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:
11 Hughes
Irvine, CA 92618

www.betabionics.com

This Annual Report is dated April 30, 2021

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, 2020. 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, 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

[1] Throughout this report, Beta Bionics, Inc. is referred to as "the Company", "we," "us," or "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 March 31, 2021, are identified in the following tables.

Directors	Principal Occupation	Main Employer(s)	Year Joined as Director
Edward R. Damiano	Founder, Chief Executive Officer and President	Beta Bionics, Inc.	2015
Jeffrey Hitchcock	President, Children with Diabetes	Children With Diabetes	2016
Finny Kuruvilla	Chief Investment Officer	Eventide Asset Management LLC	2018

Directors	Principal Occupation	Main Employer(s)	Year Joined as Director
Martha G. Aronson	Board Director	Conmed Corporation (NYSE: CNMD); and Cardiovascular Systems Inc. (NASDAQ: CSII)	2020
Sean D. Carney	Investor/Consultant	Hillhouse Capital; Care Capital	2020
Beth A. Brooke	Board Director	eHealth, Inc.	2020

Officers

Name	Principal Occupation	Start date	Term of Office
Edward R. Damiano	Founder; President and Chief Executive Officer	January 1, 2016	Indefinite
Gilbert Clarke	Chief Financial Officer	April 29, 2019	Indefinite
Veena Rao	Interim Chief Commercial Officer	February 2021	Indefinite
Michael Rosinko	Chief Technology Officer	August 2020	Indefinite
Marcie Cain	Chief People Officer	March 2021	Indefinite

Non-Employee Directors

Jeffrey Hitchcock

Jeffrey Hitchcock has served as a member of our board of directors since 2016. Mr. Hitchcock is currently also the Founder and President of Children with Diabetes, a 501(c)(3) organization, a position he has held since 2013. Mr. Hitchcock received a B.S. in Computational Mathematics from Marquette University.

Finny Kuruvilla, MD, PhD

Finny Kuruvilla has served as a member of our board of directors since October 2018. Dr. Kuruvilla is the Chief Investment Officer for Eventide Funds, the Lead Portfolio Manager for

the Eventide Gilead Fund, and a Portfolio Manager for the Eventide Healthcare & Life Sciences Fund, positions he has held since 2007. From 2008 through 2016, he was a Principal at Clarus Ventures, LLC, a healthcare and life sciences venture capital firm. Dr. Kuruvilla was a research fellow at the Broad Institute of Harvard University and at the Massachusetts Institute of Technology, or MIT, and a clinical fellow at the Harvard Medical School Fellowship Program in Transfusion Medicine. 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 M.D. from Harvard Medical School, a PhD in Chemistry and Chemical Biology from Harvard University, an MS in Electrical Engineering and Computer Science from MIT, an AM from Harvard University in Chemistry and Chemical Biology and a BS in Chemistry from the California Institute of Technology.

Martha G. Aronson, MBA

Martha G. Aronson has served as a member of our board of directors since February 2020 and as our chair since February 2021. She currently serves as Lead Independent Director of Conmed Corporation and serves on the board of Cardiovascular Systems Inc. Her previous board roles include Hutchinson Technology, Methode Electronics and Clinical Innovations. She was the Executive Vice President and President, Global Healthcare at Ecolab from 2012 – 2016. Prior to that, Ms. Aronson served as senior vice president and president, North America, at Hill-Rom Holdings. From 1991 to 2009, Ms. Aronson held a variety of general management and executive roles of increasing responsibility at Medtronic, Inc., both domestically and internationally. Ms. Aronson received a BA in Economics from Wellesley College, and an MBA from Harvard Business School.

Sean D. Carney, MBA

Sean D. Carney has served as a member of our board of directors since February 2020. Mr. Carney currently serves as a consultant with Hillhouse Capital and with Care Capital and is on the board of several privately held companies. From 1996 to 2016, Mr. Carney was a Managing Director at Warburg Pincus LLC, a private equity firm. He has served on numerous public and private company boards, including Bausch + Lomb, DexCom, Inc. and the Wright Medical Group N.V. Mr. Carney received an AB in Economics from Harvard College and an MBA from Harvard Business School.

Beth A. Brooke

Beth A. Brooke has served as a member of our board of directors since December 2020. From 2014 through her retirement in June 2019, Ms. Brooke served as the Global Vice Chair, Public Policy, at Ernst & Young LLP. Prior to that, she served as the Global and Americas Vice Chair, Public Policy, Sustainability and Stakeholder Engagement of Ernst & Young LLP from 1995. Ms. Brooke served in the U.S. Department of Treasury during the Clinton Administration from 1993 to 1995. From 1981 to 1993, Ms. Brooke was an audit and tax partner at Ernst & Young LLP. Ms. Brooke has served as a director of eHealth, Inc. since August 2019. Ms. Brooke received a BS from Purdue University and is a certified public accountant..

Officers

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

Ed Damiano is our co-Founder and has served as our President and Chief Executive Officer and as a member of our board of directors since October 2015. From 1997 to 2004, Dr. Damiano was an Assistant Professor of Mechanical Engineering at the University of Illinois at Urbana-Champaign and in 2004 he became an Associate Professor of Biomedical Engineering at Boston University. In 2015, he was promoted to Professor of Biomedical Engineering at Boston University. Dr. Damiano received his Ph.D. degree in Applied Mechanics from Rensselaer Polytechnic Institute, his MS degree in Mechanical Engineering from Washington University in St. Louis, and his BS degree in Biomedical Engineering from Rensselaer Polytechnic Institute.

Gilbert Clarke, MBA, Chief Financial Officer; Treasurer

Gibb Clarke has served as our Chief Financial Officer and Treasurer since April 2019. Mr. Clarke previously served as our Chief Operating Officer and Vice President, Finance from January 2016 to April 2019. From 2011 to 2014, Mr. Clarke served as the Chief Executive Officer of Blockade Medical LLC before serving as the Chief Executive Officer of Three Rivers Medical, Inc. from 2015 to 2019. Mr. Clarke received an MBA from Duke University and a BA from University of Colorado, Boulder.

Veena Rao, PhD, MBA, Interim Chief Commercial Officer

Veena Rao has served as our Interim Chief Commercial Officer since February 2021. She previously served as our Vice President of Business Development from October 2020 to February 2021. Prior to joining us, Dr. Rao served as the Vice President, Life Sciences Alliances at Tempus Labs, Inc. from April 2020 to October 2020. From April 2007 to April 2020, Dr. Rao served in various roles at Eli Lilly and Company, ending her tenure as Vice President, External Innovation, Partnerships and Strategy. She received an MBA from the University of Virginia Darden School, an MS and a PhD, each in Chemical Engineering from Stanford University, and a B.S. in Chemical Engineering from the University of Minnesota.

Marcie Cain, Chief People Officer

Marcie Cain has served as our Chief People Officer since March 2021. She previously served as the Senior Vice President, Head of US Human Resources for MorphoSys from July 2019 to March 2021. Prior to that, Ms. Cain was the Vice President, Head of Human Resources for Boston Heart Diagnostics and the Vice President, Global Head of Human Resources for HeartWare from August 2011 to October 2015. From 2001 to 2011, Marcie served in various HR leadership roles at Genzyme Corporation, ending her tenure as Vice President of Human Resources. She received a Bachelor's Degree in Business and Economics from Washington State University.

Michael Rosinko, MS, MBA, Chief Technology Officer

Mike Roskino has served as our Chief Technology Officer since August 2020. From 2017 to 2020, Mr. Rosinko served as our Vice President of Research and Development. From 2008 to 2016, he was Vice President of Research and Development at Tandem Diabetes Care, Inc. Prior to that, Mr. Rosinko has also worked for Biosense Webster, Inc., Baxter International Inc. and the Aubrey Group, Inc. Mr. Rosinko received an MBA degree from Claremont

Graduate University, an MS in Electrical Engineering from the University of Southern California, and a BS in Electrical Engineering from the University of Pittsburgh.

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 • 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 anti-dilution protection
Common Stock				
Class A	1,000,000	600,000	Ten votes per share	None
Class B	2,000,000	356,813	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	467,530 Class B Common Stock issuable upon exercise of stock options (Employee Incentive Option Pool) 57,470 Class B Common Stock available for future issuance (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.

On December 14, 2020, 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 525,000.

Principal Security Holders

The following table lists as of December 31, 2020, 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	82.52%

The above calculation is based on the number of shares of voting securities owned as of December 31, 2020. Each share of Class A Common Stock has 10 votes per share. Class B Common Stock has one vote 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 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 one individual. 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

Overview

We are a medical device company focused on the design, development and commercialization of an innovative solution for people with diabetes on intensive insulin therapy. Our investigational device, which we refer to as our iLet bionic pancreas, is designed to leverage continuous, subcutaneous, insulin-pump technology and adaptive control algorithms, together with continuous glucose monitoring, to autonomously compute and administer all doses of insulin, glucagon, or both, to mimic the body's natural ability to maintain a tight glycemic range. The iLet's design features a simple user interface that only requires the input of a user's body weight to initialize dosing. The iLet's simple user interface, together with its automated, adaptive control algorithms, has the potential to reduce many of the cumbersome tasks of diabetes management and decrease the cognitive and emotional burden of living with diabetes. We believe our iLet system has the potential to transform diabetes care and result in better glycemic control for a greater variety of people than currently available therapies, and thereby enable democratization of good glycemic control and associated beneficial health outcomes across a broad demographic.

The safety and effectiveness of our iLet system in its insulin-only configuration is currently being evaluated in a pivotal trial involving 440 participants with type 1 diabetes ages six and older. We are also planning to commence a pivotal clinical trial in participants with type 1 diabetes for the dual-hormone, or bihormonal configuration of our iLet bionic pancreas which, in addition to insulin, delivers glucagon to reduce or prevent hypoglycemic, or low blood sugar, episodes. Our iLet system has been designated a breakthrough device by the FDA, a designation which is intended to help patients receive more timely access to breakthrough technologies, and provides us the benefit of priority review and interactive communication with the FDA throughout the regulatory review process. If cleared, we expect our iLet system may be the first system capable of making autonomous therapeutic decisions for people living with type 1 diabetes.

Our company was founded by parents whose lives and whose children's lives have been deeply impacted by type 1 diabetes. Our mission is to help improve health outcomes and the quality of life of people living with diabetes and to bring our technology to as many people as possible. As a demonstration of our long-term commitment to this mission, we organized our company as a public benefit corporation and secured status as a Certified B Corp, which requires us to meet the high standards of verified social and environmental performance, public transparency, and legal accountability to balance profit and purpose. We believe we are the first medical device company focused on diabetes to have status as both a public benefit corporation and a Certified B Corp. We utilize this distinction to drive and motivate us to achieve our mission of improving health outcomes and the quality of life for those on intensive insulin therapy and to bring our technology to as many people living with diabetes as possible.

Public Benefit Corporation

Our leadership team strives to be ever mindful that we were founded by parents deeply affected by type 1 diabetes to help not only their own children, but all children and adults struggling to live with insulin dependent diabetes and the loved ones who support them. To this end, we were formed on October 21, 2015 as a Massachusetts public benefit corporation as a demonstration of our long-term commitment to our mission to benefit the community of people living with insulin-dependent diabetes and other conditions of glycemic dysregulation.

Market

Diabetes is a group of diseases characterized by a sustained and prolonged elevated blood glucose level, or hyperglycemia, that results from the body's inability either to produce insulin or properly utilize it. It is a chronic, life-threatening disease for which there is no known cure. The disease can give rise to a host of serious and often life-threatening complications, including cardiovascular disease, neuropathy, nephropathy, retinopathy, cognitive impairment and stroke. The daily management and long-term effects of diabetes are a tremendous burden to people with diabetes and their caregivers. We estimate in 2020, there were approximately 27 million people in the United States who had been diagnosed with diabetes, representing approximately 8% of the U.S. population. In addition to the clinical burden of diabetes, the financial burden of diabetes is substantial; the cost of diabetes to the U.S. healthcare system is estimated to be over $320 billion. The two most prevalent forms of diabetes are referred to as type 1 diabetes and type 2 diabetes.

Type 1 diabetes is an autoimmune disorder that usually develops during childhood or adolescence and is characterized by the inability of the body to produce insulin, resulting from the destruction of insulin-producing beta cells in the pancreas. Insulin is the hormone that plays a critical role in glucose metabolism by enabling the cellular uptake of glucose from the bloodstream for conversion into energy. Those with type 1 diabetes must administer insulin on a regular basis to survive, both to enable basic metabolic function, and to take up carbohydrates from the blood for fuel. People with type 1 diabetes also lose the function of glucagon, the hormone that counteracts insulin by releasing glucose from the liver in order to raise blood-sugar levels. We estimate there were approximately 1.8 million people with type 1 diabetes in the United States in 2020.

In contrast, type 2 diabetes is a progressive metabolic disorder that generally develops in adults and initially results from the inability of cells to respond appropriately to insulin, a condition

known as insulin resistance. Although the exact cause of type 2 diabetes is unknown, it is believed that a range of genetics, heredity and environmental factors such as obesity and physical inactivity are contributing factors. Type 2 diabetes generally develops more slowly than type 1 diabetes, usually over a period of years, and symptoms can appear gradually. The disease course is primarily characterized by a decline in beta cell function and worsening of insulin resistance. The disease is initially treated with diet and nutrition management along with exercise and oral medications. However, as the disease progresses, some people ultimately require intensive insulin therapy through multiple daily insulin injections or insulin pump therapy. We estimate there were a total of 25 million people in the United States who were diagnosed with type 2 diabetes in 2020, of which approximately 4.6 million people were on some form of insulin therapy. Of this number, an estimated 1.7 million managed their diabetes with intensive insulin therapy.

Collectively, the addressable U.S. market for people with diabetes on intensive insulin therapy is approximately 3.5 million people between type 1 and type 2 diabetes. Our focus initially will be on the type 1 population but over time, we expect to also focus on people with type 2 diabetes who are on intensive insulin therapy. As the U.S. population continues to age, the total prevalence of people with diabetes is expected to continue to increase, with the number of people with type 1 diabetes expected to grow in line with the general population growth rate. The prevalence of people with type 2 diabetes is expected to grow at a faster rate than the general population due to factors such as obesity, lack of exercise and the progressive nature of the disease.

Current treatment options

There are two primary means for insulin delivery: insulin injections by syringes or pens and insulin infusion by pumps, both of which are designed to supplement or replace the insulin-producing function of the pancreas.

Multiple Daily Injections—Multiple daily injections, or MDI, is the most widely used type of intensive insulin therapy in the United States and most other countries. MDI requires the use of syringes or insulin pens to make subcutaneous injections of insulin at least three times per day. MDI consists of the injection of long-acting basal insulin one to two times per day, as well as injecting rapid-acting mealtime insulin. Historically, MDI therapy has been the standard of care for insulin intensive therapy. We estimate that approximately 2.8 million people in the United States with diabetes are MDI users, consisting of approximately 1.2 million people, or 65% of people with type 1 diabetes, and approximately 1.6 million people with type 2 diabetes. We believe one of the main reasons that such a large population continues to use MDI as a therapy is due to the lack of access to specialists, specifically endocrinologists, who are more likely to prescribe and are more comfortable with insulin pump therapy.

While MDI requires less training and has a lower cost than insulin pumps, it presents a number of drawbacks that we believe make it a suboptimal option for people with diabetes. In addition to requiring multiple daily injections, MDI requires the user to self-calculate doses and therefore results in greater variability in blood glucose levels or less accurate glycemic control than pump therapy. MDI can also lead to hypoglycemia if dosing errors are made. Further, MDI therapy is typically perceived as less convenient for people with diabetes due to the need for the user to find a clean, discrete place to inject insulin if the individual is not comfortable injecting in front of others. Lastly, MDI may not be advisable for those who are not confident in their ability to adjust

and calculate appropriate insulin doses, such as children, older people or those who may find the decisions about dosing difficult to manage on a daily basis.

Insulin Pumps—Insulin pumps, first introduced over thirty years ago, perform continuous subcutaneous insulin infusion and typically involve the use of a tethered programmable pump that administers insulin through an infusion set into a person's body. Insulin pump therapy uses only rapid-acting insulin to fulfill both mealtime and basal insulin requirements.

Current pump technology allows a person to customize their bolus and basal insulin doses to meet their insulin needs throughout the day and is intended to more closely mimic the physiologic function of a healthy pancreas than MDI therapy. It offers a number of advantages relative to MDI therapy including the elimination of multiple daily insulin injections and more precise insulin administration, enabling greater control of, and reduced variability in, blood glucose levels while also providing significantly greater flexibility regarding meals, exercise and daily schedule. Recent advancements in insulin pumps include the ability to receive CGM data directly from a wearable CGM sensor. A further advancement is the introduction of hybrid closed loop systems which incorporate algorithms that modulate physician-recommended or prescribed basal/bolus pump settings to adjust the pump's insulin delivery within algorithm limitations.

The iLet bionic pancreas

We have designed the iLet bionic to meet the clear need for a simplified therapy that fits easily into the daily lives of people on intensive insulin therapy and significantly reduces the daily burden of the disorder on people with diabetes, their caregivers and healthcare providers. With a trim profile and a size equivalent to that of a credit card, this compact wearable device allows for discrete positioning on the body, usually on the waist. It is designed to be simple to use and operate in an autonomous closed-loop manner, thereby reducing the need for ongoing physician intervention or user input and monitoring in order to operate effectively. We believe that the bihormonal configuration of the iLet system is the only diabetes pump currently in development that is designed to mimic the function of the pancreas by its ability to supply both insulin and glucagon. The central elements of the iLet bionic pancreas design are summarized below:

- ***One Device with Multiple Configurations to Address a Range of Needs***. Our iLet system is designed to be able to be configured as an insulin-only or a dual-hormone presentation. The bihormonal iLet configuration is designed to allow the user to trigger a glucagon microburst to raise blood glucose without having to ingest empty calories prior to temporarily disconnecting for certain physical activities such as swimming. Small doses of glucagon can be given to counter the effects of excess insulin that has already been delivered and cannot be withdrawn, and can prevent hypoglycemic events that could not be prevented by suspending insulin delivery alone. This allows the system to require less involvement of the user and provides the user with much greater scheduling flexibility and spontaneity. If we successfully complete the pivotal trial for our iLet system in the insulin-only configuration, we intend to subsequently commence a pivotal trial for the bihormonal configuration.

- ***Proprietary Algorithms Refined Over a Decade of Research and Development***. The centerpiece of our technology is a suite of mathematical dosing algorithmic insulin

controllers working together to autonomously determine and dose insulin according to user needs.

Our model-predictive control, or MPC, algorithms base insulin doses on the glucose data and insulin absorption kinetics. We incorporate insulin pharmacokinetics into the MPC algorithm by augmenting it with a mathematical formulation for estimating the concentration of insulin in the blood and predicting its future concentration. Our algorithm takes into consideration the slow absorption rate of insulin analogs and is designed to help prevent the iLet system from delivering excess insulin. Furthermore, our MPC algorithm automatically adjusts its insulin-dosing aggressiveness in real time to accommodate the different insulin needs between individuals and the variable needs within the same person.

Running in parallel with our MPC algorithm is another algorithm that automatically modulates basal insulin delivery over multiple time scales, and an additional algorithm that automatically adapts insulin doses in response to meal announcements. Unlike current insulin pumps, and all of the insulin-only control algorithms of which we are aware, our adaptive basal insulin algorithm obviates the need for the user to set, or even know, his or her basal-rate profile.

In its bihormonal configuration, our system also includes a proportional-derivative algorithm governing micro-doses of glucagon to help prevent impending hypoglycemia. Glucagon dosing is based on the glucose level and rate of descent. It can occur preemptively even if glucose is above the target range and it includes a feedback term to account for the pending effects of recent glucagon doses. The amount of glucagon dosed also feeds back on the insulin controller, so that large amounts of glucagon dosing decrease the aggressiveness of insulin delivery.

Taken together, these mathematical algorithms provide a universal framework for a glycemic control strategy that requires no quantitative input from the user other than a body weight entry to initialize the system. Our algorithms are also intended to mitigate the tendency of people on intensive insulin therapy to intentionally dose rapid-acting insulin at close intervals, a practice known as insulin stacking, resulting in hypoglycemia.

- ***System Designed for Autonomy***. The iLet system is designed to be autonomous in determining all dosing and delivery parameters for both insulin and glucagon. Users are not required to obtain physician assistance to adjust the iLet nor are they required to count carbohydrates or set insulin delivery rates. The system recommends, but does not require, that a user announce the consumption of carbohydrates and only asks the user to provide a qualitative estimate of carbohydrate intake by selecting from three generalized levels: usual, more or less. From there the iLet makes automatic adjustments based on the user's dosing history for similar past meal announcements, thereby customizing all dosing to the individual. In the absence of meal announcements, the iLet system is designed to autonomously regulate the user's blood glucose. The iLet is also designed to automatically adapt to, and compensate

for, changes in a users' basal insulin requirements in real time due to acute hormonal fluctuations caused by illness, physical activity or emotional state or more gradual shifts related to physiological changes such as puberty or menopause.

In addition, we believe that the iLet, if cleared, will be the first device capable of making dosing decisions in situations where the iCGM is offline. During such periods, the iLet continues to autonomously manage insulin and glucagon administration either by (i) invoking the latest high-resolution basal rate profile it had converged upon using the most recent iCGM data; (ii) responding to meal prompts the same way as when the iCGM is online; or (iii) intuitively compensating for user-entered blood glucose values by delivering a correcting dose of insulin or glucagon based on the system's calculation of current user need.

Dosing flexibility is further enabled by the iLet's adjustable glucose target that allows the user to set a permanent glucose target as well as schedule recurring adjustments to targeted glucose levels to accommodate a user's immediate need. It also provides a daily readout with updated estimates of daily basal insulin, prandial insulin and correction doses to provide a recommendation of these quantities for both MDI and pump users, if, for any reason, the iLet may be temporarily unavailable to the user.

- ***Designed for Broad Compatibility and Interoperability with Third-Party iCGM Devices and Drug Providers***. We have designed the iLet technology to be compatible with multiple, commonly dosed analog insulins, including fast-acting NovoLog and ultra-fast-acting Fiasp from Novo Nordisk, and with Humalog from Eli Lilly. We intend to initially seek clearance for use with the DexCom G6 iCGM, and plan to expand the compatibility of the iLet with other cleared iCGM models. We believe that engineering our iLet bionic pancreas specifically to be compatible with multiple vendors' iCGM technologies and insulin analogs will benefit the diabetes community by enhancing access to the iLet system with fewer technology preferences or insurance restrictions.

  We are also actively advancing the incorporation of glucagon into the iLet system. A challenge to the use of exogenous glucagon has been the absence of an approved form of glucagon that can remain stable near body temperature for a period of several days in a pump reservoir. Zealand Pharma, is developing an investigational water-soluble glucagon analog, called dasiglucagon, that is designed to meet this requirement for which Zealand plans to submit a New Drug Application for FDA approval. We intend to enter into a development agreement with Zealand Pharma to initiate a pivotal clinical trial of our iLet system using dasiglucagon. This trial is intended to simultaneously serve as the pivotal trial to support the bihormonal configuration of our iLet bionic pancreas system and the Phase 3 trial to support Zealand Pharma's submission of their New Drug Application to the FDA for approval of dasiglucagon for use in our iLet system.

  We believe that the iLet bionic pancreas is a technology that could change the way in which type 1 diabetes is managed and the effectiveness with which care can be

delivered. If our iLet is system is cleared for the treatment of people with type 1 diabetes, we then intend to pursue development of the insulin-only configuration of our iLet system in people living with type 2 diabetes who require intensive insulin therapy. Over time, we may also seek future clearances for the use of our iLet system in the treatment of a number of related conditions including gestational diabetes, monogenic diabetes, cystic fibrosis-related diabetes, congenital hyperinsulinism, insulinoma syndrome, post-bariatric surgery patients and metabolic syndrome.

Licenses, patents and proprietary rights

In December 2015, we and the Trustees of Boston University, or BU, entered into a device license agreement, or the Device License Agreement, and a control algorithm agreement, or the Control Algorithm Agreement. Under these license agreements, we received a worldwide license (with the right to sublicense) to make, use, sell and import products, and practice processes, covered by certain patent rights related to the hardware and control algorithms used in the iLet system and its predecessor devices. The Device License Agreement and Control Algorithm Agreement are exclusive, subject to certain reserved rights, including BU's right to practice and/or use the patent rights for non-profit purposes such as sponsored research and collaborations, government rights and other third-party rights. Furthermore, at BU's request, we will be required to negotiate a sublicense to either agreement, in good faith, with a third party if we are unable or unwilling to use the technology granted under the Device License Agreement or Control Algorithm Agreement, as applicable, to address the unmet needs of neglected people or geographic areas that such party is willing and able to address.

Pursuant to the license agreements, we agreed to use commercially reasonable efforts to market the iLet system in the United States and elsewhere in the world. Additionally, we are obligated to meet certain milestones under the each of the agreements. To date, we have satisfied all the milestones set forth under the agreement, and the remaining milestones are submitting premarket notifications to the FDA for clearance by December 2021 and receiving regulatory clearance of the iLet system by June 2022. BU was also granted certain anti-dilution rights, which have been satisfied and extinguished.

Pursuant to the license agreements, we issued 44,940 shares of our Class B common stock to BU and 390 shares of our Class B common stock to the University of Illinois Board of Trustees. Furthermore, we are required to pay aggregate quarterly royalties of a mid single-digit percentage based on net sales (and royalties in the range of 15 to 25% of net sales by sublicensees), which royalties are creditable against the minimum royalty amount and agreed to make a lump sum payment in the range of 15 to 25% of the sublicensing revenue received by us.

Pivotal iLet clinical trials

Ongoing Pivotal Trial of Our Insulin-Only iLet Configuration

Our iLet insulin-only configuration is currently in a 13-week pivotal randomized controlled trial to evaluate its use in people with type 1 diabetes ages six and older. This multicenter trial, involving 16 clinical sites located across the United States is being conducted in association with the National Institute of Diabetes and Digestive and Kidney Diseases, or NIDDK, part of the

National Institutes of Health, or NIH. The NIH is also providing partial financial support for the trials through a grant to Boston University. Trial enrollment is intended to involve a diverse population of people living with type 1 diabetes with a third or more of trial participants having an HbA1c level of 8% of more, a third or more of trial participants on MDI therapy, and a third or more of trial participants being 50 years old or older. The Jaeb Center for Health Research Foundation, or the Jaeb Center, is acting as sponsor and is also the contract research organization conducting the trial. Steven Russell, M.D., who is affiliated with the Massachusetts General Hospital, is the principal investigator on this trial.

This pivotal trial is designed to evaluate the safety and effectiveness of our iLet system in its insulin-only configuration. 440 participants have been screened in this pivotal trial with participants being randomized, to either a 330-participant cohort using the iLet system for 13 weeks or a 110-participant cohort using usual care for 13 weeks. The primary endpoint for the trial is superiority of the iLet insulin-only configuration over usual care as measured by HbA1c values after 13 weeks of treatment. A key secondary endpoint being evaluated is the non-inferiority of the iLet as compared to usual care in the percent of time spent in clinically significant hypoglycemia, defined as CGM glucose levels below 54 mg/dl, during the 13-week trial period. Other secondary endpoints to be evaluated include superiority over usual care as measured by mean CGM glucose levels and time in target range (70-180 mg/dl).

Planned Pivotal Trial of Our Bihormonal iLet Configuration

Previous trials for the bihormonal configuration of our iLet system were conducted pursuant to a development agreement with Zealand. We expect to enter into another development agreement with Zealand Pharma to commence a 52-week pivotal randomized controlled trial to assess the safety and effectiveness of the bihormonal configuration of the iLet with dasiglucagon. The trial will include a six-month randomized controlled trial period followed by an additional six-month chronic exposure testing period. For this trial we expect to screen and enroll over 700 participants with type 1 diabetes. Trial participants will be divided into three cohorts, a cohort on usual care, a cohort using the insulin-only configuration of the iLet, and a cohort using the bihormonal configuration of the iLet. This trial will simultaneously serve as the pivotal trial to support the bihormonal configuration of the iLet as well as the Phase 3 trial to support Zealand Pharma's submission to FDA of dasiglucagon for use in the iLet. We expect to be the sponsor of this trial and the Jaeb Center is expected to be the contract research organization for the trial. Steven Russell, M.D., who is affiliated with MGH, will be the principal investigator on this trial. Based on the clinical results of this trial, we expect to be able to file 510(k) premarket notifications with the FDA for clearance of the bihormonal configuration of the iLet.

Manufacturing, suppliers and quality assurance

We currently manufacture our iLet system and its accompanying ready-to-fill insulin cartridges at our facilities located in Irvine, California. Our iLet system and our ready-to fill-insulin cartridges are manufactured with certain components supplied by outside vendors and other components that we manufacture internally. We then assemble, test and package the finished iLet systems in-house. We also have agreements with Unomedical, an affiliate of ConvaTec, for the production of the infusion sets and with Maxon Motors for the pump motors used in our iLet system.

Our Myford building in Irvine, California, is a 15,000 square foot facility that includes warehouse, production and office space and has been in operation since 2018. In 2020, we occupied and set up production at our leased Hughes building also located in Irvine, California. This is a 50,000 square foot facility, which includes 11,500 square feet of warehouse and production space. Our iLet system is assembled via manual and semi-automated equipment and our cartridge production and packaging utilizes industry standard automation. We expect our maximal annual manufacturing capacity at the Hughes building will be sufficient to support our anticipated demand for the foreseeable future. However, we may need to add supplemental warehousing space as volumes increase.

By assembling and testing our subassemblies and products, we believe that we can maintain better quality control, ensure compliance with applicable regulatory standards and our internal specifications, limit outside access to our proprietary technology, ensure adequate product supply and make design modifications in a timely manner. We have constructed custom-designed manufacturing and processing equipment and have developed enhancements for existing production machinery.

In the current generation of the iLet system, we have experienced manufacturing defects, such as improper programming of batteries, which resulted in reduced battery life, and Bluetooth connectivity issues between our iLet system and its accompanying iCGM, which could affect the functionality and safety of the iLet system. To remediate these issues, we improved the steps and handling related to programming the batteries and made modifications to boost the Bluetooth signal.

We are subject to and maintain compliance with ISO manufacturing standards including ISO 13485 certification, as well as current good manufacturing practices, or cGMP, compliance and adhere to the applicable Quality System Regulation requirements.

Our manufacturing operations are led by a team whose members have extensive experience in the commercial manufacture of medical devices including other technological advances in diabetes treatment.

Our commercialization strategy

We envision promoting sales of our iLet bionic pancreas through both a direct sales organization and distributors. We intend to focus the initial direct sales efforts on territories in the United States with high volume endocrinology practices and areas with anticipated favorable market access before expanding our efforts to primary care physicians. We believe that initially starting with a focus on these providers will help ensure that specialist clinicians will gain experience with the iLet so that they can become advocates of our solution. We intend to optimize the efforts of our sales team with an internal customer sales and support team. Their responsibilities will include following up on leads generated through promotional activities, differentiating the benefits of our products and technologies, and advising existing users regarding the conversion process. We will also plan to support our sales organization with strategic marketing and practice development initiatives and to launch with an omnichannel marketing approach to supplement the efforts of our field staff.

We have begun to construct our sales and marketing organization in anticipation of a potential launch of our iLet bionic pancreas. To date we have filled a number of key sales and marketing management positions. If our iLet system is cleared, we expect to commence product sales and then expand the number of sales territories covered by our direct sales organization after commercial launch. To accommodate this expansion, we expect to add additional personnel to our sales and marketing organization.

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.

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.

Future products/indications for use

After we introduce our iLet system to people with type 1 diabetes, if cleared or approved, we intend to pursue expanded use of our iLet system by people living with type 2 diabetes who require intensive insulin therapy. Over time, we may also seek future clearances for the use of our iLet system in the treatment of a number of related conditions including gestational diabetes, monogenic diabetes, cystic fibrosis-related diabetes, congenital hyperinsulinism, insulinoma syndrome, post-bariatric surgery patients and metabolic syndrome.

Facilities

Our main facilities are located in Irvine, California, where we lease approximately 50,000 square feet of office, laboratory and manufacturing space. We lease an additional 15,000 square foot facility in Irvine, California, that includes warehouse, production and office space. We also lease corporate offices in Concord, Massachusetts that consist of approximately 13,000 square feet of office space. The leases for our office, laboratory and manufacturing spaces in Irvine, California expire in March 2023, the lease for our second, smaller facility in Irvine, California expires in May 2027, and the lease for our Concord, Massachusetts office expires in May 2026. We believe that our facilities are adequate for our current needs and that suitable additional or substitute space would be available if needed.

Government grants

From time to time, the Company has entered into arrangements with government agencies for the purposes of obtaining funding for qualifying research and development activities. The Company recognizes payments earned under contracts with government agencies as a reduction of research and development expenses as the related qualifying expenses being funded are incurred. For

qualifying equipment purchases, the payments earned are recorded as a reduction of the carrying amount of the asset. Government grants recognized in advance of the receipt of funding are recorded as grants receivable, which is a component of prepaid expenses and other current assets.

During the year ended December 31, 2019, the Company recognized reductions of research and development expenses of $0.8 million in the statement of operations and comprehensive loss and did not record any reductions for qualifying equipment purchases. During the year ended December 31, 2020, the Company recognized reductions of research and development expenses of $0.7 million in the statement of operations and comprehensive loss and reductions of the carrying amount of qualifying equipment purchases of $0.5 million.

NUMBER OF CURRENT EMPLOYEES

As of February 12, 2021, we employed 84 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

We have incurred significant net losses since inception and expect to incur significant additional losses for the foreseeable future. We have no products that have generated any commercial revenue and we may never achieve or maintain profitability.

We have incurred significant net losses since our inception in 2015. Our net losses for the years ended December 31, 2019 and 2020 were $14.7 million and $29.6 million, respectively. As of December 31, 2020, we had an accumulated deficit of $66.0 million. The vast majority of our net losses resulted from expenses related to research and development and general administrative expenses. Our expenses have included, but are not limited to, employee-related expenses, consulting services, contract services, pre-commercialization activities and manufacturing costs associated with the development of our investigational device, which we refer to as the iLet bionic pancreas.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- continue our research and development efforts, and complete the ongoing and planned clinical trials related to and apply for clearances from the U.S. Food and Drug Administration, or FDA, under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or FDCA, for our iLet system in its insulin-only and bihormonal configurations, in each case for the treatment of type 1 diabetes;

- conduct additional clinical trials of the iLet system for future indications;

- add operational, financial and management information systems and personnel, including personnel to support the development of our iLet system;

- hire and retain additional personnel, such as clinical, quality control, scientific, commercial and administrative personnel;

- seek marketing authorizations from the FDA for our iLet system in any configuration for the treatment of type 1 diabetes or future indications;

- develop and expand a sales, marketing and distribution infrastructure and scale up manufacturing capabilities, whether alone or with third parties, to commercialize the iLet system if cleared or approved;

- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed products; and

- expand, maintain and protect our intellectual property portfolio.

We have no products approved for commercial sale, have not generated any revenue from commercial sales of our iLet system, and are devoting substantially all of our financial resources and efforts to research and development of our iLet system for the treatment of type 1 diabetes, in both its insulin-only and bihormonal configurations. Because of the numerous risks and uncertainties associated with medical device product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing our iLet system, in any configuration, for one or more indications, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory clearances or approvals for, and market additional indications and configurations. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

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

Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.

In our financial statements for the year ended December 31, 2020, we concluded that our recurring losses from operations and need for additional financing to fund future operations raise substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2020 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional funding. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to raise capital when needed or on acceptable terms, we would be forced to significantly delay, scale back

or discontinue the development or commercialization of our iLet system or other research and development initiatives, or may be forced to reduce or terminate our operations. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or a part of their investment. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.

We are substantially dependent on the success of our iLet system for the treatment of type 1 diabetes, which is in clinical development. If we are unable to obtain regulatory clearance or approval for, and successfully commercialize our iLet system, our business may be materially harmed.

We only have one investigational device, the iLet system, which is in clinical development in its insulin-only and bihormonal configurations for the treatment of type 1 diabetes. Our business primarily depends on the successful clinical development, regulatory clearance or approval, and commercialization of the iLet system. We currently have no products cleared for sale and may never be able to develop marketable products. Our iLet system will require additional clinical development, testing and regulatory clearance or approval before we are permitted to commercialize it in any configuration for type 1 diabetes or any future indication. The future regulatory and commercial success of our iLet system is subject to a number of risks, including the following:

- successful completion of planned and future clinical trials, including the ongoing pivotal trial for the iLet in its insulin-only configuration and planned pivotal trial for its bihormonal configuration;

- sufficiency of our financial and other resources to complete the necessary clinical trials and regulatory activities;

- successful patient enrollment in clinical trials;

- successful data from our clinical program that supports an acceptable risk-benefit profile of the iLet in the intended populations;

- whether we are required by the FDA to conduct additional clinical trials or to modify the design of current or planned trials to support the approval of the iLet;

- receipt and maintenance of marketing authorizations from applicable regulatory authorities;

- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our iLet system;

- making arrangements with third-party manufacturers for components of our iLet system;

• scaling up our manufacturing capabilities, for both clinical and commercial supplies of our investigational devices;

• entry into collaborations to further the development of our iLet's system's capabilities;

• developing and expanding sales, marketing and distribution capabilities and launching commercial sales of the iLet system, when and if cleared or approved, whether alone or in collaboration with others;

• successfully launching commercial sales of the iLet system, if and when cleared or approved;

• acceptance of the iLet system, if and when cleared or approved, by people with diabetes, the medical community and third-party payors;

• maintaining a continued acceptable safety profile following clearance or approval;

• maintaining regulatory compliance if the iLet system is cleared or approved;

• effectively competing with other treatment options for type 1 diabetes and the availability, perceived advantages, relative cost, relative safety and relative effectiveness of alternative and competing treatments;

• the emergence of competing technologies and other adverse market developments, and our need to enhance the iLet system and/or develop new products to maintain market share in response to such competing technologies or market developments; and

• enforcing and defending intellectual property rights and claims.

Many of these risks are beyond our control, including the risks related to clinical development, the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborator. If we are unable to develop, receive regulatory clearance or approval for, or successfully commercialize our iLet system for the treatment of type 1 diabetes, or if we experience delays as a result of any of these risks or otherwise, our business could be materially harmed.

Furthermore, even if we do receive regulatory clearance or approval for our iLet for any type 1 diabetes, any such clearance or approval may be subject to limitations on the patient populations for which we may market the product. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we cannot assure you that we will successfully develop or commercialize our iLet system in any configuration for the treatment of type 1 diabetes or any future indication we may pursue. If we are unable to develop, or obtain regulatory clearance or approval for, or, if cleared or approved, successfully commercialize the iLet system for the treatment of type 1 diabetes, we may not be able to generate sufficient revenue to continue our business.

We are subject to extensive regulation by the FDA, which could delay the development, review and marketing authorization of our iLet system and could cause us to incur significant costs.

We are developing a medical device that is subject to extensive regulation by the FDA. These regulations relate to testing, manufacturing, labeling, sale, promotion, distribution and shipping. Before we can market or sell a new product regulated as a medical device in the United States, we must obtain marketing authorization under one of the three following regulatory pathways: (i) Section 510(k) of the FDC Act (ii) a premarket approval application, or PMA, or (iii) de novo classification of our product. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data are sometimes required to support substantial equivalence. In the second pathway, the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, preclinical study, clinical trial, manufacturing and labeling data. The PMA process is typically required for products that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, and is significantly more involved than the 510(k) process. The third pathway is called de novo classification, which is generally used for low- to moderate-risk products that have not previously been classified by the FDA and therefore no predicate device is available. Devices not previously classified by the FDA are automatically placed into Class III; through the de novo process a manufacturer may request reclassification as a Class I or II device. If the FDA agrees to reclassify the device, it will then clear the device through the de novo process, and future devices of a similar nature may use the device cleared through the de novo process as a predicate device for a 510(k) submission. We currently intend to pursue the 510(k) pathway for the iLet system. However, the FDA may ultimately disagree that the 510(k) pathway is appropriate for the insulin-only and/or the bihormonal configurations of the iLet system for the treatment of type 1 diabetes, or any other indications we may pursue, and may require us to obtain a PMA. In particular, there are currently no approved pump therapies that utilize both insulin and glucagon to treat type 1 diabetes. As such it is difficult to accurately predict the developmental and regulatory challenges we may incur for our iLet system in its bihormonal configuration as it proceeds into a pivotal trial. FDA also may disagree that certain features we plan to incorporate in the iLet system have appropriate predicate devices that would allow us to utilize the 510(k) pathway, and we may have to initially pursue a 510(k) for the iLet without these features or seek a de novo classification or PMA. Obtaining a PMA is generally more costly and uncertain than the 510(k) clearance process or the de novo classification process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained, if ever. Additionally, even if FDA agrees that the 510(k) pathway is appropriate for the iLet system, different components of the system will require individual 510(k)s. The timing for FDA's review of individual components may vary, and we will not be able to market the iLet until each component is cleared.

The FDA's review of any of our 510(k)s could be delayed due to the FDA devoting resources to products that are intended to address the COVID-19 pandemic. We expect that our iLet system will be reviewed by the FDA's Center for Devices and Radiological Health's Office of In Vitro Diagnostics and Radiological Health, which is also responsible for reviewing tests for COVID-19. That office has stated that it has begun putting non-COVID submissions on hold, and those submissions not on hold, in most cases, will move forward more slowly. Although the office has stated that it is meeting its timelines for initial breakthrough device designation review, the office indicated on January 3, 2021, that it may not be able to meet other review and feedback goals for devices that have received breakthrough device designation, such as the iLet system. We cannot

be certain whether or for how long any such delays will persist or whether the FDA will be able to meet review timelines for breakthrough devices.

Additionally, we could encounter delays or difficulties if the FDA determines that our financial relationships with our principal investigators resulted in a perceived or actual conflict of interest that may have affected the interpretation of a study, the integrity of the data generated at a particular clinical trial site or the utility of the clinical trial itself. Principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash compensation and/or stock options in connection with such services. If these relationships and any related compensation to or ownership interest by the clinical investigator carrying out the study result in perceived or actual conflicts of interest, or if the FDA concludes that the financial relationship may have affected interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of our marketing application by the FDA. Any such delay or rejection could prevent us from commercializing any of our products in development.

Use of our iLet system may cause adverse events or present other safety concerns that could halt its clinical development, prevent, delay, or cause the withdrawal of its regulatory clearance or approval, limit its commercial potential, or result in significant negative consequences, including death. If any configuration of our iLet system receives regulatory clearance or approval for an indication and we, or others, later discover that it is less effective than previously believed or has the potential for safety issues that were not previously identified, our ability to market the iLet system could be compromised.

The use of our iLet system could be associated with adverse events or serious adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Unacceptable safety concerns caused by our iLet system could cause us or regulatory authorities to interrupt, delay, or halt clinical trials.

Adverse events or safety concerns during clinical development could affect patient recruitment or the ability of enrolled participants to complete the trial, or could result in potential product liability claims. We may experience safety issues during our clinical trials that are not a result of the iLet system but may cause negative public perception or may cause an investigation by the FDA. In the insulin-only pivotal trial of the iLet, we have experienced device related adverse events from infusion set failures leading to hyperglycemia and ketosis, and hyperglycemia related to user error with the infusion set. There has been one serious adverse event, or SAE, of severe diabetic ketoacidosis in one study participant who had been randomized into the iLet study arm in the ongoing pivotal trial of our iLet system in its insulin-only configuration. The participant had been observed to have high blood glucose (>400 mg/dL) for several hours and large amounts of ketones. The participant was advised by study staff to disconnect the iLet, administer insulin by syringe, switch to her non-study pump and immediately go to the emergency room. The participant did not switch to her non-study pump and did not go to the emergency room. She was later found nonresponsive when emergency medical services were called to her home when she was unreachable for follow-up. The participant is currently in a rehabilitation facility. Based on our subsequent analysis of the iLet's dosing history logs and sensor data, we believe the cause of the SAE was a significant kink in the infusion set's Teflon cannula, which is a well understood product

complication in Teflon infusion sets. We continue to evaluate the cause of this SAE, and our ultimate determination of whether the event was related to the iLet system may change, or the FDA may disagree with the determination we or the sponsor of the trial have made. As a result of this event, the sponsor paused randomization of additional participants in the trial and submitted an Investigational Device Exemption supplement to the FDA containing proposed protocol changes in response to this incident. The FDA subsequently approved the supplement and permitted the trial to resume randomization. We cannot assure that future instances of kinked cannulas or other safety concerns may not result in SAEs that could be interpreted to be related to the safety of our iLet system. In addition, these adverse events may not be appropriately or timely recognized or managed by the treating medical staff, particularly outside of the research institutions that collaborate with us. Inadequate training in recognizing or managing the adverse events of our iLet system could result in adverse events to patients, including death. Any of these occurrences may materially and adversely harm our business, financial condition, results of operations and prospects.

If our iLet system receives regulatory clearance or approval for the treatment of type 1 diabetes or any other indication and we, or others, discover safety concerns that were not previously identified, a number of potentially significant negative consequences could result, including:

- regulatory authorities may seek to reclassify a cleared 510(k) device thus triggering the need for a PMA, withdraw approvals, seize the product, or seek an injunction against its manufacture or distribution;

- we, or any future collaborators, may be required to recall the product, change the way such product is administered to patients or conduct additional clinical trials;

- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;

- regulatory authorities may require additional warnings on the label, such as a “black box” warning or impose distribution or use restrictions;

- we, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;

- we, or any future collaborators, could be sued and held liable for harm caused to patients;

- the product may become less competitive; and

- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of our iLet system, in its insulin-only or bihormonal configuration, for the treatment of type 1 diabetes or any other indication, which would significantly harm our business, results of operations and prospects, and could adversely impact our financial condition, results of operations or the market price of our common shares.

We are developing our iLet system in combination with other therapies and devices, which exposes us to additional risks.

The approval and commercialization of our iLet system in its bihormonal configuration requires FDA approval of Zealand Pharma A/S's, or Zealand's, dasiglucagon for the chronic use setting of our iLet system. Our planned pivotal trial for the bihormonal configuration of our iLet system will utilize Zealand's dasiglucagon, which trial would also serve as a Phase 3 trial supporting Zealand's application New Drug Application for approval of dasiglucagon in our iLet system. Even if the FDA clears our iLet system in the bihormonal configuration based on the results of the bihormonal pivotal trial, we would not be able to commercialize the bihormonal configuration until dasiglucagon, or another glucagon which has conducted clinical trials with our iLet system, is approved for use in that configuration, as there are currently no approved glucagon analogues with the ability to remain stable near body temperature for a period of several days in a pump reservoir, as required by our iLet system. Zealand has also announced that it submitted an application for FDA approval of dasiglucagon for use in a rescue pen for treatment of severe hypoglycemia. In the event the FDA rejects, delays or significantly conditions the approval of dasiglucagon for use in this setting, our development plans for our iLet system in its bihormonal configuration may be materially adversely affected. In addition, even if the FDA approves dasiglucagon for use in a rescue-pen setting, the FDA may not approve dasiglucagon for use in the chronic use setting of our iLet system, or it may subject such approval to delays or conditions that would materially impair our ability to successfully develop our iLet system in its bihormonal configuration. Zealand is also currently conducting independent trials for use of dasiglucagon for the treatment of other indications, and in the future, Zealand may conduct independent trials for use of dasiglucagon for the treatment of type 1 diabetes or other indications. Zealand has reported that an ongoing trial of dasiglucagon in another indication did not meet its primary endpoint. To the extent its other ongoing or any future trials result in negative clinical data, it could negatively impact our clinical development, commercialization efforts, if the iLet is cleared, and public perception about the iLet in its bihormonal configuration.

We have designed our iLet system to be compatible with multiple, commonly dosed analog insulins, including fast-acting NovoLog and ultra-fast-acting Fiasp from Novo Nordisk A/S, or Novo Nordisk, and with Humalog from Eli Lilly and Company, or Eli Lilly. If our iLet system, in its insulin-only or bihormonal configuration, were to receive marketing authorization or be commercialized for use in combination with these other therapies, including dasiglucagon if approved, we would continue to be subject to the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with our iLet system or that safety, effectiveness, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

Similarly, we will initially seek clearance for use with any approved iCGM models that are compatible with our iLet system. Currently, the only iCGM model that is compatible with our iLet system is DexCom, Inc.'s, or DexCom's, G6 device. Although we are actively working to expand the compatibility of our iLet system with other iCGM models, there is no assurance we will be successful in our efforts. This exposes us to similar risk in the event the DexCom G6, or any other approved iCGM device that may be compatible with our iLet system in the future, has its regulatory approval revoked or encounters other difficulties which could negatively affect the

public's perception and use of such product and have a corresponding adverse effect on the use and public perception of the iLet system. Furthermore, our development agreement with DexCom does not require DexCom to indefinitely support compatibility of its older generation iCGMs with our iLet system as it introduces new generations. As such, people with diabetes may be unwilling to buy our iLet system, if approved, or continue to use the iLet system, if they are unwilling or unable to purchase newer generations of DexCom iCGMs as they are developed and commercialized. If such difficulties occur with the DexCom G6 device, or future generations of DexCom iCGMs, at a time when our iLet system is not compatible with any other iCGM devices, or if any such compatible devices are or are perceived to be inferior to the DexCom G6 device, sales of our device would be adversely affected.

We face competition from numerous competitors, most of whom have far greater resources than we have, which may make it more difficult for us to achieve significant market penetration and which may allow them to develop additional products for the treatment of diabetes that compete with our iLet system.

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, or other market activities of industry participants. We compete with a number of companies that manufacture insulin delivery devices, including manufacturers of prefilled insulin syringes and insulin pens, such as Eli Lilly, Novo Nordisk and Sanofi S.A. In the United States, we expect our primary competitors for insulin infusion to be companies that manufacture insulin pumps, including Medtronic, Insulet Corporation and Tandem Diabetes Care. However, the market for insulin pumps is currently undergoing significant changes and it is difficult to predict the potential impact of these changes on our competitive landscape. The t-Slim X2 pump from Tandem Diabetes Care with predictive hyperglycemic and hypoglycemic capabilities was launched in the United States in January 2020. Medtronic's most advanced insulin pump, the model 780G, is a hybrid, closed-loop system with predictive low blood glucose detection and dosing capabilities and has received CE Mark from European regulators. The Insulet Omnipod 5 insulin pump, which is a smartphone-controlled, hybrid, closed-loop system, is expected to be compatible with CGMs offered by both DexCom and Abbott Laboratories. Medtronic's and Insulet's pumps are each in late-stage development.

Our current primary competitors are publicly traded companies that have several competitive advantages over us, including greater financial resources for sales and marketing and product development, established relationships with healthcare providers and third-party payors, and larger and more established distribution networks. Most of these competitors are large, well-capitalized companies with significantly more market share and resources than we have. As a consequence, they are able to spend more aggressively on product development, marketing, sales and other product initiatives than we may be able to. In some instances, our competitors also offer products that include features that our iLet system does not include. For instance, Insulet offers a tubeless insulin delivery system which integrates the pump and infusion set in a single, disposable unit. The introduction by competitors of new products may create market saturation that may make it difficult to differentiate the potential benefits of the iLet system over other products in development or approved products.

In addition, we may face competition from a number of medical device and pharmaceutical companies and academic and government-sponsored medical researchers that are pursuing new

delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and prevention of diabetes.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for the iLet system, if approved. The inability to compete with existing or subsequently introduced devices would have an adverse impact on our business, financial condition and prospects. In addition, the reimbursement structure of approved devices by other companies could impact the anticipated reimbursement structure of the iLet system and our business, financial condition, results of operations and prospects.

We currently have a limited marketing and sales organization and have no experience as an organization in marketing devices. If we are unable to grow our marketing and sales capabilities or enter into agreements with third parties to market and sell devices, if approved for commercial sale, we may not be able to generate product revenue.

We currently have limited sales marketing and distribution capabilities, and we have no experience as an organization in marketing approved medical devices. We intend to substantially grow our in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish commercial-scale sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, if licensed. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our investigational devices ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our investigational devices.

There can be no assurance that we will be able to develop commercial-scale sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas for which we are able to obtain regulatory approval.

We rely and will continue to rely on third parties to conduct clinical trials of our iLet system, which means we do not have full control over the conduct of such trials.

We have relied and will continue to rely on third parties, such as medical institutions, clinical investigators and contract laboratories, to conduct clinical trials of our investigational device, and some of the clinical trials of our iLet system conducted to date have been sponsored by third parties. Our iLet system has been studied in a number of trials sponsored by third parties, such as the pivotal trial for the iLet system in its insulin-only configuration, sponsored by the Jaeb Center for Health Research Foundation, or the Jaeb Center. We have also relied on Massachusetts General Hospital to sponsor earlier trials of our iLet system. Third party-sponsored clinical trials pose similar risks as those set forth elsewhere in this section relating to clinical trials initiated by us. While third-party trials may provide us with clinical data that can inform our future development

strategy, we do not have full control over the protocols, administration, or conduct of the trials. As a result, we are subject to risks associated with the way such trials are conducted and there is no assurance the clinical data from any of third-party clinical trials will be accepted by the FDA or other comparable regulatory authorities to support our submissions for marketing authorization. Third parties sponsoring such clinical trials may not perform their responsibilities for the clinical trials on our anticipated schedule or consistent with clinical trial protocols or applicable regulations. Further, any data integrity issues or patient safety issues arising out of any of these trials would be beyond our control yet could adversely affect our reputation and damage the clinical and commercial prospects for our iLet system. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues, and difficulties or differences in interpreting data. Third parties may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. As a result, our lack of control over the design, conduct and timing of, and communications with the FDA regarding such trials expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the prospects for our iLet system.

We and third-party collaborators, such as the Jaeb Center, are required to comply with all applicable regulations governing clinical research, including good clinical practice, or GCP, regulations. The FDA and similar foreign authorities enforce these regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our third-party collaborators fail to comply with GCP regulations, the clinical trials may be delayed or the data generated in trials may be deemed unreliable and the FDA may require us to perform additional studies before granting us authorization to market, if at all. We cannot be certain that, upon inspection, the FDA and similar foreign regulatory authorities will determine that any of trials of our iLet system comply or complied with applicable regulations, including GCPs. In addition, the FDA may require a large number of test subjects. Our failure or the failure of our third-party contractors to comply with the applicable regulations may require us to repeat studies or trials, which could delay or prevent us from obtaining regulatory clearance or approval. Furthermore, our third-party collaborators may be delayed in conducting trials of our iLet system for reasons outside of their control.

If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to clinical protocols or regulatory requirements or for other reasons, the non-clinical development activities or clinical trials for our iLet system for type 1 diabetes may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, the iLet system or any future investigational devices on a timely basis, if at all, and our business, results of operations, financial condition and growth prospects may be adversely affected.

We are substantially dependent on Zealand for the development and commercialization of our iLet system in its bihormonal configuration. Our current and future collaborators may control aspects of our clinical trials, which could result in delays or other obstacles in the commercialization of the investigational devices we develop. If our collaborations are not successful, we may not be able to capitalize on the market potential of these investigational devices.

Although we have previously entered into development agreements with Zealand for the development and supply of dasiglucagon for use with our bihormonal configuration of the iLet in previous trials, we do not currently have an agreement in place for our planned pivotal trial. As such, we will need to negotiate and enter into a development agreement with Zealand before commencing our pivotal trial for our iLet system in its bihormonal configuration. We may be unable to enter into an agreement with Zealand on commercially reasonable terms in a timely manner, if at all. If we are unable to enter into an agreement with Zealand for our pivotal trial, the development of our bihormonal configuration could be substantially delayed. We will be responsible for obtaining regulatory approval of our iLet system in its bi-hormonal configuration and Zealand will be responsible for obtaining regulatory approval for dasiglucagon.

We have also entered into collaboration agreements with each of Novo Nordisk and Eli Lilly to research and incorporate their respect proprietary insulins in our iLet system. Under these agreements, we have agreed with each of Novo Nordisk and Eli Lilly to work together to support the development of and approval of the iLet system with each of their respective proprietary forms of insulin. As such, the development and commercialization of our iLet system, in both its insulin-only and bihormonal configurations, is dependent upon the cooperation and collaboration of these parties. If either of these parties terminated their agreement with us, we would be required to purchase their approved insulin and fill empty insulin cartridges fitted for the iLet to evaluate their insulin in trials, which would increase our costs and could delay the timing of trials. Although there are other producers of insulin, there is no assurance we could enter into agreements with them on commercially reasonable terms, if at all, and receive regulatory clearance for the use of their insulin in the iLet system.

Our current collaboration agreements pose, and potential future collaborations involving our iLet system may pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our iLet system;

- collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation;

- disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the investigational device, or that result in costly litigation or arbitration that diverts management attention and resources;

- if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and

- collaboration agreements may restrict our right to independently pursue new investigational devices.

As a result, if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to any investigational device we develop could delay the development and commercialization of our investigational devices, which would harm our business prospects, financial condition, and results of operations.

In addition, we rely on infusion sets manufactured by our supplier Unomedical, and we may require cooperation from Unomedical to obtain 510(k) clearance for the particular configuration of the infusion set that is compatible with the iLet. If we are unable to coordinate this regulatory submission with Unomedical, our ability to obtain clearance of the infusion set and, as a result, clearance of the iLet system, may be adversely affected.

We rely on DexCom to provide us with iCGM technology for our iLet system, and the termination of our existing commercial agreement with DexCom would disrupt our ability to commercialize the iLet system or develop future products.

Our iLet system is currently only compatible with DexCom's G6 iCGM. Although we are actively working to expand the compatibility of our iLet system with other iCGM models, there is no assurance we will be successful in our efforts. Our development agreement with DexCom provides us non-exclusive licenses to integrate the currently available generation of DexCom's iCGM technology with our iLet system. Under our current agreement with DexCom, we possess the right to integrate future generations of DexCom iCGM technology with any of our current or future products if agreed to by DexCom in its sole and absolute discretion. Termination of our agreement with DexCom could require us to redesign our iLet system, and attempt to integrate an alternative iCGM system into our iLet system, if we can obtain rights to do so, which could result in an interruption or substantial delay in the development of the iLet system. The termination of our existing agreement with DexCom would disrupt our ability to commercialize the iLet system, if approved, which could have a material adverse impact on our financial condition and results of operations, negatively impact our ability to compete and cause the price of our Class B common stock to decline.

We do not own all of the intellectual property underlying our iLet system and, if either one of our license agreements with the Trustees of Boston University is terminated, we could lose our rights to commercialize our iLet system.

In addition to patent rights that we own, we license certain patents and patent applications from the Trustees of Boston University to make, have made, and use, and eventually to sell and offer to sell, various technologies that are material to the operation of the iLet system. While we are a co-owner of two patent families that we license from the Trustees of Boston University, we do not own the remaining patents and patent applications that underlie the licenses. A first license grants us exclusive worldwide rights to exploit the U.S. and foreign patent rights of five patent families and the copyrights related to software, including the control algorithm run by the iLet system. A second license grants us exclusive worldwide rights to exploit the U.S. and foreign patent rights

of three patent families relating to disposable and nondisposable components of the iLet system, including infusion sets that subcutaneously deliver the glucagon and/or insulin hormones. Our rights to use these technologies and employ the inventions claimed in the licensed patent rights are subject to our abiding by the terms and conditions of the licenses, and meeting certain milestones set forth in the applicable license agreements, and are subject to certain reserved and preexisting rights of governmental and not-for-profit institutions. If we fail to comply with our obligations under these licenses or if the licenses are terminated, we could lose these license rights and other information rights that are important to our business, which would be harmful to our competitive position, business, financial condition, results of operations or prospects. In addition, while we have significant input on and participation in the strategy for the prosecution of the patent rights, the Trustees of Boston University have ultimate contractual control over the prosecution strategies relating to the patent rights subject to these licenses, and there are restrictions on our and the Trustees of Boston University's rights to enforce certain patents against third parties engaged in the exploitation of certain products in certain markets. As a result, we are largely dependent upon the Trustees of Boston University to determine the appropriate strategy for prosecuting the patent rights under the license agreements.

If we obtain FDA clearance or approval of the iLet system or any future products we may develop, we will be subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

Even if we obtain FDA clearance for the iLet system in its insulin-only or bihormonal configuration for the treatment of type 1 diabetes, we may be required to submit a new 510(k) for significant post-market changes or modifications to the iLet system. This process can be expensive and lengthy, and entail significant user fees, unless exempt.

Medical devices may be marketed only for the indications for which they are approved or cleared. We intend to obtain clearance for the management of type 1 diabetes. However, any future clearance or approval we obtain can be revoked if safety or effectiveness problems develop. Further, we may not be able to obtain additional 510(k)s for new products or for modifications to, or additional indications for, the iLet system in a timely fashion or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner which in turn would harm our revenue and future profitability. If cleared or approved, we will also be subject to numerous post-marketing regulatory requirements, which include the Quality System Regulation, or QSR, related to the manufacturing of our products, labeling regulations and the Medical Device Reporting regulation, which will require us to report to the FDA if our products may have caused or contributed to a death or serious injury, or malfunction in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us. If we fail to comply with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by the FDA, which may include any of the following:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future products;

• administrative detention by the FDA of medical devices believed to be adulterated or misbranded;

• operating restrictions, suspension or shutdown of production;

• refusing our requests for clearance or pre-market approval of new products, or new intended uses or modifications to the iLet system;

• suspending or withdrawing clearances or approvals that have already been granted; and

• criminal prosecution.

In addition, if the FDA determined there was a potential safety issue with our future products or products in the same class, the FDA could issue a Safety Communication. The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

INDEBTEDNESS

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 under Securities Act §4(2)	Series A Preferred Stock	$5,000,000 for 5% of our outstanding shares	General business operations and further iLet bionic pancreas development
Novo Nordisk A/S (September 20, 2016)	Private offering exempt from registration under Securities Act §4(2)	Series — A-2 Preferred Stock	$5,000,000 for 4.7% of our outstanding shares	General business operations and further iLet bionic pancreas development
Various investors through Wefunder	Regulation Crowdfunding. Exempt from registration	Class C Common Stock	$969,100 for .7% of our outstanding shares	General business operations and further iLet

(September 8, 2016)	under Securities Act §4(a)(6)			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
July 2019 and September 2020	Private offering exempt from registration under Securities Act §4(2)	Class B Common Stock	$0 for 106,813 of our outstanding shares	Issued as a result of an agreement entered into with two of our investors in exchange for the waiver of certain ongoing anti-dilution rights in connection with our Series B-2 preferred stock financing.

TRANSACTIONS WITH RELATED PARTIES

From time to time, the Company may engage in transactions with a related persons. A "Related Person" is defined as (i) a director or officer of the issuer; (ii) a person who is, as of the most recent practicable date but no earlier than 120 days prior to the date the offering statement or report is filed, the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power; (iii) if we were incorporated or organized within the past three years, any of our promoters; or (iv) a member of the family of any of the foregoing persons, which includes a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, and shall include adoptive relationships. The term "spousal equivalent" means a cohabitant occupying a relationship generally equivalent to that of a spouse.

The Company has not engaged in any transactions with a Related Person since the beginning of our prior fiscal year that involves an amount which exceeds five percent (5%) of the aggregate amount of capital raised by us in the last twelve (12) months in reliance on section 4(a)(6).

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Financial Statements

Our financial statements for the years ending December 31, 2020 and 2019 can be found in Exhibit A to this report.

Overview

We are a medical device focused on the design, development and commercialization of the iLet bionic pancreas, which has not yet achieved and may never achieve regulatory approval. As a result, our only revenues through 2020 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 (which is not guaranteed to ever occur), we may recognize revenues from sales of iLet and related components to other companies or institutions for use in research, including clinical trials. From our inception to December 31, 2020, we focused on design, development, engineering and clinical testing of the iLet, preparing to manufacture the iLet and related components, developing strategic partnerships, and building corporate infrastructure to support existing and planned operations.

Summary Financial Information

At or For the Year Ended December 31,	2019	2020
Total Assets	$108,052,000	$83,527,000
Cash & Cash Equivalents	20,379,000	67,297,000
Account Receivable	492,000	-
Current Liabilities/ Short-Term Debt	2,872,000	5,180,000
Long-term Debt	1,311,000	1,569,000
Revenues/Sales	526,000	672,000
Cost of Goods Sold	-	-
Net Income (Loss)	$(14,658,000)	$(29,593,000)

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. To date, research and development, market development and pre-commercial launch activities have accounted for a significant portion of our overall operating expenses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our iLet system for the treatment of type 1 diabetes, including our planned pivotal trial for our iLet system in its bihormonal configuration. We reported net losses of $14.7 million and $29.6 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an

accumulated deficit of $66.0 million. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

To date, we have funded our operations primarily with proceeds from sales of our equity securities and payments received in connection with collaboration arrangements and government grants. Through December 31, 2020, we had received gross proceeds of $137.4 million from sales of our equity securities and $4.5 million from payments received in connection with collaboration arrangements and government grants. As of December 31, 2020, we had cash, cash equivalents and short-term investments of $77.3 million.

Additionally, we will need to raise significant amounts of capital or other funds to fund our operating expenses and capital expenditure requirements beyond September 30, 2021. 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.

EXHIBIT A

FINANCIAL STATEMENTS

COMPANY CERTIFIED FINANCIALS

I, Edward Damiano, certify that the financial statements of Beta Bionics, Inc. included in this Form are true and complete in all material respects.

/s/ Edward Damiano
Edward Damiano
Beta Bionics, Inc.
Chief Executive Officer

BETA BIONICS, INC.

BALANCE SHEETS
(In thousands, except share amounts)

	December 31, 2019	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 20,379	$ 67,297
Short-term investments	82,848	10,000
Accounts receivable—related party	492	—
Prepaid expenses and other current assets	1,454	1,483
Total current assets	105,173	78,780
Property and equipment, net	2,572	4,086
Restricted cash	100	100
Deferred offering costs	—	190
Other long-term assets	207	371
Total assets	$ 108,052	$ 83,527
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 432	$ 1,316
Accrued expenses and other current liabilities	2,221	3,736
Deferred revenue—related party and deferred revenue	219	128
Total current liabilities	2,872	5,180
Funded R&D liability—related party	1,140	1,140
Deferred revenue—related party and deferred revenue	109	96
Deferred rent	62	333
Total liabilities	4,183	6,749
Commitments and contingencies (Note 13)		
Convertible preferred stock (Series A, A-2, B and B-2), no par value; 970,000 shares authorized at December 31, 2019 and 2020; 915,793 shares issued and outstanding at December 31, 2019 and 2020; liquidation preference of $136,413 at December 31, 2020	138,049	138,049
Stockholders' deficit:		
Class A common stock, no par value; 1,000,000 shares authorized at December 31, 2019 and 2020; 600,000 shares issued and outstanding at December 31, 2019 and 2020	12	12
Class B common stock, no par value; 2,000,000 shares authorized at December 31, 2019 and 2020; 308,920 and 356,813 shares issued and outstanding at December 31, 2019 and 2020, respectively	939	939
Class C common stock, no par value; 500,000 shares authorized at December 31, 2019 and 2020; 9,691 shares issued and outstanding at December 31, 2019 and 2020	950	950
Additional paid-in capital	308	2,810
Accumulated deficit	(36,389)	(65,982)
Total stockholders' deficit	(34,180)	(61,271)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 108,052	$ 83,527

BETA BIONICS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2019	2020
Collaboration revenue	$ —	$ 672
Collaboration revenue—related party	526	—
Total collaboration revenue	526	672
Operating expenses:		
Research and development	9,072	16,930
Sales and marketing	1,736	4,847
General and administrative	5,113	9,433
Total operating expenses	15,921	31,210
Loss from operations	(15,395)	(30,538)
Other income (expense):		
Interest income	737	954
Other income	7	—
Interest and other expense	(7)	(9)
Total other income, net	737	945
Net loss and comprehensive loss	(14,658)	(29,593)
Deemed dividend to Series A and Series A-2 convertible preferred stock	(8,291)	—
Net loss attributable to common stockholders	$ (22,949)	$ (29,593)
Net loss per share attributable to common stockholders, basic and diluted	$ (25.81)	$ (31.43)
Weighted-average common shares outstanding, basic and diluted	889,232	941,642

BETA BIONICS, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2018	519,793	$ 65,071	859,691	$ 1,901	$ 475	$ (19,260)	$ (16,884)
Collection of subscriptions receivable from issuance of Series B preferred stock in prior period	6,499						
Issuance of Series B-2 preferred stock, net of issuance costs of $132	396,000	63,228	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	613	—	613
Extinguishment of Series A and Series A-2 convertible preferred stock:							
Issuance of Class B common stock	—	—	58,920	—	3,212	—	3,212
Contingent commitment to issue Class B common stock	—	—	—	—	1,828	—	1,828
Derecognition of carrying value of Series A and Series A-2 convertible preferred stock	(10,000)						
Recording of fair value of Series A and Series A-2 convertible preferred stock after modification	13,251						
Deemed dividend to Series A and Series A-2 convertible preferred stock	—	—	—	—	(5,820)	(2,471)	(8,291)
Net loss	—	—	—	—	—	(14,658)	(14,658)
Balance at December 31, 2019	915,793	138,049	918,611	1,901	308	(36,389)	(34,180)
Issuance of Class B common stock	—	—	47,893	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,502	—	2,502
Net loss	—	—	—	—	—	(29,593)	(29,593)
Balance at December 31, 2020	915,793	$ 138,049	966,504	$ 1,901	$ 2,810	$ (65,982)	$ (61,271)

BETA BIONICS, INC.

STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2019	2020
Cash flows from operating activities:		
Net loss	$ (14,658)	$ (29,593)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	549	974
Stock-based compensation expense	613	2,502
Loss on disposal of property and equipment	380	2
Changes in operating assets and liabilities:		
Accounts receivable—related party	(492)	492
Prepaid expenses and other current assets	(556)	(29)
Other long-term assets	(12)	(164)
Accounts payable	(353)	639
Accrued expenses and other current liabilities	1,951	1,319
Deferred rent	51	271
Deferred revenue—related party and deferred revenue	(34)	(104)
Net cash used in operating activities	(12,561)	(23,691)
Cash flows from investing activities:		
Proceeds from maturities of short-term investments	20,000	111,848
Purchases of short-term investments	(102,848)	(39,000)
Purchases of property and equipment	(2,440)	(2,189)
Net cash provided by (used in) investing activities	(85,288)	70,659
Cash flows from financing activities:		
Collection of subscriptions receivable from issuance of convertible preferred stock in prior period	6,499	—
Payments of issuance costs of convertible preferred stock issued in prior period	(154)	—
Proceeds from the issuance of convertible preferred stock, net of issuance costs	63,228	—
Payments of offering costs	—	(50)
Net cash provided by (used in) financing activities	69,573	(50)
Net increase (decrease) in cash, cash equivalents and restricted cash	(28,276)	46,918
Cash, cash equivalents and restricted cash at beginning of period	48,755	20,479
Cash, cash equivalents and restricted cash at end of period	$ 20,479	$ 67,397
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 2	$ —
Supplemental disclosure of non-cash investing and financing information:		
Purchases of property and equipment included in accounts payable	$ 7	$ 301
Deemed dividend to Series A and Series A-2 convertible preferred stock	$ 8,291	$ —
Deferred offering costs included in accrued expenses and other current liabilities	$ —	$ 140
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 20,379	$ 67,297
Restricted cash	100	100
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 20,479	$ 67,397