clinical trial liability insurance that we believe will mitigate appropriate levels of risk, this insurance is subject to deductibles and coverage limitations and may not continue to be available to us on acceptable terms or at all. Even if available, the coverages may not be adequate to protect us against any future product liability claims. Further, if additional products are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain acceptable insurance, or otherwise protect against potential product liability claims, we will be exposed to significant liabilities. These liabilities may harm our business. A product liability claim, with respect to uninsured liabilities or for amounts in excess of insured liabilities, could result in significant costs and significant harm to our business, financial condition and operating results.

We may be subject to claims against us even if the apparent injury is due to the actions of others or misuse of our product. Our customers, either on their own or following the advice of their physicians, may use our product in a manner not proscribed in the product's labeling and which differs from the manner in which it was used in clinical studies and approved by the FDA. Such misuse could result in liability, which could prevent or interfere with our product marketing efforts. The defense of a suit, regardless of merit, could be costly, could divert management attention, and could result in adverse publicity. Such circumstances could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our product in the market. Any of these events could have a material adverse effect on our business, financial condition and operating results.

Marketing our product abroad requires regulatory approval and can involve pricing approval.

We may seek to market our product in foreign jurisdictions. Outside the U.S., we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from the time required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We might not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We have not taken any actions to obtain foreign regulatory approvals. We may not be able to file for regulatory approvals and may not receive necessary approvals to market our products in any jurisdiction outside the United States on a timely basis, or at all. Even if we obtain regulatory approvals to market our product in other countries, the price of our approved product may not meet our profitability requirements.

Possible Inability to Remain a Going Concern

Our ability to continue as a going concern for the next twelve months and beyond is dependent primarily upon our ability to raise additional equity or debt financing or other funds. If we fail to obtain sufficient additional funds, we may need to modify or even curtail our operations and our business may not survive. Additionally, if we are unable to raise sufficient funds, we could be in material breach of the terms of our licensing agreements with BU, which may result in BU revoking our rights to the intellectual property that is critical to our business. Any of the foregoing, if they occur, would have a material adverse effect on our business, financial condition, and results of operations which in turn could materially and adversely affect the value of our capital stock.

Even If We Achieve Regulatory Approval, Our Public Benefit Corporate Structure Deemphasizes Shareholder Return and Emphasizes the Delivery of a Public Benefit to the T1D Community

We emphasize that even if we are financially successful, our corporate structure as a Massachusetts public benefit corporation and a "B Lab certified B Corporation" requires our management and Board to make decisions that balance our responsibility to investors with our obligation to our public benefit mission. In short, our interest in making money for investors does not supersede the interests of the T1D community. However, we believe that serving the interests of the T1D community will result in maximum long-term financial benefit to our investors.

Assuming We Can Obtain Regulatory Approval and Raise Enough Money to Launch the iLet, Our Projected Revenues in a Rapidly Evolving Payer Market Are Uncertain.

Our projections of the revenues from sales of iLets and related consumables, and the costs to achieve such sales, may prove grossly inaccurate. The earliest that we expect to generate revenue is in 2020 which we expect to come from sales of iLets in the insulin-only configuration in the U.S. However, that estimate can easily be delayed for multiple reasons, such as failure to raise enough funds to conduct or complete clinical trials, lack of funds to operate our Company, lack of volunteer subjects to compete clinical trials, or our inability to obtain regulatory approval.

Even if we are successful in meeting all of these challenges, a model for reimbursement of an autonomous glucose control system does not exist. The only analogous reimbursement structure is that which applies to insulin pumps and CGM reimbursements. As recently as May 2016, at least one payer has disclosed that its covered patients 18 years of age and over will no longer be permitted to choose their own insulin pump supplier due to an exclusive relationship between the payer and a pump manufacturer. We are working to better understand the nature of this exclusive relationship, but given this development, it is conceivable that payers may develop exclusive arrangements with manufacturers of autonomous or partially autonomous glucose control systems, which may operate to preclude us from ever obtaining third-party reimbursements. Such a result may even after achieving regulatory approval would have a material adverse effect on our business, financial condition, and results of operations, which in turn could materially and adversely affect the value of our capital stock.

INDEBTEDNESS

In late 2015, our CEO, Ed Damiano, advanced our Company $125.00 to open a business checking account. The advance does not accrue any interest and is payable on demand. We anticipate repaying this loan in 2018. Aside from the above-mentioned advance and certain contractual obligations with our contract manufacturers and other service providers, we have not taken on any debt. In addition to continuing to raise money through equity financing, in the future it may be necessary, or we may elect, to raise funds through debt financing as well. There are no guarantees that any debt or equity financing will be available to the Company on favorable terms or at all.

EXEMPT OFFERINGS

Since inception, we have raised approximately $13.5 million in gross proceeds through equity issuances as set forth in the following table.

Investor (Closing Date)	Exemption	Security	Amount Sold	Use of Proceeds
Eli Lilly and Company (December 31, 2015)	Private offering exempt from registration under Securities Act §4(2)	Series A Preferred Stock	$5,000,000 for 5% of our outstanding shares	General business operations and further iLet development
Novo Nordisk A/S (September 20, 2016)	Private offering exempt from registration under Securities Act §4(2)	Series A-2 Preferred Stock	$5,000,000 for 4.7% of our outstanding shares	General business operations and further iLet development
Various investors through Wefunder (September 8, 2016)	Regulation Crowdfunding. Exempt from registration under Securities Act §4(a)(6)	Class C Common Stock	$1,000,000 for .99% of our outstanding shares	General business operations and further iLet development
Zealand Pharma A/S*, family offices and other accredited investors (Ongoing; first closing was Dec. 20, 2017)	Private offering exempt from registration under Securities Act §4(2)	Series B Preferred Stock	$2,452,916 for 1.5% of our outstanding shares	General business operations and further iLet development

Zealand Pharma has also committed to purchase an additional $3.5 million of Series B Preferred subject to certain conditions, which we may or may not meet.

TRANSACTIONS WITH RELATED PARTIES

We have entered into a sublease with a related party for our West Coast facilities. The related party has disclosed the material terms of the sublease. We are not paying the related party a premium for the sublease. Rather, the costs are exactly those borne by the related party for the master lease. Additionally, prior to our formation, we incurred certain startup expenses. Related parties were compensated for pre-incorporation expenses and services in an amount not exceeding $50,000 in cash.

FINANCIAL CONDITION OF THE ISSUER

A. Overview

We are a development stage medical technology company developing the iLet, our bionic pancreas, which has not yet achieved and may never achieve regulatory approval. As a result, our only revenues through 2017 have been from a collaboration with another company that paid us under a development contract. In future periods, and prior to approval of the iLet (which is not guaranteed to ever occur), we may recognize revenues from sales of iLets and related components to other companies or institutions for use in research, including clinical trials. From our inception to December 31, 2017, we focused on design, development, engineering and clinical testing of the iLet, preparing to manufacture the iLet and related components, developing strategic partnerships, and building corporate infrastructure to support existing and planned operations.

B. Unaudited Summary Financial Information

At or For the Year Ended December 31,	2015	2016	2017
Total Assets	$5,015,954	$7,863,770	$3,419,889
Cash & Cash Equivalents	125	7,277,339	2,460,089
Account Receivable	-	-	-
Current Liabilities/ Short-Term Debt	267,069	245,374	1,162,353
Long-term Debt	-	-	-
Revenues/Sales	-	-	630,000
Cost of Goods Sold	-	-	-
Taxes Paid	-	456	40,374
Net Income (Loss)	(230,546)	(3,197,488)	(8,026,295)

In addition to the Summary Financial Information above, more complete financial statements are included elsewhere in this Annual Report.

Statement Regarding Unaudited Financial Information

The financial information set forth in this Annual Report is unaudited. Although we believe it fairly presents our results of operations and financial condition for the periods or at the dates indicated, our financial statements have not been audited or reviewed by an independent accounting firm. There is no assurance that our financial statements comply in all material respects with United States Generally Accepted Accounting Principles and thus may present financial data differently than had they been audited or reviewed by an independent accounting firm. Adjustments and modifications to the financial statements may be identified in the future, which could result in significant differences from the information provided in this Annual Report. Our principal executive officer has reviewed our financial statements and, as required by Regulation Crowdfunding §227 Rule 201, certified that they are true and complete in all material respects.

Net Income (Loss)

From inception through December 31, 2017, we have accumulated total net losses of $11,454,329. The vast majority of our net losses resulted from expenses related to research and development and from general administrative expenses. Our expenses have included but are not limited to those for salaries and benefits, consultants and professional services, engineering costs, materials, costs related to patents and other intellectual property, and travel. We expect that our operating expenses will increase significantly in 2018 and beyond as we hire additional employees and contractors, incur costs associated with building the iLet, conduct additional clinical trials, pursue regulatory approval of the iLet in the U.S. and elsewhere, and prepare for the commercial launch of iLet if regulatory approvals are received. Since our revenues are limited until we receive regulatory approval to commence commercial iLet sales, and no such approvals are guaranteed, we expect that our net losses will continue to increase at an accelerated pace based on these increased expenses. There is no assurance that we will ever become profitable or that, if we do, that profitability will be sustained.

Liquidity and Capital Resources

We have financed our operations primarily through sales of equity securities and through increases in accounts payable to trade vendors and others. From inception through December 31, 2017, we raised total gross proceeds of approximately $13.5 million through issuances of equity securities.

As of December 31, 2017, our working capital was $1,417,618 representing primarily cash of $2,460,089 and current liabilities of $1,162,353. Our budget for 2018 calls for spending approximately $10,429,662, which means we need to raise additional capital or other funds to support planned spending. Additionally, we will need to raise significant amounts of capital or other funds to meet requirements beyond 2018 including for pivotal trials, pursuit of regulatory approvals of the iLet, and for commercialization if the iLet is approved for commercial sale. The amounts that we actually spend for any specific purpose and in any specific period may vary significantly from our estimates depending on a number of factors, including the pace of progress of our development efforts, actual costs of product testing, research and development,

legal or regulatory spending, and competitive developments as well as expenses that arise that were not anticipated.

We generally hold the cash we need to meet our short-term requirements in accounts maintained with U.S. banks. Our policy is to invest any cash in excess of these amounts in high-quality, liquid investments, typically demand deposit accounts and money market funds that provide only minimal returns. We do not enter into investments for trading or speculative purposes.

REGULATORY INFORMATION

The Company has not previously failed to comply with the requirements of Regulation Crowdfunding.

OTHER MATERIAL INFORMATION

In April 2017, the Company received a demand letter under Massachusetts General Laws Chapter 93A, Section 9 ("Chapter 93A") from an attorney representing Kirk Ramey, a former research scientist in Ed Damiano's lab at Boston University from 2013 to 2015. The attorney threatened to sue the Company as well as Ed Damiano, Firas El-Khatib and BU. Mr. Ramey claims that he was promised an equity stake in Beta Bionics in exchange for his work on the bionic pancreas related technology in the BU lab. Mr. Ramey also claims that the Company, Firas El-Khatib, Ed Damiano and BU have interfered with his rights as an inventor on various patents and thereby deprived him of his rights to certain royalties. In addition to claims under Chapter 93A, Mr. Ramey is threatening to bring claims for alleged violations of the breach of fiduciary duty, breach of contract, breach of the covenant of good faith and fair dealing, promissory estoppel, negligent and fraudulent misrepresentation, tortious interference, as well as a request for a declaratory judgment confirming Mr. Ramey's alleged equity interest in the Company. The Company denies that it or any of its officers or employees ever promised Mr. Ramey any equity in Beta Bionics in exchange for the work Mr. Ramey performed at BU or that it or its officers or employees engaged in any of the other alleged unlawful activities, including, without limitation, any alleged interference with Mr. Ramey's rights, if any, to royalties as an inventor. The Company is prepared to vigorously defend itself and its officers and employees in the threatened litigation. Even if we ultimately prevail, the threatened litigation could burden us with substantial unanticipated costs. In addition, the threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other Company business. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or enter into strategic partnerships that would help us bring the iLet to market.