Beta Bionics

A Massachusetts Public Benefit Corporation

Certified B Corporation

ANNUAL REPORT

Physical address within the Commonwealth:
300 Baker Ave., Suite 301
Concord, MA 01742

Corporate headquarters:
14150 Myford Road,
Irvine, CA 92606

www.betabionics.com

This Annual Report is dated April 29, 2020

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, 2019. A copy of this Report may be found on our website at www.betabionics.com/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,

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

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.

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.

Information related to the iLet® bionic pancreas is preliminary and developing. The iLet bionic pancreas is an investigational device that is not yet approved by the FDA or by any other regulatory body in any other country. Regulatory approval of the iLet bionic pancreas is critical to our success and to ensuring that we meet our public benefit mission. To date, we have not generated any revenues from commercial product sales and do not expect to do so in the near future.

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 within the Commonwealth:
300 Baker Ave., Suite 301
Concord, MA 01742

Website of issuer: www.betabionics.com

DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES

The members of our board of directors and our officers as of December 31, 2019, 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 Biomedical Engineering	Beta Bionics, Inc. and Boston University	2015

Director	Principal Occupation	Main Employer(s)	Year Joined as Director
Edward B. Raskin	Founder, Attorney and VP, Public Benefit Development & Corporate Strategy	Beta Bionics, Inc.	2015
Jeff Hitchcock	President, Children with Diabetes	Children With Diabetes	2016
Adam Steensberg*	Chief Medical & Development Officer, EVP, Development, Regulatory and QA	Zealand Pharma A/S	2018
Finny Kuruvilla	Chief Investment Officer	Eventide Asset Management LLC	2019
Martha Goldberg Aronson**	Board Director	Conmed Corporation (NYSE: CNMD); and Cardiovascular Systems Inc. (NASDAQ: CSII)	2020
Sean Carney**	Investor/Consultant	Hillhouse Capital; Care Capital	2020

*Resigned April 2020
**Joined April 2020

Officers

Name	Principal Occupation	Start date	Term of Office
Edward R. Damiano	Founder; President and Chief Executive Officer; Professor of Biomedical Engineering	January 1, 2016	Indefinite

Gibb Clarke	VP, Finance; Chief Financial Officer; Treasurer	April 29, 2019	Indefinite
Joe Conkey	VP, Quality Assurance	September 21, 2018***	Indefinite
Mads Dall	VP, Commercial Strategy	February 5, 2018	Indefinite
Firas El-Khatib	Founder; VP, Clinical and Regulatory Affairs	January 1, 2016	Indefinite
Max Gill	VP, Market Access	August 26, 2019	Indefinite
Holly Purcell	Corporate Controller	September 16, 2019	Indefinite
Edward B. Raskin	Founder; VP, Public Benefit Development & Corporate Strategy	January 1, 2016	Indefinite
Serafina Raskin	Founder; General Counsel; Corporate Secretary; VP, Human Resources	January 1, 2016	Indefinite
Michael Rosinko	VP, Research & Development	January 2, 2017	Indefinite

*** Hired on January 9, 2017 as Director, Quality; Promoted to VP, Quality on September 21, 2018

Non-Employee Directors

Jeff Hitchcock

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 partnership with other non-profit organizations, in Canada and the United Kingdom. Since founding Children with Diabetes in 1995, Mr. Hitchcock and Children with Diabetes have hosted almost 100 conferences and educational events focused on improving the lives of families living with diabetes.

Finny Kuruvilla, MD, PhD

Finny Kuruvilla is the Chief Investment Officer for Eventide Funds, Lead Portfolio Manager for the Eventide Gilead Fund, and Portfolio Manager for the Eventide Healthcare & Life Sciences Fund. Dr. Kuruvilla has a unique background in healthcare, statistics, and investing. Concurrent with Eventide, from 2008 through 2016, he was a Principal at Clarus Ventures, a leading healthcare and life sciences venture capital firm. Prior to joining Eventide, from 2006-2008, Dr. Kuruvilla was a research fellow at the Broad Institute of Harvard and MIT, and from

2005-2008, Dr. Kuruvilla was a clinical fellow at the Brigham and Women's Hospital and Children's Hospital Boston and a postdoctoral scientist at MIT. He holds an MD from Harvard Medical School, a PhD in Chemistry and Chemical Biology from Harvard University, a master's degree in Electrical Engineering and Computer Science from MIT, and a bachelor's degree from Caltech in Chemistry.

Martha Goldberg Aronson, MBA

Martha Goldberg Aronson served as Executive Vice President and President-Global Healthcare, from September 2012 to November 2015 at Ecolab, Inc., a specialty chemical company. Prior to Ecolab, Ms. Goldberg Aronson served as Senior Vice President and President, North America, of Hill-Rom Holdings, Inc., a leading worldwide manufacturer and provider of medical technologies and related services for the health-care industry. Before joining Hill-Rom, she served as Senior Vice President at Medtronic, Inc., from March 2008 to November 2009, and in various other domestic and international management positions with Medtronic throughout her 18 years at the company. She is also a director of CONMED Corporation and Cardiovascular Systems Inc. She previously served as a director of Hutchinson Technology, Methode Electronics and Clinical Innovations, LLC. Ms. Goldberg Aronson holds a BA degree in Economics from Wellesley College, and an MBA degree from Harvard Business School.

Sean D. Carney, MBA

Sean Carney currently serves as a consultant with Hillhouse Capital and Care Capital and is on the Board of IAT Insurance Group, a private property and casualty insurance company. From 1996 to 2016, Mr. Carney was a Managing Director at Warburg Pincus LLC, the global private equity firm. He has served on numerous public and private company boards, including and Wright Medical. Prior to joining Warburg Pincus in 1996, Mr. Carney was a consultant with McKinsey & Company. Mr. Carney received an AB degree in economics from Harvard College and an MBA degree from Harvard Business School.

Adam Steensberg*, MD

Adam Steensberg is currently the Executive Vice President, Chief Medical and Development Officer for Zealand Pharma A/S. Prior to joining Zealand, Dr. Steensberg led clinical research teams as the medical director at Novo Nordisk and worked as a clinician at Rigshospitalet, University of Copenhagen. Dr. Steensberg was a medical and scientific advisor in the areas of endocrinology, cardiology, gastroenterology and rheumatology, and has significant experience of leading regulatory strategies. Dr. Steensberg holds a Doctor of Medical Sciences degree (D.M.Sc./dr.med.) from the University of Copenhagen, Denmark, and an MBA from International Institute for Management Development, Switzerland.

*Note, Dr. Steensberg resigned his position as a Beta Bionics director on March 2020 and currently serves as a Beta Bionics board observer.

Officers

Gilbert Clarke, MBA, VP of Finance; Chief Financial Officer; Treasurer

Gibb Clarke is a serial med-tech entrepreneur who has launched several successful medical device companies. At Beta Bionics, Mr. Clarke has applied his nearly 20 years of leadership

experience in the medical device field to help streamline operations, manage suppliers, and lead finance. From 2015 to 2019, Mr. Clarke was the Chief Executive Officer of Three Rivers Medical. Prior to that role, he was the Chief Executive Officer of Blockade Medical LLC from 2011 to 2014. Mr. Clarke holds an MBA degree from Duke University.

Joe Conkey, VP of Quality Assurance

Joe Conkey started at Beta Bionics in January 2017 as the Director of Quality Assurance. He has over 25 years of experience in the medical device industry with over 22 years as a Quality professional, holding various positions within Design Quality, Supplier Quality, Manufacturing Quality and Quality Systems. Mr. Conkey has been involved in bringing innovative devices to market not only in the U.S., but globally including CE Marking in Europe and device registrations in Canada, Brazil, and Asia-Pacific regions.

Mads Dall, Chief Commercial Officer

Mads Dall has more than 25 years of diabetes industry experience from a broad range of executive management and management consulting positions as well as board positions. Mr. Dall has been Corporate Vice President at Novo Nordisk responsible for advanced insulin delivery and glucose monitoring systems, leading global development and commercialization of novel diabetes technologies. He has led commercial organizations in diabetes, introducing new products and building new brands, as well as growing sales of existing product portfolios. Over the past 10 years Mr. Dall has been working with a number of diabetes technology organizations on international commercialization strategies, corporate strategy, M&A, and financing. Mr. Dall holds an MA in Sinology (China Studies) from the University of Copenhagen, Denmark, and a Masters in Business Economics from Copenhagen Business School, Denmark.

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

Ed Damiano is a Professor of Biomedical Engineering at Boston University (BU), where he 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 (T1D) at 11 months of age, he has been committed to creating and integrating closed-loop glycemic 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 bionic pancreas. In 2015, Drs. Damiano and El-Khatib, along with Ed Raskin and Serafina Raskin, founded Beta Bionics, Inc. as a Massachusetts public benefit corporation with the goal of bringing the iLet bionic pancreas through clinical trials, regulatory clearance and into the hands of people with T1D.

Firas El-Khatib, PhD, VP, Clinical and Regulatory Affairs

In addition to his role at Beta Bionics, Firas El-Khatib is a senior research scientist (and prior to that, was a postdoctoral research associate) in Dr. Damiano's laboratory in the Department of Biomedical Engineering at Boston University, a role he has held since 2006. Prior to that, Dr. El-Khatib was Dr. Damiano's PhD student at the University of Illinois. Working closely with Dr. Damiano, Dr. El-Khatib created the control algorithms that run the insulin-only, glucagon-only and bihormonal configurations of the iLet bionic pancreas. At Beta Bionics, Dr.

El-Khatib directs all algorithm development and implementation as well as clinical and regulatory affairs to support clinical trials and regulatory approval of the iLet bionic pancreas.

Max Gill, MBA, VP, Market Access

Max Gill has more than 20 years of health economic, health policy, and reimbursement experience in the medical device industry. Before joining Beta Bionics, Mr. Gill led Health Economics & Reimbursement teams at Medtronic Diabetes, Covidien (Surgical Division), and Cyberonics. Prior to that, he spent six years working at Blue Cross Blue Shield in Kansas City. At Beta Bionics, Mr. Gill is a subject matter expert in market access and reimbursement who provides strategic insight and planning aimed at ensuring rapid and comprehensive access for the launch of the Company's first product following FDA clearance. He holds an MBA degree and a BA degree in management from Southeastern Louisiana University, as well as a Bachelor of Commerce degree in cost accounting from Punjab University in India.

Holly Purcell, MBA, Corporate Controller

Holly Purcell is an experienced corporate controller and a trusted business partner to executive leaders and operational management. Ms. Purcell has more than 15 years of experience working in financial and accounting teams, both in private and public companies. Prior to joining Beta Bionics, Ms. Purcell spent 8 years at working at Vapotherm (NYSE: Vapo) where she advanced through progressively increasing roles of responsibility. She spent the last four and a half years of her tenure as the corporate controller at Vapotherm, where she was responsible for oversight of the integrity of global accounting systems, corporate and manufacturing accounting, consolidation of global financial results and had first-hand involvement in SEC Reporting and S-1 preparation. At Beta Bionics, Ms. Purcell is responsible for financial reporting, planning and budgeting, systems of internal controls, and corporate accounting. Holly holds an MBA degree (with a focus in Corporate Social Responsibility) from Southern New Hampshire University and a BA degree in Accounting from Assumption College.

Edward Raskin, JD, VP Public Benefit Development & Corporate Strategy, Director

Ed Raskin 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. Mr. Raskin's son was diagnosed with T1D at the age of 7. In December 2018, Mr. Raskin became even more intimately familiar with the burdens of managing T1D when he was also diagnosed with T1D. Mr. Raskin holds a JD degree from the University of California, Berkeley, and a BA degree in Political Science from the University of California, Irvine. Mr. Raskin and Serafina Raskin are husband and wife.

Serafina Raskin, JD, VP, General Counsel; VP, Human Resources; Corporate Secretary

Prior to becoming the General Counsel and Corporate Secretary for Beta Bionics, Serafina Raskin was a partner with Kassinove & Raskin LLP where she lead a team of attorneys in serving hospital systems, physicians' groups, long-term care organizations and other healthcare providers and payers. She worked 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 to Beta Bionics. Ms. Raskin is admitted to practice law in California and is registered as an in-house attorney with the Massachusetts Bar Association. Her son was diagnosed with T1D in 2013 and is the impetus for her work at Beta Bionics and community service for T1D organizations like the American Diabetes Association (ADA). Her husband, Ed Raskin was recently also diagnosed with T1D. Mrs. Raskin holds a JD degree from the University of California, Hastings, and a BA degree in Political Science from the University of California, Irvine. Ms. Raskin and Ed Raskin are husband and wife.

Michael Rosinko, MS, MBA, VP, Research and Development

Mike Roskino joined Beta Bionics from Tandem Diabetes Care, where he was Vice President of Research & Development since 2008. Mike led product development for the t:slim insulin pump 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. Mr. Rosinko brings over 25 years of experience in the medical device field to Beta Bionics, as well as specialized knowledge necessary to gain regulatory clearance and commercialize a novel device. Mr. Rosinko holds an MBA degree from Claremont Graduate University, an MS degree in Electrical Engineering from the University of Southern California, and a BS degree in Electrical Engineering from the University of Pittsburgh, where he graduated cum laude. In addition, he holds more than 40 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 are:

(i) 1,000,000 shares of Class A Common Stock;
(ii) 2,000,000 shares of Class B Common Stock;
(iii) 500,000 shares of Class C Common Stock;
(iv) 50,000 shares of Series A-1 Preferred Stock;
(v) 50,000 shares of Series A-2 Preferred Stock;
(vi) 420,000 shares of Series B Preferred Stock; and
(vii) 450,000 shares of Series B-2 Preferred Stock.

The respective rights of each class of stock, as provided in our Sixth 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	50,000 50,000	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 • Broad-based 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	420,000	419,793	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 • Board seat • Broad based anti-dilution protection

Series B-2 Preferred	450,000	396,000	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 Broad based
Common Stock				
Class A	1,000,000	600,000	Ten votes per share	None
Class B	2,000,000	308,920	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	400,000 Class B Common Stock (Employee Incentive Option Pool)
Antidilution	None
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, Series B-2 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, 2018, 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.

On March 21, 2018, our Board of Directors authorized, subject to shareholder approval, our officers to amend the Plan by increasing the number of shares available for issuance to the company's employees, directors or consultants under the Plan to 200,000.

On December 12, 2019, our Board of Directors authorized, subject to shareholder approval, our officers to amend the Plan by increasing the number of shares available for issuance to our employees, directors or consultants under the Plan to 400,000.

Principal Security Holders

The following table lists as of December 31, 2019, 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**	**Series A, A-2 & B, Preferred Stock**	**% of Voting Power**
Edward Damiano and Toby Milgrome (husband and wife)	600,000	-	-	999	83%

The above calculation is based on the number of shares of voting securities owned as of December 31, 2019. 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 to Class B Common Stock.

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 our preferred investors, certain holders of preferred stock have rights to review certain Company records and observe all Board meetings. Other accredited investors, who participated in our preferred raises, have certain information rights.

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 our securities, which makes valuing our securities difficult. Further, as a development-stage

company, we do not have commercial 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

Majority voting control of our Company is held by two individuals. As a result, other shareholders have limited 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. DBA Carta, 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 trusted partner for those living with or caring for those diagnosed with type 1 diabetes (T1D). Beta Bionics is working to commercialize the iLet® bionic pancreas to transform the lives of people living with or affected by T1D.

The iLet bionic pancreas is an investigational device, which is designed to be a fully automated, closed-loop system for the control of glycemia in T1D. This pocket-sized, wearable medical device is the result of more than 15 years of research at Boston University (and several years of research at the University of Illinois before that), including 19 clinical studies conducted in collaboration with six academic researcher centers (including Harvard Medical School, Stanford University Medical School, the University of Massachusetts Medical School, the University of North Carolina, Chapel Hill, the University of Colorado, and Nemours Children's Health System), in addition to over 4 years of commercial development efforts by the team at Beta Bionics.

After regulatory clearances, the iLet bionic pancreas expects to be the world's first fully automated closed-loop system and has been designated a "breakthrough device" by the FDA. Breakthrough device designations are limited to therapies that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

What makes the iLet bionic pancreas a breakthrough technology? Standard T1D care places a heavy burden on patients to be "compliant" with unreasonably complex and burdensome treatment regimens. There is a clear need for a simple therapy that fits easily into the daily life of people with T1D and reduces the daily burden of the disease on patients, their caregivers and key stakeholders, while achieving better outcomes.

The iLet bionic pancreas consists of:

1. an integrated dual-chamber pumping platform capable of delivering analog insulin alone (via either a prefilled cartridge, or an empty cartridge that the user fills with insulin from a vial), analog glucagon alone (from a prefilled cartridge), or both analog insulin and analog glucagon, depending on how the device is configured, at extremely precise doses meeting FDA's ACE pump special controls;

2. an integrated CGM meeting FDA's iCGM standard (such as the Dexcom G6);

3. a suite of adaptive control algorithms that autonomously determines and commands doses of insulin and/or glucagon based on CGM glucose data, and will comply with the FDA's Integrated Controller special controls;

4. custom single-cannula or dual-cannula infusion sets; and

5. an integrated touchscreen user interface.

The iLet bionic pancreas makes dosing decisions on the delivery of analog insulin, analog glucagon or both, every 5 minutes based on glucose sensor values received from an iCGM. Unlike standard insulin pump therapy, the iLet bionic pancreas is designed to offer users turnkey simplicity of use; the user enters only a body weight and tells the system to "**Go Bionic™**". From there, the iLet bionic pancreas and its proprietary suite of algorithms begin controlling blood-sugar levels autonomously, without requiring the user to count carbohydrates, set insulin delivery rates, or deliver bolus insulin for meals or corrections.

The system has been successfully tested in several pre-pivotal trials. Extensive investigator-initiated pivotal trials testing the iLet bionic pancreas in over 1,100 people with T1D are planned to commence in 2020.

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

The Beta Bionics benefit mission. 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 our 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 bionic pancreas, supporting clinical testing of the iLet technologies, developing our business plan, negotiating strategic alliances and other agreements, and raising capital.

Clinical research testing the iLet bionic pancreas. The various clinical trials conducted in 2018 and 2019 testing the insulin-only and bihormonal configurations of the iLet bionic pancreas (which were fully or partially supported by Beta Bionics) have resulted in compelling data.

2018 iLet Insulin-Only Bridging Study

- In 2018, Dr. Bruce Buckingham and the clinical research team at Stanford University, and Dr. Steven Russell and the clinical research team at the Massachusetts General Hospital (MGH) ran a home-use randomized, 14-day (two 7 day periods) cross-over clinical trial comparing the iLet bionic pancreas in the insulin-only configuration to usual care.
- The trial was first of its kind in a number of ways, including the first trial to test an ultra-rapid-action insulin analog (Fiasp®, Novo Nordisk) in a closed-loop system.
- It was also the first study of a fully automated insulin delivery system for people on MDI therapy, with no run-in or training period needed.

- All 34 test subjects (22 pump users and 12 MDI users) initiated therapy on the iLet bionic pancreas in the same way—by entering only their body weight with no "run-in" period.
- The 2018 Insulin-Only Bridging Trial was also the first test of a closed-loop system using two different continuous glucose monitors in the same trial (the Dexcom G5 CGM in half of the adult cohort and the Senseonics Eversense in the other half of the adult cohort).
- The cohort had very good glucose control at baseline, with an average screening A1c of 7.5 ± 1.1%.
- The iLet bionic pancreas significantly increased the percentage of time spent in the range of 70–180 mg/dl compared to usual care (70% vs. 62%). During the overnight period there was a lower mean CGM glucose in the iLet bionic pancreas arm compared to usual care (146±18 mg/dl vs. 166±32 mg/dl), but no difference in time spend <54 mg/dl (*median*: 0% [0–0.95] vs. 0% [0–1.47]), and similar for time spent <70 mg/dl (*median*: 2.3% [0–4.5] vs. 2.9% [0–4.8]).
- The results also showed that there was no statistically significant difference between the iLet and usual care for mean CGM glucose (155±12 vs. 162±26 mg/dl).
- Time spent in hypoglycemia (time < 54 mg/dl) when on the iLet was lower for Dexcom G5 CGM users (0.4 ± 0.5%) than Senseonics Eversense CGM users (0.9 ± 0.7%), however, it is unclear whether this represents an actual difference in hypoglycemia or a difference in the detection of hypoglycemia between the two sensors.
- The mean insulin total daily dose was not significantly different between the iLet bionic pancreas and usual care groups (44±20 vs. 42±20 u/day).
- The results of the Insulin-Only Pivotal Trial were released during the American Diabetes Association Scientific Sessions in 2019.

2019 iLet Bihormonal / Insulin-Only Cross-Over Trial

- In 2019, Dr. Steven Russell and the clinical research team at the Massachusetts General Hospital (MGH) conducted a home-use randomized, two-period cross-over clinical trial testing the iLet bionic pancreas.
- The trial compared operational performance of the iLet bionic pacreas in the insulin-only configuration for one week versus its bihormonal configuration (using Zealand Pharma's investigational dasiglucagon) for one week in 10 adult participants with T1D.
- Trial participants started therapy by entering only their body weight into the device; there was no device training period and no physician intervention to optimize therapy.
- The iLet bionic pancreas operated as expected, meeting the primary aim of the study.
- In the trial, the bihormonal iLet bionic pancreas demonstrated superior mean glucose control and time in range when compared with the insulin-only control.
    - During the bihormonal period, participants achieved a mean glucose level, as measured by continuous glucose monitoring (CGM), of 139 mg/dL on days 2–7 of use, versus 149 mg/dL during the insulin-only period ($p < 0.01$).

    - During the bihormonal period, participants spent 79% of the time with their CGM glucose level in range (70–180 mg/dL) on days 2–7 of use, versus 72% during the insulin-only period ($p<0.01$).
    - During the bihormonal period, 90% of participants had a mean CGM glucose level of ≤ 154 mg/dL, a level that corresponds to an HbA1c level of 7%, the therapeutic goal for adults recommended by the American Diabetes Association. In contrast, 50% of participants had a mean CGM glucose level ≤ 154 mg/dL during the insulin-only period.
    - Hypoglycemia was observed to be low throughout the study. The median percentage of time CGM glucose was < 54 mg/dL was 0.2% during the bihormonal period versus 0.6% during the insulin-only period. The mean percentage of time CGM glucose was < 70 mg/dL was 2.0% during the bihormonal period versus 4.0% during the insulin-only period.
- As far as we know, the 2019 home use bihormonal trial was the first closed-loop trial testing a glucagon analog in a closed-loop system with a potential commercial presentation (i.e. prefilled cartridge).
- It was also the first trial testing a closed-loop system initialized with body weight only.
- The topline results of foregoing bihormonal clinical trial were released in 2019 and detailed results are expected to be presented during the American Diabetes Association Scientific Sessions in 2020.

2019 iLet–Fiasp Exploratory Trial

- In 2019, Dr. Steven Russell and the clinical research team at the Massachusetts General Hospital (MGH) conducted a home-use randomized, sequential three-cohort, two-period, single-blind cross-over clinical trial testing the iLet bionic pancreas with Fiasp®.
- In each cohorts of , the trial compared the performance of the iLet in the insulin-only configuration using Fiasp with the control algorithm's t_{max} setting at default (t_{65} =65 min) for one week versus a non-default setting (t_{50}=50 min in cohort 1, t_{40}=40 min in cohort 2, or t_{30}=30 min in cohort 3) for another week, in eight subjects with type 1 diabetes per cohort, for a total of 24 subjects.
- The trial proceeded from cohort 1 (t_{65} vs. t_{50}) to cohort 2 (t_{65} vs. t_{40}), and from to cohort 2 to cohort 3 (t_{65} vs. t_{30}), only after verifying that escalation stopping criteria were not met in the previous cohort.
- In the trial, improvements in glycemic control at non-default t_{max} settings were observed.
    - Mean time in low sensor glucose (<54 mg/dL, primary endpoint) was <1.0% for all t_{max} settings, specifically 0.98% for t_{50} vs 0.89% for t_{65} in cohort 1, 0.69% for t_{40} vs 0.50% for t_{65} in cohort 2, and 0.61% for t_{30} vs 0.37% for t_{65} in cohort 3.
    - Mean glucose in cohorts 1 and 2 was significantly lower at non-default versus default t_{max} settings (150.3 mg/dL t_{50} vs 157.7 mg/dl at t_{65} in cohort 1, and 150.1 mg/dL t_{40} vs 157.6 mg/dl at t_{65} in cohort 2), with comparable insulin dosing.

    - Except for the default t_{max} setting in cohort 1, the mean time in range (70–180 mg/dL) was >70%.
    - No severe hypoglycemic episodes were reported and there were no clinically significant differences in adverse events between the groups.
- The trial showed the importance of optimizing insulin device settings to maximize the potential benefits that new insulin therapies might offer to patients.
- A future wider-scale study is planned to rigorously investigate the advantage and benefit that specific tmax settings offer in the iLet using Fiasp.

Completed Series B-2 Financing. Additionally, in 2019 Beta Bionics successfully raised additional investments amounting to approximately $63 million from institutional investors. This additional investment completed the Series B/B-2 raise, which totaled just over $126 million. These fundraising events marked important corporate milestones for Beta Bionics and has provided us resources to continue development, clinical, regulatory and preparatory commercialization activities for the iLet bionic pancreas.

B. Labor of love

Dr. Edward R. Damiano, a Boston University (BU) professor of biomedical engineering, and Dr. Firas H. El-Khatib, a senior research scientist at BU (who began working with Ed as a graduate student when Ed was an assistant professor of mechanical engineering at the University of Illinois), began their journey to develop a wearable bionic pancreas not long after Ed's wife, Dr. Toby Milgrome, a pediatrician, diagnosed their son, David, with T1D when he was an infant. Managing David's blood-sugar levels well was extremely arduous, and managing it perfectly proved impossible. The fear of the grave consequences that could result from mis-dosing David's insulin weighed heavily on them day and night. Despite meticulous attention to detail, it was clear that David's insulin requirements varied greatly from day to day and even hour to hour, and for myriad reasons, so that decisions made under apparently similar circumstances on one day would have inexplicably different outcomes on another.

People living with T1D are constantly reminded that circumstances can be misleading. Children with T1D present a host of different kinds of challenges each unique to each stage of their development. As a child grows, becomes sick, feels content or anxious, eats a lot or a little, has different combinations of carbs, fats, and proteins from one meal to that next, plays hard or not at all, his or her insulin requirements can vary dramatically. The result can be a child who is fine, or sometimes dangerously hypoglycemic, or all-to-often hyperglycemic and facing a lifetime of potential disability, including blindness, organ failure, and amputations. 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.

The technology that grew out of the theoretical work, animal studies, and clinical research carried out by Ed's lab — in collaboration with Drs. Steven Russell and David Nathan at the Massachusetts General Hospital, and other physician scientists across the US — was ultimately licensed from BU by Beta Bionics. The team at Beta Bionics is deeply motivated to bring the iLet bionic pancreas to the loved ones of many on our own team, and to the millions of families living

with T1D. 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 T1D.

- 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, during conventional therapy, 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.

Hypoglycemia causes confusion, combative irrational behavior, shakiness, feeling of extreme stress due to catecholamine release, loss of mental acuity, and, if left untreated, unconsciousness, seizure, coma and even death.

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 T1D but can significantly reduce long-term complications. The required vigilance and diligence in maintaining the critical balance of enough insulin to prevent hyperglycemia, yet not too much insulin to cause hypoglycemia, renders the T1D management process challenging, aggravating and daunting for many people living with the condition.

D. Current treatment options

Currently, there is no system that autonomously makes all, or even substantially 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 known systems prospectively competitive to the iLet bionic pancreas technology share several commonalities as reflected in publicly available information during the relevant time period of this report:

- all require the patient to count carbohydrates and bolus for meals;
- 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;
- none are initialized by body weight alone; and
- none appear to have any capability of incorporating glucagon into their systems.

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;

- 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 the Minimed 670G, which was approved by the FDA on September 29, 2016, and which has an "Auto Mode" option that, under certain circumstances, automatically adjusts basal insulin delivery every five minutes based on blood glucose levels);

- an insulin pump paired with a continuous glucose monitor that operates in a "predictive low blood glucose basal insulin suspend" configuration (the only known system with this feature is the Tandem X2 with Basal-IQ, which was approved by the FDA on June 21, 2018, and which is designed to look 30 minutes into the future, and then attempt to predict where glucose levels are heading, suspend insulin delivery when low glucose is predicted, and then automatically resume insulin delivery once glucose levels begin to rise); and

- most recently, an insulin pump paired with a continuous glucose monitor that operates in an "advanced hybrid closed-loop" configuration (the only known system with this feature

is the Tandem X2 with Control-IQ, which was cleared by the FDA on December 13, 2019). The Tandem X2 with Control-IQ uses CGM values, in conjunction with other variables such as insulin on board, to attempt to predict glucose levels 30 minutes ahead and adjust insulin delivery accordingly. If glucose values are predicted to drop below 112.5 mg/dL, basal insulin delivery is reduced; if glucose values are predicted to be below 70 mg/dL, basal insulin delivery is stopped. If glucose values are predicted to be above 160 mg/dL in the next 30 minutes, basal insulin will be increased. If glucose values are predicted to be above 180 mg/dL, Control-IQ technology uses physician-prescribed insulin correction factors to calculate a correction bolus with a target of 110 mg/dL, and then delivers 60 percent of that value up to once per hour during daytime hours as needed (up to 12 corrections boluses per day). Control-IQ technology also offers optional settings for sleep and exercise that will change the treatment values to attempt to match physiologic needs that these activities sometimes demand.

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. Pre-pivotal clinical trials have shown that the iLet bionic pancreas shows promise for achieving tighter glucose control while reducing burden on user, when compared with conventional care. Based on past clinical data, we hypothesize that automated insulin and glucagon administration by the iLet bionic pancreas has the potential to materially reduce the burden associated with day-to-day management of T1D and improve clinical outcomes relative to conventional therapies. We plan on conducting pivotal trials in 2020 and 2021 to further test this hypothesis.

E. More about the iLet bionic pancreas

The iLet bionic pancreas is designed to provide a simple-to-use solution for people with T1D that comprehensively manages glycemia across a broad range of individual needs and a large spectrum of circumstances and challenges. Pre-pivotal clinical trial testing of the bionic pancreas have shown significant improvement in glycemic control, as well as fewer hypoglycemic and hyperglycemic events when compared to Standard of Care (SoC). The main takeaways from the iLet bionic pancreas pre-pivotal studies and the iLet bionic pancreas design are summarized below:

- ***Tested under real world living conditions***. The bionic pancreas has been tested under real world living conditions and without restrictions on exercise or other activities.

- ***Wide-ranging age spectrum and insulin needs***. In clinical trials, the bionic pancreas has demonstrated an ability to cope with a wide range of insulin needs across a wide age spectrum (ages 6 to 76).

- ***One device, multiple configurations***. It can be configured in the insulin-only, glucagon-only, or bi-hormonal configurations. While the data from the insulin system are impressive, the bihormonal configuration of our iLet bionic pancreas 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 and further reduce hypoglycemia.

- ***Autonomous***. The iLet bionic pancreas is designed to be completely autonomous in determining all dosing and deliveries of insulin and/or glucagon.

- ***Adaptive***. The iLet bionic pancreas autonomously adapts in real-time to changes in an individual's basal metabolic insulin needs, and hormonal changes whether they are acute (e.g., hormonal fluctuations, illness, physical activity, or emotional state) or gradual (e.g., those that occur during puberty or menopause).

- ***Initialized with body weight; no manual settings***. The iLet bionic pancreas is initialized with a user's body mass and then comes online immediately, with no "run-in" period where physicians have to adjust insulin dosing settings. Users are completely spared from having to determine, set and adjust their "basal-rate profiles," "correction factors," and "insulin-to-carbohydrate ratios".

- ***Interoperable with multiple iCGMs***. The device is designed to be interoperable with third-party iCGM devices and has been tested with Dexcom iCGM.

- ***Compatible with multiple medicaments***. The iLet bionic pancreas is designed to be compatible with NovoLog™, Fiasp™, Humalog™, and/or with a pumpable glucagon and has been tested with Zealand's dasiglucagon candidate.

- ***Data show comparable total daily insulin use; more efficient dosing***. Published clinical trials data demonstrate that iLet users do not use any more insulin than those under usual care, while dramatically improving mean glycemia and reducing incidence of hypoglycemia.

- ***Controls to reduce insulin stacking and overdosing***. The iLet bionic pancreas uses sophisticated controls to reduce the chances of stacking or overdosing insulin.

- ***Capable of making dosing decisions while CGM is offline***. The iLet bionic can continues 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.

- ***Intuitive UI with minimal user "touches"***. The iLet bionic pancreas features an intuitive user interface with a touchscreen that requires minimal user touches as most decisions are made autonomously.

- ***Meals without carb-counting***. The iLet bionic pancreas recommends, but does not require, that users announce meals containing carbohydrates. Meal announcements

do not require the user to count carbohydrate. Instead, users are asked to categorize the amount of carbohydrates in their meal into one of three general "buckets". From there, the adaptive meal dose controller makes automatic adjustments based on dosing history for similar past meal announcements, customizing all dosing to the individual.

- ***Adjustable glucose targets***. The iLet bionic pancreas 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.

- ***Glucagon instead of empty calories***. In the bihormonal configuration, the bionic pancreas is designed to allows the user to trigger a glucagon microburst to raise blood glucose (without having to ingest empty calories) prior to temporarily disconnecting from the iLet for activities such as swimming, white-water rafting, etc.

- ***Tested in C-Peptide negative and positive subjects***. The iLet bionic pancreas has been tested in C-peptide-negative as well as C-peptide-positive subjects in the outpatient setting.

We believe that the iLet bionic pancreas 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 look forward to further testing the iLet bionic pancreas in 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.

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 bionic pancreas.

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 bionic pancreas 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 bionic pancreas. 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 bionic pancreas development and manufacturing processes that remains a trade secret. We currently have confidentiality and non-disclosure agreements with all of our employees, consultants, vendors, board members, 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, certification as a B 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 technology integrated into the iLet bionic pancreas in pre-pivotal 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. **Pre-pivotal** clinical trial data (summarized in more detail in section I below), have shown significant improvement in glycemic control, as well as fewer hypoglycemic and hyperglycemic events when compared to Standard of Care (SoC).

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 bionic pancreas. 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 estimate that the bionic pancreas is capable of achieving a mean 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.

In 2015, our clinical collaborators at Stanford and MGH conducted the first two home-use studies testing the insulin-only configuration of the iPhone-based bionic pancreas system in 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 estimate 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. By comparison with clinical results testing the bihormonal configuration of the iPhone-based bionic pancreas, we estimate that system would achieve an HbA1c of ~ 6.5 ± 0.4%. Based on these results, and results of the Diabetes Control and Complications Trial (DCCT) or the 1980's and early 90's, such glycemic control would like substantially reduce, and possibly eradicate, all long-term complications that are directly attributable to T1D.

Ed Damiano's academic team at BU also tested an early prototype of our fully-integrated iLet bionic pancreas in diabetic swine. Notably, results of the swine study showed no difference in the performance of the iPhone-based bionic pancreas platform relative to the early iLet prototype.

Despite challenging real-world conditions, and with no restrictions on diet, exercise or other activity, previous generations of the 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 or clearance in any jurisdiction.

I. Published clinical data related to the bionic pancreas technology integrated into the iLet bionic pancreas

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

- The Lancet, 2017:
    - 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, as well as 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 over several 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 easing the psychological burdens of managing T1D.

All prior published clinical data are 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/ clearance to commercially distribute 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 mid-2020. Separately, we aim to continue working with our clinical teams to initiate our Bihormonal Bionic Pancreas Pivotal Trial near the close of 2020.[2]

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 bionic pancreas. All 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, 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 bionic pancreas 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 bionic pancreas in controlling glycemia in the bihormonal configuration, to evaluate the behavioral and psychosocial impact of the bihormonal configuration of the iLet bionic pancreas 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 a number of factors, including but not limited to, securing FDA and institutional review board (IRB) approvals to conduct these trials, manufacturing sufficient product and maintaining necessary funding to support the trials.

K. Manufacturing of the iLet bionic pancreas

Through December 31, 2018, we did not have our own manufacturing facilities adequate to manufacture the iLet bionic pancreas in-house. Instead, we relied on an ISO 13485 certified third-party contract manufacturing facilities to build iLet bionic pancreas units for testing. Similarly, infusion sets used with the iLet bionic pancreas have been manufactured by a third-party facility that is fully compliant with relevant manufacturing protocols and standards.

In early 2019, we achieved ISO 13486:2016 certification through a notified body, allowing us to move forward towards being able to manufacture certain devices and components in-house. Our plan is to manufacture and assemble the iLet bionic pancreas and parts of its associated disposables at our facility in Southern California. Manufacturing facility space and associated clean room

[2] This timeline estimates and statements in this report are made as of December 31, 2019. Timelines have not been reassessed and no statements are being made with respect to the COVID-19 global pandemic, which will likely affect timelines estimated as of December 31, 2019.

space has been secured and appropriately validated. We have a partnership with ConvaTec, Inc. for manufacture of infusions sets compatible with the iLet bionic pancreas.

L. Sales and marketing

After regulatory clearance approval we plan to start with a focused launch in key markets nationwide, initially focused on gaining experience with payers and supporting early commercialization efforts. As we gain commercial experience and expand our operational capacity, 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 expand outwards to other health-care markets, including Europe, the Middle East, Asia, South America and Africa.

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 and Concord, Massachusetts.

Q. Government grants

On September 14, 2018, we were awarded a SBIR grant from the National Institute of Diabetes and Digestive and Kidney Diseases ("NIDDK") of the National Institutes of Health ("NIH") in connection with building a commercially scalable bionic pancreas for automated diabetes management. Funding of $424,973 for the approved Phase I stage of the grant provided support for establishing and implementing the final design and use requirements of the iLet bionic

pancreas. Phase II was awarded on September 19, 2019. Supported activities will include R&D activities centered around designing, testing, implementing, and optimizing automation equipment within the Beta Bionics manufacturing facility. Phase II funding of $1,598,025 was approved by the NIDDK.

On March 22, 2019, we were awarded and STTR contract from the Department of Defense in connection with building an autonomous glycemic control system for hyperglycemia of critical illness. Funding of $224,995.60 was approved for the Phase I stage of the contract award.

NUMBER OF CURRENT EMPLOYEES

As of December 31, 2019, we employed 39 people. Additionally, we engage a number of independent contractors to perform various services. Contractors we employ include clinical consultants, 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 bionic pancreas.

We rely on licenses from the Trustees of Boston University to use the various technologies that are material to operation of the iLet bionic pancreas. 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 bionic pancreas. 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, directors, 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 do not have exclusive rights to intellectual property we develop under U.S. federally funded research grants and contracts, including with DARPA and DOD, and we could ultimately share or lose the rights we do have under certain circumstances.

Some of our intellectual property rights have been or may be developed in the course of research funded by the U.S. government, including under our agreements with the Defense Advanced Research Project Agency ("DARPA"), and the Department of Defense ("DOD"). As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future products pursuant to the Bayh-Dole Act of 1980. Government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us, or an assignee or exclusive licensee to such inventions, to grant licenses to any of these inventions to a third party if they determine that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; (iii) government action is necessary to meet requirements for public use under federal regulations; or (iv) the right to use or sell such inventions is exclusively licensed to an entity within the U.S. and substantially manufactured outside the U.S. without the U.S. government's prior approval. Additionally, we may be restricted from granting exclusive licenses for the right to use or sell our inventions created pursuant to such agreements unless the licensee agrees to additional restrictions (e.g., manufacturing substantially all of the invention in the U.S.). The U.S. government also has the right to take title to these inventions if we fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. In addition, the U.S. government may acquire title in any country in which a patent application is not filed within specified time limits. Additionally, certain inventions are subject to transfer restrictions during the term of these agreements and for a time-frame thereafter, including sales of products or components, transfers to foreign subsidiaries for the purpose of the relevant agreements, and transfers to certain foreign third parties. If any of our intellectual property becomes subject to any of the rights or remedies available to the U.S. government or third parties pursuant to the Bayh-Dole Act of 1980, this could impair the value of our intellectual property and could adversely affect our business.

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 are unable to advance our current or future product candidates into and through clinical trials, obtain marketing approval and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.

Our product candidate in still in clinical development and as such will require extensive preclinical and clinical testing. We cannot predict with any certainty if or when we might submit a premarket approval, or PMA, to the U.S. Food and Drug Administration, or FDA, or whether any such PMA will be accepted for review by the FDA.

Our ability to generate product revenues, which we do not expect to occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Before we are able to generate any revenues from product sales, our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts. The success of our current and future product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- successful enrollment and completion of clinical trials;

- successful data from our clinical program that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- scale-up of our manufacturing processes and formulation of our product candidates for later stages of development and commercialization;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- successfully launching commercial sales of our product candidates, if and when approved;
- acceptance of the product candidate's benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- the prevalence and severity of adverse events experienced with our product candidates;
- maintaining a continued acceptable safety profile of the product candidates following approval;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and
- qualifying for, maintaining, enforcing and defending intellectual property rights and claims.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business.

The regulatory approval processes of the FDA, the European Medicines Agency (EMA) and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval from the FDA, the EMA and other comparable international regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our current or future product candidates will ever obtain regulatory approval.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, the EMA or other comparable international regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or other comparable foreign regulatory authorities that a product candidate is safe, pure and potent or effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or other comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or preclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a PMA to the FDA, or similar foreign submission to the EMA or other comparable foreign regulatory authority, to obtain approval in the United States, the European Union or elsewhere;
- the FDA, the European Medicines Agency (EMA) or other comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third‑party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, the EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy review process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval/clearance to market any product candidate we develop, which would significantly harm our business, results of operations and prospects.

We have conducted, and intend to conduct, clinical trials of certain of our product candidates outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of this data is subject to certain conditions imposed by the FDA, including compliance with all applicable U.S. laws and regulations. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practice, or GCP, including review and approval by an independent ethics committee and informed consent from subjects. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. There can be no assurance the FDA will accept data from trials conducted outside of the United States.

The FDA, the EMA and other comparable foreign regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other comparable foreign regulatory authorities.

Even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of any of our product candidates, which would prevent or delay regulatory clearance and commercialization.

Clinical trials that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of our ongoing or future clinical trials are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be delayed in obtaining marketing approval, if at all.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue from future drug sales and regulatory and commercialization milestones. Clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates, if approved, or allow our competitors to bring comparable products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business, financial condition, results of operations and prospects.

Even if the trials are successfully completed, clinical data are often susceptible to varying interpretations and analyses, and we cannot guarantee that the FDA, the EMA, or other comparable international regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. We cannot guarantee that the FDA, the EMA or other comparable international regulatory authorities will view our product candidates as having efficacy even if positive results are observed in our planned clinical trials. To the extent that the results of the trials are not satisfactory to the FDA, the EMA or other comparable international regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

Results of past studies and trials of our product candidates may not be predictive of future trial results.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Even if we are able to commence clinical trials, issues may arise that could suspend or terminate such clinical trials. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in clinical trials, even after positive results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or efficacy observations made in clinical trials, including previously unreported adverse events. Notwithstanding any potential promising results in earlier studies and trials, we cannot be certain that we will not face similar setbacks. In addition, the results of our preclinical animal studies, including our oncology mouse studies and animal studies, may not be predictive of the results of outcomes in human clinical trials. For example, our oncology product candidates that are in preclinical development may demonstrate different chemical and biological properties in patients than they do in laboratory animal studies or may interact with human biological systems in unforeseen or harmful ways.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before the manufacturing and infusion of our product candidates or trial completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates or similar areas, and this competition will

reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion or commencement of these trials and adversely affect our ability to advance the development of our product candidates.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a drug candidate, our business may suffer.

Our projections of both the number of people who have the T1D. These estimates have been derived from a variety of sources, including scientific literature, commissioned reports, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Further, new therapies may change the estimated incidence or prevalence of T1D. The number of patients may turn out to be lower than expected.

Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community.

A pandemic, epidemic or outbreak of an infectious disease in the United States or Europe may adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States, Europe or worldwide, our business may be adversely affected. In December 2019, a novel strain of coronavirus, COVID-19, was identified in Wuhan, China. This virus continues to spread globally and, as of March 2020, has spread to over 70 countries, including the United States, and was declared a pandemic by the World Health Organization in March 2020. The spread of COVID-19 has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities, regulatory reviews and our supply chain. For example, the COVID-19 outbreak may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our

clinical trials, any of which could materially affect our business, financial condition and results of operations. The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. A significant outbreak of coronavirus and other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

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 clearance for our product, such product, along with the manufacturing processes, post-clearance 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 clear our products; withdrawal of the product from the market; withdrawal of clearance 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 clearance of a product is granted, the clearance 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 bionic pancreas, 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 clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act or clearance via the 510(k) with special controls mechanism of the FDA for the various components of the iLet bionic pancreas.

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 premarket approval (PMA) process.

The FDA can delay, limit or deny clearance 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 our application; or the failure of our manufacturing process or facilities to meet applicable requirements.

In addition, the FDA may change its clearance or 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 clearance for our product, or our failure to maintain clearance 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 clearance, and the suspension or withdrawal of existing clearance 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 a new regulatory clearance, or to cease marketing or recall the modified product until clearance is obtained.

If we are not able to avail ourselves of the 510(k) with special controls FDA process, or if the 510(k) with special controls process is modified or extinguished, we will likely need to comply

with the PMA process. If we were to modify our product after a 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 clearance or approvals are necessary. If we determine that a modification is unnecessary, and the FDA disagrees with our determination and requires us to submit a PMA for modifications to our previously-cleared product, we may be required to cease marketing or to recall the modified product until we obtain PMA 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 cleared product, either by imposing stricter requirements as to when to initiate a new PMA submission for a modification to a previously cleared product, or by imposing more strenuous review criteria to such submissions.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, undertaking preclinical studies and clinical trials of product candidates, securing related intellectual property rights and conducting discovery, research and development activities for our programs. We intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other biotechnology, medical device and pharmaceutical companies to recruit, hire, train and retain marketing and sales personnel. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. In addition, there can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

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 various global 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 international 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 country's regulatory authority does not ensure approval by regulatory authorities in other countries or by the FDA. We have not taken any actions to obtain regulatory approvals outside the US. 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.

Even if we achieve regulatory clearance, our public benefit corporate structure re-prioritizes 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 long-term financial benefit to our investors.

Assuming we can obtain regulatory clearance and raise enough capital to launch the iLet bionic pancreas, our projected revenues in a rapidly evolving payer market are uncertain.

Our projections of the revenues from sales of iLet bionic pancreas and related consumables, and the costs to achieve such sales, may prove grossly inaccurate. The earliest that we expect to generate revenue is in 2021 which we expect to come from sales of iLet bionic pancreas 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. In 2016, at least one payer 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. 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 2018, the Company entered into a multi-year master lease agreement for its Irvine, California facility, secured by a personal guarantee by Toby Milgrome and Ed Damiano. In 2019, the Company entered into a multi-year lease agreement for an office lease for a facility in Concord, Massachusetts.

Aside from 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 $137,400,000 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	Series A Preferred Stock	$5,000,000 for 5% of our outstanding shares	General business operations and further iLet bionic pancreas development

	under Securities Act §4(2)			
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 bionic pancreas development
Various investors through Wefunder (September 8, 2016)	Regulation Crowdfunding. Exempt from registration under Securities Act §4(a)(6)	Class C Common Stock	$969,100 for .7% of our outstanding shares	General business operations and further iLet bionic pancreas development
Various accredited investors (first closing was Dec. 20, 2017 and final closing was December 31, 2018)	Private offering exempt from registration under Securities Act §4(2)	Series B Preferred Stock	$63,052,909 for 30.43% of our outstanding shares	General business operations and further iLet bionic pancreas development
Various accredited investors (June 30, 2019)	Private offering exempt from registration under Securities Act §4(2)	Series B-2 Preferred Stock	$63,360,000 for 17.72% of our outstanding shares	General business operations and further iLet bionic pancreas bionic pancreas development

TRANSACTIONS WITH RELATED PARTIES

Prior to our formation, we incurred certain startup expenses. Related parties (all directors, officers, and stockholders owning 5% or more of our outstanding shares) 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 bionic pancreas, our bionic pancreas, which has not yet achieved and may never achieve regulatory approval. As a result, our only revenues through 2019 have been from collaborations with other companies which pay us under development and/or clinical supply contracts. In future periods, and prior to approval of the iLet bionic pancreas (which is not guaranteed to ever occur), we may recognize revenues from sales of iLet bionic pancreas and related components to other companies or institutions for use in research, including clinical trials. From our inception to December 31, 2019,

we focused on design, development, engineering and clinical testing of the iLet bionic pancreas, preparing to manufacture the iLet bionic pancreas and related components, developing strategic partnerships, and building corporate infrastructure to support existing and planned operations.

B. Summary Financial Information

At or For the Year Ended December 31,	2017 (audited)	2018 (audited)	2019 (unaudited)
Total Assets	$3,390,000	$50,902,000	$108,079,000
Cash & Cash Equivalents	2,460,000	48,755,000	103,226,000
Account Receivable	-	-	492,000
Current Liabilities/ Short-Term Debt	1,437,000	1,410,000	2,331,000
Long-term Debt	-	-	-
Revenues/Sales	80,000	1,928,000	854,000
Cost of Goods Sold	-	-	-
Net Income (Loss)	$(8,562,000)	$(5,216,000)	$(13,932,000)

Statement Regarding Unaudited Financial Information. The 2019 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 2019 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, 2019, we have accumulated total net losses of $32,052,126. 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 2020 and beyond as we hire additional employees and contractors, incur costs associated with building the iLet bionic pancreas, conduct additional clinical trials, pursue regulatory approval of the iLet bionic pancreas in the U.S. and elsewhere, and prepare for the commercial launch of the iLet bionic pancreas, if regulatory approvals are received. Since our revenues are limited until we receive regulatory approval to commence commercial iLet bionic pancreas 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, 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, 2019, we raised total gross proceeds of approximately $137,400,000 through issuances of equity securities.

As of December 31, 2019, our working capital was $102,800,000 representing primarily cash of $103,200,000 and current liabilities of $2,300,000.

Additionally, we will need to raise significant amounts of capital or other funds to meet requirements beyond 2020 including for pivotal trials, pursuit of regulatory approvals of the iLet bionic pancreas, and for commercialization if the iLet bionic pancreas 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 such as certificates of deposit through FDIC Certificate of Deposit Account Registry Service. We do not enter into investments for trading or speculative purposes.

REGULATORY INFORMATION

We have not previously failed to comply with the requirements of Regulation Crowdfunding.

OTHER MATERIAL INFORMATION

On or about October 18, 2018, Kirk Ramey, a former research scientist in Ed Damiano's lab at Boston University, filed a Complaint against the Company, Ed Damiano, Firas El-Khatib and Boston University ("BU") (collectively, "Defendants" captioned *Kirk Ramey v. Beta Bionics, Inc., Trustees of Boston University (A/K/A Boston University), Edward Damiano, Firas El-Khatib, Case No. 18-3240*, in the Commonwealth of Massachusetts, Superior Court Department of the Trial Court. On September 9, 2019, Plaintiff filed an Amended Complaint. The original Complaint and the Amended Complaint collectively are referred to as the "Action". In the Amended Complaint, Mr. Ramey alleges that while working on the bionic pancreas project at Boston University he was promised a 5% equity stake in the commercialization of the bionic pancreas. Mr. Ramey also asserts 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. The Amended Complaint brought by Mr. Ramey seeks to redress alleged violations of M.G.L. c. 93A, breach of contract, breach of the implied covenant of good faith and fair dealing, intentional or fraudulent misrepresentation, negligent misrepresentation, promissory estoppel, breach of fiduciary duty and unjust enrichment. Mr. Ramey seeks actual damages, consequential damages,

compensatory damages, exemplary damages, punitive damages, double or treble damages and attorneys' fees and costs.

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 has engaged counsel from Seyfarth Shaw to represent it and its named officers in the Action. The Company is committed to vigorously defend itself and its officers and employees in the litigation, however, even if we ultimately prevail, the Action could burden us with substantial unanticipated costs. In addition, the Action could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other Company business.