Beta Bionics

A Massachusetts Public Benefit 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 Amendment No. 1 to the Annual Report is dated May 14, 2021

This Amendment No. 1 is being filed as an amendment to the Annual Report filed by Beta Bionics, Inc. on April 30, 2021 in order to include the Company's audited financial statements for the years ended December 31, 2019 and December 31, 2020 and make certain other updates to the report previously filed.

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

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

inherently susceptible to uncertainty and changes in circumstances. Our actual results may vary materially from those expressed or implied in our forward-looking statements. Important factors that could cause actual results to differ materially from those in our forward-looking statements include government regulation, our ability to raise additional capital, results of clinical trials, our ability to achieve regulatory approval, competitive developments, economic, strategic, political and social conditions and the risk factors set forth herein.

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

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

Name of issuer: Beta Bionics, Inc.
Legal status of issuer:
Form: Public Benefit Corporation
Jurisdiction of Incorporation/Organization: Massachusetts
Date of organization: October 21, 2015
Physical address of issuer within the Commonwealth:
300 Baker Ave., Suite 301
Concord, MA 01742

Website of issuer: www.betabionics.com

DIRECTORS, EXECUTIVE OFFICERS AND SIGNIFICANT EMPLOYEES

The members of our board of directors and our officers as of 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. Dasiglucagon has received FDA approval in the rescue pen setting. 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

The risks described below are not the only risks facing us. Additional risks and uncertainties not currently known to us or those we currently view to be immaterial may also materially adversely affect our business, financial condition or results of operations.

Risks Related to Our Financial Position and Need for Additional Capital

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

Our operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.

As an organization, we have not demonstrated an ability to successfully complete pivotal trials, obtain regulatory approvals, manufacture our iLet system at commercial scale, conduct sales and marketing activities necessary for successful commercialization, or obtain reimbursement in the countries of sale. Consequently, any predictions you make about our future success or viability

may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products. We may encounter unforeseen expenses, difficulties, complications and delays in achieving our business objectives. Our operating history makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities, then our business will suffer. In addition, we will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

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 accountants included an explanatory paragraph in their 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.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

As of December 31, 2020, we had U.S. federal net operating loss carryforwards, or NOLs, of $55.9 million, which may be available to reduce future taxable income, of which $11.5 million expire at various dates beginning in 2035 while the remaining $44.4 million do not expire but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2020, we had state NOLs of $13.2 million, which may be available to reduce future taxable income and expire at various dates beginning in 2029. These NOLs and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs or tax credits to offset future taxable income or reduce tax liabilities. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its

ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period.

We have not conducted an analysis for our historical transactions to determine if we have undergone a change of control, and we may undergo an ownership change in connection with future changes in our stock ownership (many of which are outside of our control), whereby our ability to utilize NOLs or tax credits could be further limited by Sections 382 and 383 of the Code or under corresponding provisions of state law. Furthermore, our ability to utilize our NOLs or tax credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income.

Risks Related to the Development and Commercialization of our iLet Bionic Pancreas

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.

Delays in conducting clinical trials could result in increased costs to us and delay our ability to obtain regulatory clearance or approval for our iLet system.

Any delays in conducting clinical trials and related device development programs could materially affect our development costs and delay regulatory clearance or approval of our iLet system for the treatment of type 1 diabetes or any other indication we may pursue. We do not know whether clinical trials will begin on time, will need to be redesigned, will be subject to delay due to safety or other concerns, or will be completed on schedule, if at all. A clinical trial can be delayed for a variety of reasons, including:

- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to the iLet system, or similar investigational devices, competitive or comparator products or failure to follow regulatory requirements;

- delays or failures in obtaining components of our iLet system and manufacturing sufficient quantities of our iLet system for use in clinical trials;

- delays or failures in reaching agreement on acceptable terms with prospective study sites or other contract research organizations, or CROs;

- delays or failures in obtaining approval of the clinical trial protocol from an institutional review board, or IRB, to conduct a clinical trial at a prospective study site;

- delays in recruiting or enrolling participants for clinical trials, including for reasons such as the COVID-19 pandemic;

- failure of a clinical trial or clinical investigators to be in compliance with Good Clinical Practices, or GCPs;

- unforeseen safety issues;

- malfunctioning of devices;

- inability to monitor subjects adequately during or after treatment;

- difficulty monitoring multiple trial sites;

- the FDA requiring alterations to any of the study designs, our nonclinical strategy or our manufacturing plans;

- failure of our third-party clinical trial sponsors or monitors to satisfy their contractual duties, comply with regulations, or meet expected deadlines; and

- determination by regulators that the clinical design of a trial is not adequate.

Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by the trial sponsor, the FDA, the IRBs at the sites where the IRBs are overseeing a trial, or a data safety monitoring board overseeing the clinical trial at issue, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or the clinical protocols;

- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;

- unforeseen safety issues, including serious adverse events associated with our investigational device, or lack of effectiveness; and

- lack of adequate funding to continue the clinical trial.

If we are required to conduct additional clinical trials or other testing beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing, if the results of these trials or tests are not positive or are not as positive as we expect or if there are safety concerns, our business and results of operations may be adversely affected and we may incur significant additional costs.

Clinical failure may occur at any stage of clinical development, and the results of completed and planned clinical trials may not support the clearance or approval of our iLet system for the treatment of type 1 diabetes or any future indication we may pursue. If the clinical trials fail to demonstrate effectiveness and safety to the satisfaction of the FDA or other regulatory authorities, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development of our iLet system.

We cannot be certain that existing and planned clinical trial results will be sufficient to support regulatory clearance of our iLet system. The results of earlier trials of the iLet system and its predecessor devices, including results of trials from earlier versions of the iLet system that used a substantially similar algorithm, may not be predictive of the results of the ongoing or future clinical trials. A number of companies in the medical device industry have suffered significant setbacks in clinical trials, even after promising results in earlier preclinical studies or clinical trials. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway and safety or effectiveness observations made in clinical trials, including previously unreported adverse events. The results of preclinical studies and early clinical trials of our investigational device may not be predictive of the results of later clinical trials. Investigational devices in later stages of clinical trials may fail to show the desired safety and effectiveness traits despite having progressed through preclinical studies and initial clinical trials. A failure of a clinical trial to meet its predetermined endpoints would likely cause us to abandon an investigational device and may delay development of any other investigational devices. Any delay in, or termination of, clinical trials of our investigational device will delay the submission of a 510(k) to the FDA, or other similar applications with other relevant foreign regulatory authorities and, ultimately, our ability to commercialize our investigational device and generate revenue.

We have encountered, and may continue to encounter, difficulties enrolling participants in clinical trials, and our clinical development activities could thereby be delayed or otherwise adversely affected.

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

- the participant eligibility criteria defined in the protocol;
- the proximity of participants to trial sites;
- the design of the trial;
- our ability to engage a trial sponsor, if necessary, and recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or new technologies;
- the perceptions of clinicians and of people with diabetes as to the potential advantages of the iLet system;

- our ability to obtain and maintain participant consents;
- the risk that participants enrolled in clinical trials will not complete a clinical trial; and
- the COVID-19 global pandemic.

In addition, our clinical trials will compete with other clinical trials for insulin pumps and investigational therapies in clinical development for the treatment of type 1 diabetes, and this competition will reduce the number of participants available to us, because some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. We may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of people who are available for our clinical trials at such clinical trial sites.

Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in participant enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our iLet system for our current and future indications.

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 has since been released from the hospital. 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 the FDA has approved dasiglucagon for use in a rescue pen for treatment of severe hypoglycemia. In the event the FDA withdraws this approval or significantly conditions the use 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 though the FDA has approved 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.

A breakthrough device designation by the FDA for the iLet system may not lead to a faster development, regulatory review or clearance process, and it may not increase the likelihood that the iLet system will receive marketing authorization from the FDA.

In December 2019, we announced that the FDA granted breakthrough device designation for the iLet Bionic Pancreas System for the proposed indication of subcutaneous delivery of insulin and glucagon at autonomously calculated variable rates for the management of diabetes mellitus or other conditions of glycemic dysregulation in persons requiring insulin and/or glucagon. The FDA's breakthrough devices program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and healthcare providers with timely access to these medical devices by speeding up their development, assessment and review, while preserving the statutory standards for premarket approval, 510(k) clearance and de novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

The receipt of a breakthrough device designation for the iLet system may not result in a faster development process, review or clearance compared to conventional FDA procedures and does not assure ultimate marketing authorization by the FDA. In addition, even if a product qualifies as a breakthrough device, the FDA may later decide that the product no longer meets the conditions for qualification.

Manufacturing risks may adversely affect our ability to manufacture our iLet system, which could negatively impact the ongoing and planned clinical trials of our iLet system, and if approved, our sales and operating margins.

We manufacture our iLet system and its accompanying ready-to-fill insulin cartridges at our facilities located in Irvine, California. Our business strategy depends on our ability to manufacture the iLet system in its insulin-only and bihormonal configurations in sufficient quantities and on a timely basis so as to meet our clinical trial needs, and if cleared or approved, our commercial needs, while adhering to product quality standards, complying with regulatory

requirements and managing manufacturing costs. We are subject to numerous risks related to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers, including the infusion sets we purchase from Unomedical, an affiliate of ConvaTec, and the supplier of the motors used in the pump of the iLet system;
- our inability to secure product components in a timely manner, in sufficient quantities and on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our failure to increase production of products to meet demand, if the iLet system is cleared or approved;
- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently produce future products or implement any necessary or desired changes in response to regulatory requirements; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facilities.

In earlier generations of the iLet system, we had experienced various design and manufacturing issues including defective seals and improperly tuned alarms. 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. To remediate these issues, we improved the steps and handling related to programming the batteries and made modifications to boost the Bluetooth signal. While we believe we have remediated these issues, there is no assurance we will not encounter similar or other unanticipated issues in the future.

As we begin to increase production of our insulin-only iLet system in anticipation of a potential regulatory clearance or approval for the treatment of type 1 diabetes, we will have to invest additional resources in purchasing components, hiring and training employees, and enhancing our manufacturing processes and quality systems. We may also increase our utilization of third parties to perform contracted manufacturing services for us, and we may need to acquire additional custom designed equipment to support the expansion of our manufacturing capacity. If we fail to increase our production capacity to meet clinical and commercial requirements while also maintaining product quality standards, we may fail to obtain and maintain regulatory clearances or approvals and efficiently manage costs, and our sales and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results.

Further, we perform all of our manufacturing activities at our facility in Irvine, California. Our facilities, equipment and inventory would be costly to replace and could require substantial lead time to repair or replace. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, earthquakes, flooding, fire and power outages, which may render it difficult or impossible for us to perform our research, development and commercialization activities for some period of time. The inability to perform those activities, combined with the time it may take to rebuild our inventory of finished product, may result in delays in clinical trials, the loss of customers or harm to our reputation. Although we possess insurance for damage to our property and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

We have never manufactured the iLet system in commercial quantities and may encounter related problems or delays that could result in lost revenue.

We must manufacture and assemble the iLet system in compliance with regulatory requirements and at an acceptable cost in order to achieve and maintain profitability. We have never manufactured the iLet system in commercial quantities and, as a result, we may have difficulty manufacturing and assembling the iLet system in sufficient quantities in a timely manner. To manage our manufacturing and operations with our suppliers, we will need to forecast anticipated product orders and material requirements to predict our inventory needs in advance and enter into purchase orders on the basis of these requirements. Our limited manufacturing history may not provide us with enough data to accurately predict future component demand, fluctuations in availability and pricing of commodity materials of supply, and to anticipate our costs and supply needs effectively. We may in the future experience delays in obtaining components from suppliers, which could impede our ability to manufacture and assemble the iLet system on our expected timeline. As a result of this or any other delays, we may encounter difficulties in production of the iLet system, including problems with quality control and assurance, component supply shortages or surpluses, increased costs, shortages of qualified personnel and difficulties associated with compliance with local, state, federal and foreign regulatory requirements.

If the quality of the iLet system does not meet the expectations of physicians or patients, if cleared or approved, then our brand and reputation or our business could be adversely affected.

In the course of conducting our business, we must adequately address quality issues that may arise with the iLet system, including defects in third-party components included in the iLet system. Although we have established internal procedures designed to minimize risks that may arise from quality issues, we may not be able to eliminate or mitigate occurrences of these issues and associated liabilities. In addition, even in the absence of quality issues, we may be subject to claims and liability if the performance of the iLet system does not meet the expectations of physicians or patients. If the quality of the iLet system does not meet the expectations of physicians or patients, then our brand and reputation with those physicians or patients, and our business, financial condition and results of operations, could be adversely affected.

If cleared or approved, we will bear the risk of warranty claims on our iLet.

If our iLet system is cleared or approved for commercial sales, we will bear the risk of warranty claims on our iLet. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or third-party manufacturers. In the event of a successful warranty claim against us by a customer, any recovery from any such supplier or third-party manufacturer could be inadequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers or third-party manufacturers expires, which could result in costs to us.

Coverage and reimbursement may be limited or unavailable in certain market segments for our iLet system, if cleared or approved, which could make it difficult for us to sell any investigational devices profitably.

The success of our iLet system for the treatment of type 1 diabetes, if cleared or approved, depends on the availability of adequate coverage and reimbursement from third-party payors.

In the United States and markets in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new device acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and devices they will cover and the amount of reimbursement. Coverage may be more limited than the purposes for which the drug or device is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines and devices are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine or device will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Further, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-

effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for our iLet system, in either configuration for type 1 diabetes or other indications, the resulting reimbursement payment rates might not be adequate for us to maintain pricing sufficient to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of investigational devices. Patients are unlikely to use our investigational devices unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our investigational devices. Because our iLet system may have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our investigational devices.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our investigational devices. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect to experience pricing pressures in connection with the sale of any of our investigational devices due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

The COVID-19 pandemic may materially and adversely affect our business and financial results.

The outbreak of SARS-CoV-2, the novel strain of coronavirus that causes COVID-19, has evolved into a global pandemic. The extent to which COVID-19 impacts our business and operating results will depend in part on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, including potential variants thereof, and the actions taken to contain COVID-19 or treat its impact, among others.

Infections and deaths related to the pandemic have disrupted and may continue to disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay FDA review and/or approval with respect to, our clinical trials. Any elongation or de-prioritization of our clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and commercialization of our iLet system.

In response to these public health directives and to help reduce the risk to our employees, we took precautionary measures, including implementing work-from-home policies for our

employees. We plan to continue these measures and are assessing when and how to resume normal operations. The effects of our work-from-home policies may negatively impact productivity, disrupt our business and delay the development of our iLet system and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, results of operations and financial condition, including our ability to obtain financing.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, has impacted the timetable for development of our iLet system for the treatment of type 1 diabetes, in both its insulin-only and bihormonal configurations, and may continue to have an adverse effect on our business. In particular, the COVID-19 pandemic impacted the trial execution plans for the iLet insulin-only configuration pivotal trial and caused delays in the timeline of the clinical trial.

While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and may result in further, significant disruption of global financial markets, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business, prospects, operating results and financial condition, and the price of our Class B common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely.

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.

Our ability to achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize the iLet system for the treatment of type 1 diabetes as an option that offers distinct features and functionality, is easy-to-use, provides improved glycemic control, receive adequate coverage and reimbursement from third-party payors, and are otherwise more appealing than available alternatives.

Our primary competitors, as well as a number of other companies and medical researchers are pursuing new delivery devices, delivery technologies, sensing technologies, treatment techniques, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for our products or render the iLet system obsolete, before or after regulatory approval, which could adversely affect our business operations. In addition, even the perception that new products may be introduced, or that technological or treatment advancements could occur, could cause consumers to delay the purchase of our iLet system for the treatment of type 1 diabetes, if approved.

Because the insulin-dependent diabetes market is large and growing, we anticipate companies will continue to dedicate significant resources to developing competitive products and technologies. The introduction by competitors of products may create market confusion that may

make it difficult to differentiate the potential benefits of the iLet system over other products in development or approved products. Our competitors may introduce products that offer features not available in our iLet system. For example, Insulet is developing a hybrid, tubeless, closed-loop insulin pump that may be perceived by patients as a better alternative to the iLet system.

Moreover, we have designed our products to resemble modern consumer electronic devices to address certain aesthetic and functionality concerns consumers have raised with respect to traditional pumps. The consumer electronics industry is itself highly competitive, and characterized by continuous new product introductions, rapid developments in technology, and subjective and changing consumer preferences. If, in the future, consumers cease to view our products as contemporary or convenient as compared to then-existing consumer electronics technology, our products may become less desirable.

Our current business strategy is highly dependent on the iLet system, in its insulin-only mode for the treatment of type 1 diabetes achieving market acceptance, if cleared or approved. To do so, we must demonstrate to people with diabetes, their caregivers and healthcare providers that our iLet system is a better treatment option compared to diabetes treatments, including traditional insulin pump products and multiple daily injection, or MDI, therapies, as well as alternative diabetes monitoring, treatment or prevention methodologies. Market acceptance and adoption of the iLet system, if approved, depends on educating people with diabetes, as well as their caregivers and healthcare providers, about the distinct features, ease-of- use, treatment outcomes, and other perceived benefits as compared to competitive products. If we are not successful in convincing existing and potential customers of the benefits of the iLet system, or if we are not able to achieve the support of caregivers and healthcare providers for our products, our business and results of operations will be adversely affected.

Market acceptance of the iLet system in its insulin-only or bihormonal configuration for the treatment of type 1 diabetes could be negatively impacted by many factors, including:

- the failure to achieve and maintain widespread acceptance among people with insulin-dependent diabetes, their caregivers, healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;

- lack of evidence supporting the safety, ease-of-use or other perceived benefits of our iLet system over competitive products or other currently available insulin treatment methodologies;

- perceived risks or uncertainties associated with the use of our iLet system, or its components, or of similar products or technologies of our competitors;

- adverse regulatory or legal actions relating to our iLet system or other insulin pump technologies; and

- results of our clinical trials.

If our iLet system for the treatment of type 1 diabetes, if and when cleared or approved, does not achieve and maintain widespread market acceptance, we may fail to achieve sales

consistent with our projections, in which case our business, financial condition and operating results could be materially and adversely affected.

Our long-term growth depends, in part, on our ability to develop and enhance the iLet system, and if we fail to do so we may be unable to compete effectively.

It is important to our business and our long-term growth that we continue to develop and enhance the iLet system. We intend to continue to invest in research and development activities focused on improvements and enhancements to the iLet system. Additionally, we intend to pursue regulatory clearance or approval for other indications in the United States in the future.

Developing enhancements to the iLet system can be expensive and time-consuming and could divert management's attention away from the commercialization of the iLet system and divert financial resources from other operations. The success of any new product enhancements, including approval of the iLet system for additional indications, will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs, and develop enhancements to meet those needs;
- demonstrate, if required, the safety and effectiveness of new enhancements to the iLet system, including additional indications, with data from preclinical studies and clinical studies;
- obtain, and obtain in a timely manner, the necessary regulatory clearances or approvals for new enhancements to the iLet system, product modifications or expanded indications;
- avoid infringing upon the intellectual property rights of third parties;
- be fully FDA-compliant with marketing of new devices or modified products;
- develop an effective and dedicated sales and marketing team to provide adequate education and training to potential users of the iLet system; and
- receive adequate coverage and reimbursement for procedures performed with the iLet system.

If we are not successful in commercializing the iLet system, expanding the indications for which it may be approved and developing and commercializing new product enhancements, our ability to achieve and maintain market share and increase our revenue may be impaired, which could have a material adverse effect on our business, financial condition and results of operations.

The market opportunities for our iLet system for the treatment of diabetes may be smaller than we anticipated.

Our current and future target patient populations are based on our beliefs and estimates regarding the incidence or prevalence of type 1 and type 2 diabetes, including the patient

population using intensive insulin therapy for treatment, which is derived from a variety of sources including scientific literature and third-party estimates. Our projections may prove to be incorrect and the number of potential patients may turn out to be lower than expected. Even if we obtain significant market share for our investigational devices, because the potential target populations could be smaller than we expect, we may never achieve profitability without obtaining regulatory approval for the iLet system in additional indications.

We may expend our resources to pursue a particular indication and forgo the opportunity to capitalize on indications that may ultimately be more profitable or for which there is a greater likelihood of success.

We have limited financial and personnel resources and are placing significant focus on the development of our iLet in its insulin-only and bihormonal configurations for the treatment of type 1 diabetes. 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. This will require the successful completion of additional trials, submission of a 510(k) and significant resources, which may not result in clearance of the use of the iLet system in type 2 diabetes. 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 and metabolic syndrome. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for specific indications may not yield any commercially viable future investigational devices.

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.

Obtaining and maintaining marketing authorization for our iLet system in any configuration for type 1 diabetes or other indication in one jurisdiction does not mean that we will be successful in obtaining marketing authorization of the iLet system in any configuration or indication in other jurisdictions.

Obtaining and maintaining marketing authorization for our iLet system in any configuration for type 1 diabetes or other indication in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing authorization in any other jurisdiction, while a failure or delay in obtaining marketing authorization in one jurisdiction may have a negative effect on the marketing authorization process in others. For example, even if the FDA grants marketing authorization of an investigational device, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the investigational device in those countries. Procedures for obtaining marketing authorization vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, an investigational device must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of investigational devices with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing authorization and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing authorizations, our target market will be reduced and our ability to realize the full market potential of our investigational devices will be harmed.

Risks Related to Our Reliance on Third Parties

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.

If conflicts arise between us and our collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Our current or future collaborators or strategic partners, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights,

may result in the withdrawal of partner support for our investigational devices. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts.

We obtain some of the components and subassemblies included in our iLet system from single source suppliers, and the partial or complete loss of one or more of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.

We rely on a number of suppliers who manufacture the components of the iLet system. We have a contract manufacturing agreement with Unomedical, an affiliate of ConvaTec, for the production of infusion sets for our iLet system, and Unomedical is our only supplier of infusion sets. If Unomedical was to terminate its contract with us, or be unable to provide infusion sets to us in the quantities ordered, we would need to identify and qualify a new supplier. Similarly, we obtain the pump motors for our iLet from a single- source supplier. Although there are other manufacturers of infusion sets and pump motors, we may not be able to identify a new manufacturer or enter into a contract with terms substantially the same as our current agreement in a timely manner, if at all. Any disruption in the supply of our infusion sets or pump motors could have a materially adverse impact on our clinical trials and commercial sales, if the iLet system is approved.

We do not currently have long-term supply agreements with the suppliers of most of our components, and, in most cases, we purchase these components on a purchase order basis. Although we are in active discussions to enter into long-term supply agreements for certain components, there is no assurance we will be able to enter into such agreements on commercially reasonable terms in a timely manner, if at all. In some other cases, where we do have agreements in place, our agreements with our suppliers can be terminated by either party upon short notice. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

- our suppliers, especially new suppliers, may make errors in manufacturing components that could negatively affect the effectiveness or safety of the iLet system or cause delays in shipment or in the conduct of our clinical trials;

- we may have difficulty locating and qualifying alternative suppliers for our sole-source supplies;

- switching components may require product redesign, and any product redesign may affect FDA's review of our 510(k) submissions;

- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and

- we may not be able to quickly establish additional or replacement suppliers, particularly for our sole-source components.

Risks Related to our Intellectual Property and Potential Litigation

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 non- disposable 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 pre- existing 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.

Our development and commercialization rights to our current and future investigational devices and technology are subject, in part, to the terms and conditions of licenses granted to us by others.

Our patent portfolio consists of a combination of issued patents and pending patent applications licensed-in from a third party, jointly owned with a third party, and assigned solely to

us based on our ongoing development activities. We are reliant upon certain of these third-party rights and proprietary technologies, including the licenses from the Trustees of Boston University, for the engineering and development of our current and future investigational devices.

We also engage in collaborations with scientists at academic and non-profit institutions to access information, technologies, and materials that may not otherwise be available to us. Although the agreements that govern these collaborations may include an option to negotiate an exclusive license to the institution's rights in any inventions that are created in the course of these collaborations, we may not be able to come to a final agreement for an exclusive license with an institution.

Such licenses and other contracts may also be the subject of disagreements with the grantors or various third parties regarding the interpretation of such licenses and contracts. The resolution of any such disagreements that may arise could affect the scope of our rights to the relevant technology, or affect financial or other obligations under the relevant agreement, either of which could inhibit our ability to utilize the underlying technology in a cost-effective manner to develop and commercialize our investigational device, which in turn could have a materially adverse effect on our competitive position, business, financial condition, results of operations, or prospects.

Under certain circumstances, such as a material breach of terms, our licensors could terminate our license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors could have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications directed to the technology that we ultimately license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with our best interests. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be impaired. For example, if we or our licensors fail to maintain the patents and patent applications covering our investigational device and technologies, we may not be able to prevent a competitor from marketing products that are the same as or similar to our investigational device. Further, our competitors and others commercializing products similar or identical to ours may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, which could increase competition for our investigational device and materially adversely affect our business, financial condition, results of operations and growth prospects. Additionally, we may be required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement, and defense of patents and patent applications that we in-license from them. If we are responsible for

patent prosecution and maintenance of patent rights in-licensed to us, we could be exposed to liability to the applicable patent owner.

Furthermore, our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in- licensed. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could harm our competitive position, and our business.

The U.S. government may exercise certain rights with regard to inventions developed under government-funded research, which could eliminate our exclusive use of such technology or require us to commercialize our investigational device in a way we consider sub-optimal.

We are party to funding agreements with the U.S. government. Pursuant to the Bayh-Dole Act, the U.S. government has certain rights with regard to any inventions conceived or first actually reduced to practice under the terms of such agreements. These rights include, for example, a nonexclusive, nontransferable, irrevocable, paid-up license to use those inventions for governmental purposes. In addition, the U.S. government can exercise its march-in rights to require us to grant licenses to such inventions to a third party if it determines that action is necessary (i) because we fail to achieve practical application of the technology funded under the funding agreements, (ii) to alleviate health or safety needs, (iii) to meet requirements of federal regulations, or (iv) to give preference to U.S. industry. Our inventions that could be subject to these rights relate to both software, including improvements to the control algorithm and user interface of the iLet system, and hardware, including improvements to the disposable and non-disposable components of the iLet system. The U.S. government also has the right to take title to such technology if we fail to disclose the inventions to the government, fail to file patent applications with respect to the inventions within specified time limits, or fail to elect to retain title of the inventions. The U.S. government also has the right to acquire title to patent rights in any country in which a patent application is not filed within specified time limits. Inventions made with U.S. government support are subject to certain reporting requirements. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. If we are unable to obtain a waiver from the government agency that provided the research funding, we may be limited in our ability to contract with non-U.S. manufacturers for products related to such intellectual property. Furthermore, the patent rights that we license from the Trustees of Boston University claim inventions that are subject to similar U.S. government rights, as such inventions were conceived or first actually reduced to practice using U.S. government funds received by the Trustees of Boston University. These patents relate to both software, including the control algorithm run by the iLet system, and disposable and non-disposable components of the iLet system, including infusion sets that subcutaneously deliver the glucagon and/or insulin hormones. While rare, any exercise by the government of any of the foregoing rights could prevent us from enjoying the exclusive use of inventions developed with government support, or could cause us to incur additional expenses in the commercialization of our products. Any of the foregoing could be harmful to our competitive position, business, financial condition, results of operations, or prospects.

Our success depends on our ability to protect our intellectual property and proprietary technology.

The market for diabetes treatment is highly competitive and subject to rapid technological change. Our success depends in large part on our ability to obtain and maintain patent protection and trade secret protection with respect to our products. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business. To protect our proprietary position, in addition to the patent rights we have licensed from the Trustees of Boston University, we have filed patent applications related to the iLet system in the United States and under the Patent Cooperation Treaty. However, the patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. If we are unable to protect our intellectual property, our competitive position would be materially adversely affected, as third parties may be able to make, use, or sell products and technologies that are substantially the same as ours without incurring the sizeable development and licensing costs that we have incurred. This, in turn, would materially adversely affect our ability to compete in the market. Moreover, we cannot assure you that:

- any of our current or future products or processes will be patentable;
- we will identify all patentable aspects of the inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them;
- the inventors named on the patents and patent applications we own or license were the first to make the technologies claimed in those patents and patent applications or that those were the first-filed patents and patent applications for the claimed technology;
- our products or processes will not infringe the patents of third parties;
- our patents will protect us in the jurisdictions where our patents have been granted;
- all of the potentially relevant prior art that may be used to invalidate our patents or that may prevent a patent from issuing from one of our pending patent applications has been found and been provided to the relevant patent examining authorities; or
- we will have the resources to defend against charges of patent infringement or other violation or misappropriation of intellectual property by third parties or to protect our own intellectual property rights against infringement, misappropriation or violation by third parties.

Because the patent position of medical device companies involves complex legal and factual questions, we cannot predict the validity and enforceability of our patents, or provide any assurances that any of our patent applications will be found to be patentable. Our issued patents may not provide us with any competitive advantages, may be narrowed or held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Our competitors may also independently develop processes, technologies or products similar to ours or design around or otherwise circumvent any patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide adequate protection against competitors. Our pending patent applications, those we may file in the future or those we may

license from third parties in the future may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford relatively limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. After the completion of development and issuance of our patents, third parties may still manufacture or market our products despite our patent protected rights. If the protection of our proprietary rights is inadequate to prevent use or appropriation by third parties, the value of our brand and other intangible assets may be diminished and competitors may be able to more effectively mimic our technology. If competitors were to mimic our technology, it may result in loss of sales and material litigation expenses. Such infringement of our patent protected rights is likely to cause us damage and lead to a reduction in the prices of our products, thereby reducing our anticipated profits.

Patent expiration dates may be shortened or lengthened by a number of factors, including terminal disclaimers, patent term adjustments and patent term extensions. Patent term extensions may be impacted by the regulatory process and may not significantly lengthen patent term. Our patent protection could also be reduced or eliminated for noncompliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies. In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights.

Due to the extensive time needed to develop, test and obtain regulatory approval for our products, any patents that protect our products may expire early during commercialization. For example, the first- expiring U.S. patents that we license from the Trustees of Boston University, relating to aspects of the control algorithm run by the iLet system, are scheduled to expire in 2026. The patent terms of some of our patents may, therefore, be inadequate to protect our competitive position on our products for an adequate amount of time. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of competing products into the market and a subsequent decline in market share and profits.

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

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

We have a number of non-U.S. patents and patent applications, and we expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. However, filing, prosecuting, and defending patents relating to our investigational device, including all of our in- licensed patent rights, in all countries throughout the world, would be prohibitively expensive. We must ultimately seek patent protection on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Furthermore, the protection offered by intellectual property rights in certain countries outside of the United States may be less extensive than the protection offered in the United States. Consequently, we may not be able to prevent third parties from utilizing proprietary technology in all countries outside of the United States, even if we pursue and obtain issued patents in particular foreign jurisdictions, or from selling or importing products made using our proprietary technology in or into the United States or other jurisdictions. Such products may compete with our products, and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing. If such competing products arise in jurisdictions where we are unable to exercise intellectual property rights to combat them, our business, financial condition, results of operations and growth prospects could be materially adversely affected.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.

The Leahy-Smith America Invents Act, or AIA, which was passed in September 2011, resulted in significant changes to the United States patent system. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned from a "first-to-invent" to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. A third party that filed or files a patent application with the United States Patent and Trademark Office, or USPTO, after March 16, 2013 but before us (or before our licensor, the Trustees of Boston University) could therefore be awarded a patent covering an invention of ours even if we made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are changes that alter where a patentee may file a patent infringement suit and that provide opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our United States patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. It is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Additionally, the United States Supreme Court has ruled on several patent cases in recent years either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations, and there are other open questions under patent law that courts have yet to decisively address. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways and could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. In addition, the European patent system is relatively stringent in the type of amendments that are allowed during prosecution, and the complexity and uncertainty of European patent laws has also increased in recent years. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own, have licensed, or might obtain or license in the future, which in turn could materially adversely affect our business, financial condition and operating results. Complying with these laws and regulations could limit our ability to obtain new patents in the future that may be important for our business.

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

The USPTO, European and other patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO, European and other patent agencies over the lifetime of the patent. While an unintentional failure to make payment of such fees or to comply with such provisions can in many cases be cured by additional payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance with such provisions will result in the abandonment or lapse of the patent or patent application, and the partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents within prescribed time limits. If we or any licensors fail to maintain the patents and patent applications relating to our products or if we or any licensors otherwise allow our patents or patent applications to be abandoned or lapse, it can create opportunities for competitors to enter the market, which would hurt our competitive position and could impair our ability to successfully commercialize our products in any indication for which they are approved.

It is possible that defects as to form in the preparation, filing or prosecution of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope or requests for patent term adjustments. If we fail to establish, maintain or protect such patent rights and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Foreign patent protection is particularly uncertain, and if we are involved in opposition proceedings in foreign countries, we may have to expend substantial sums and management resources.

Patent rights are territorial; thus, the patent protection we currently have will extend only to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the United States. For example, certain countries do not grant patent claims that are directed to the treatment of humans. Competitors may successfully challenge our patents, produce similar devices that circumvent and do not infringe our patents, or manufacture devices in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is difficult to predict the scope of claims that will be allowed in pending applications and it is also difficult to predict which claims of granted patents, if any, will be deemed enforceable in a court of law. We may participate in opposition proceedings to determine the validity of our foreign patents or our competitors' foreign patents, which would result in substantial costs and diversion of our management's efforts, thus adversely affecting our results of operations.

If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

In addition to filing patent applications, we also use trade secret laws to protect our proprietary information, including know-how and technology. However, trade secrets are difficult to protect. We also rely in part on confidentiality or non-disclosure agreements with parties that have access to our proprietary information, such as our development or commercialization partners, employees, contractors and consultants, to protect our trade secrets and other proprietary information. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, we cannot ensure that all such agreements have been duly executed.

Moreover, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develops, or uses independently developed, intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable and a court may determine that the right belongs to a third party, which could materially adversely affect our business, results of operations and ability to capitalize on our proprietary information.

We may fail to obtain or enforce assignments of intellectual property rights from our employees and contractors.

While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Furthermore, our assignment agreements may not be self-executing or may be breached, and we may be forced to bring or defend claims to determine the ownership of what we regard as our intellectual property, and we may not be successful in such claims. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially adversely affect our business, financial condition, results of operations and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Even after issuance, our owned and in-licensed patents may be subject to challenge and/or attempts to amend or alter the scope of the claims issued therein, which if successful could require us to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the use of the underlying technology, which could materially adversely affect our business.

The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents, even after issuance, may be challenged in the courts or patent offices in the United States and abroad. Third-party challenges, such as oppositions, inter partes reviews, post-grant reviews, reissues, re- examinations or other proceedings, may result in a loss of exclusivity or in our patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to prevent others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and investigational device.

Even if our patents are determined to be enforceable and not to be invalid, they may not be interpreted sufficiently broadly enough to prevent others from marketing products similar to ours or designing around our patents.

We currently have one reissue patent application pending with the USPTO that was filed on January 28, 2021 and seeks a broadening reissue of U.S. Patent No. 10,188,795, a patent that is in-licensed from the Trustees of Boston University. U.S. Patent No. 10,188,795 relates generally to meal and basal controllers responsible for sending dosing signals to a fluid delivery device like

those implemented in the investigational device. Although we plan to work with the Trustees of Boston University to vigorously protect our intellectual property rights, as with all legal proceedings, there can be no guarantee as to the outcome, and such proceedings are time-consuming and costly. As a result of such broadening reissue application, we may be afforded the opportunity to seek claims with different and/or broader scope than were originally issued in U.S. Patent No. 10,188,795, either in the pending broadening reissue application or in continuing applications we may choose to file claiming priority thereto. Nevertheless, also as a result of such broadening reissue application, our rights under the relevant patents could instead be narrowed and/or lost, and in the course of such proceedings, we may incur substantial costs, and the time and attention of our management may be diverted from the development and commercialization of our investigational device.

There may be other opportunities in which we may seek to broaden or otherwise amend the scope of issued claims in patents that are owned and/or in-licensed. As a result of such opportunities, we may be afforded the chance to seek claims with different and/or broader scope than were originally issued in the relevant patents. Nevertheless, also as a result of such opportunities, our rights under the relevant patents could be narrowed and/or lost, and in the course of such proceedings, we may incur substantial costs, and the time and attention of our management may be diverted from the development and commercialization of our investigational device.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope, or expiration of a third-party patent, which could materially adversely affect our ability to develop, manufacture, and market our investigational device.

There are many patents issued or applied for in the medical device industry, and we may not be aware of patents or patent applications held by others that relate to our business. We cannot guarantee that any of our or our licensors' patent searches or analyses, including, but not limited to, the identification of relevant patents, analysis of the scope of relevant patent claims, or determination of the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and elsewhere that is relevant to or necessary for the development and commercialization of our investigational device in any jurisdiction.

For example, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications directed to our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to patents directed to such technologies. If third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the USPTO itself, to determine who was the first to invent any of the subject matter recited by the patent claims of our applications. Such a proceeding could involve substantial uncertainties and cost, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be upheld as valid in court. Depending on the effective filing date of the application, rather than the interference

proceeding, we may instead be required to participate in a derivation proceeding with similarly substantial uncertainty, lack of assurances and cost.

Furthermore, after issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, and we may incorrectly determine that our investigational device is not covered by a third party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or elsewhere that we consider relevant may also be incorrect. If we fail to correctly identify or interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our investigational device. We may also be forced to attempt to redesign our investigational device in a manner that no longer infringes third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to the development and commercialization of our investigational device.

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

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

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

- stop selling our products or using technology that contains the allegedly infringing intellectual property;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing;

- redesign those products that contain the allegedly infringing intellectual property which may be costly or not feasible; or

- attempt to acquire or obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, prevent or delay us from developing or commercializing our investigational devices, and harm our reputation. Results of any such litigation are difficult to predict and may require us to stop providing certain features, obtain licenses or modify our investigational device while we develop non-infringing substitutes, or may result in significant settlement costs. Litigation can involve substantial damages for infringement (and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees), and the court could prohibit us from selling or require us to take a license from a third party, which the third party is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties, upfront fees, milestone fees, or grant cross-licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use, or sale. Further, as the number of participants in the diabetes market increases, the possibility of intellectual property infringement claims against us increases.

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

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

We may not be able to effectively monitor unauthorized use of our intellectual property and enforce our intellectual property rights against infringement, and we may become involved in

lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products for potential infringement of our rights. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully monitor unauthorized use of our intellectual property could result in competitors offering products that incorporate our product or service features, which could in turn reduce demand for our products.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may, from time to time, seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property, or we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. The other party may also challenge our patents through proceedings before the Patent Trial and Appeal Board, or PTAB, including inter partes and post-grant review. Proceedings to challenge patents are also available internationally, including, for example, opposition proceedings and nullity actions. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability and PTAB challenges are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement during prosecution. Third parties may also raise similar claims before the PTAB, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our investigational device. There is also a risk that, even if the validity of such patents is upheld, the court will construe a patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert those patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Similarly, if we assert trademark infringement claims, a court may determine that the trademarks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the trademarks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Additionally, for certain of our existing and future in-licensed patent rights, we may not have the right to bring suit for infringement and may have to rely on third parties to enforce these rights for us. If we cannot or choose not to take action against those we believe infringe our intellectual property rights, we may have difficulty competing in certain markets where such potential infringers conduct their business, and our commercialization efforts may suffer as a result.

If our trademarks and trade names are denied by regulatory authorities or are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and we have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved in a timely manner or at all. During the trademark registration process, we may receive office actions from the USPTO objecting to the registration of our trademarks. Although we would be given an opportunity to respond to those objections, we may be unable to overcome them. Our registered or unregistered trademarks or trade names may be denied by other regulatory authorities or challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may be unable to use these trademarks and trade names or protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks throughout the world. For example, we currently plan to market our investigational device, if cleared or approved by regulatory authorities, as the iLet and/or the iLet Bionic Pancreas System. If we are required to use an alternative trademark, any goodwill and recognition that we have built for these trademarks would be lost. If any party infringes any of the trademarks on which we rely, enforcing those trademarks may be difficult, costly, time-consuming and ultimately unsuccessful.

Risks Related to Government Regulation

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.

Our products, if cleared or approved, may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

With respect to clinical trials for which we are a sponsor, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. We have in the past conducted several voluntary recalls of devices with lot-specific quality issues. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of our devices. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If the iLet system or any future products we may develop are defectively designed or manufactured, contain defective components or are misused, or if someone claims any of the foregoing, including from the use of our investigational devices in a clinical trial, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our devices or failing to adhere to the operating guidelines of the iLet system could cause significant harm to patients, including death. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we believe that we are reasonably insured against these risks, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce future revenues. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

If our iLet system is approved for the treatment of type 1 diabetes, either in its insulin-only or bihormonal configuration, the regulatory clearance or approval will be limited by the FDA to the specific indication for which approval has been granted. We will be prohibited from marketing the iLet system for other indications, such as type 2 diabetes. We may be subject to fines, penalties or injunctions if we are determined to have promoted or be promoting the use of the iLet system for unapproved or "off-label" uses, resulting in damage to our reputation and business.

We are currently pursuing the development and clearance of our iLet system for the treatment of type 1 diabetes. Although type 2 diabetes is also a disease stemming from excess glucose in the blood, we will be prohibited from promoting the iLet system for type 2 diabetes or any other indication unless we are granted FDA clearance or approval for such indication. The FDA strictly regulates the promotional claims that may be made about medical devices, and the iLet system may not be promoted for uses that are not approved by the FDA as reflected in its approved labeling. If we are not able to obtain FDA approval for any desired future indications, our ability to effectively market and sell our iLet system may be reduced and our business may be adversely affected.

While physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, we are prohibited from marketing and promoting the products for indications that are not specifically cleared or approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biotechnology or medical device companies on off-label use. If the FDA determines that our promotional activities constitute

promotion of an off-label use, it could request that we modify our promotional materials and subject us to FDA regulatory or enforcement actions as well as actions by other agencies, such as the Federal Trade Commission, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, mandatory or voluntary recalls, civil fines, disgorgement of money, operating restrictions, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement, injunctions or criminal prosecution, any of which could significantly harm our business.

Our relationships with healthcare providers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to significant penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of products. Arrangements with third-party payors and customers can expose device manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the False Claims Act, laws and regulations related to the reporting of payments to physicians and teaching hospitals, and HIPAA (defined below), which may constrain the business or financial arrangements and relationships through which such companies research, sell, market and distribute products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to, the below.

- The federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering, paying or providing any remuneration (including any kickback, bribe, or rebate), directly or indirectly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. On November 20, 2020, the Office of Inspector General, or OIG finalized further modifications to the federal Anti-Kickback Statute. Under the final rules, OIG added safe harbor protections under the Anti-Kickback Statute for certain coordinated care and value-based arrangements among clinicians, providers, and others. The final rule (with some exceptions) were to become effective January 19, 2021. However, the effective date of the final rules has

since been delayed. We continue to evaluate the status of these final rules and what effect, if any, these rules will have on our business.

- Federal civil and criminal false claims laws, including the False Claims Act, and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery.

- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, which impose, among other things, requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information as well as their covered subcontractors, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

- The federal Physician Payment Sunshine Act created under the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively ACA, which requires manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain

exceptions) to report annually to CMS information related to any payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

- Additional federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. For instance, state anti-kickback and false claims laws may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients. Laws related to insurance fraud may provide claims involving private insurers. State laws may require pharmaceutical or medical device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources. State and local laws may also require the licensure of sales representatives, and require drug or device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. Further data privacy and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, or GDPR, which became effective in May 2018). Analogous state laws may additionally govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

Pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in the ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws.

The distribution of products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and significant settlements in the healthcare industry.

Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations, guidance or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a device manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, the approval and commercialization of any of our investigational devices outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA and, in the European Union and the European Economic Area, or EEA, the GDPR (Regulation 2016/679). New privacy rules are being enacted in the United States and globally, and existing ones are being expanded, updated and strengthened. For example, California enacted the California Consumer Privacy Act, or CCPA, took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Complying with these numerous, complex and often changing laws and regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, whether by us, one of our business associates or another third party, could adversely affect our business, financial condition and results of operations, including but not

limited to: investigation costs, material fines and penalties; compensatory, special, punitive and statutory damages; litigation; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief.

Further, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. New legislation proposed or enacted in various other states will continue to shape the data privacy environment nationally. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. The privacy laws in the European Union have been significantly reformed and also continue to undergo change. On May 25, 2018, the GDPR entered into force and became directly applicable in all EU member states. The GDPR implements more stringent operational requirements than its predecessor legislation. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, will require the appointment of data protection officers when sensitive personal data, such as health data, is processed on a large scale, provides more robust rights for data subjects, introduces mandatory data breach notification through the European Union, imposes additional obligations on us when contracting with service providers and requires us to adopt appropriate privacy governance including policies, procedures, training and data audit. If we do not comply with our obligations under the GDPR, we could be exposed to fines of up to the greater of €20 million or up to 4% of our total global annual revenue in the event of a significant breach. In addition, we may be the subject of litigation and/or adverse publicity, which could adversely affect our business, results of operations and financial condition.

Further, the Court of Justice of the European Union ruled in July 2020 that the Privacy Shield, used by thousands of companies to transfer data between the European Union and United States, was invalid and could no longer be used. In September 2020, Switzerland concluded that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. Alternative transfer mechanisms may be used, including the standard contractual clauses ("SCCs"), while the authorities interpret the decisions and scope of the invalidated Privacy Shield, but the SCCs have also been called into question in the same ruling that invalidated Privacy Shield. At present, there are few if any viable alternatives to the SCCs, so future developments may necessitate further expenditures on local infrastructure, changes to internal business processes, or may otherwise affect or restrict sales and operations.

Additionally, the United Kingdom's withdrawal from the European Union, commonly referred to as Brexit, took effect in January 2020, which will lead to further legislative and regulatory changes. While the Data Protection Act of 2018, that "implements" and complements the GDPR achieved Royal Assent on May 23, 2018 and is now effective in the United Kingdom, it is still unclear whether transfer of data from the EEA to the United Kingdom will remain lawful in the long-term under GDPR. With the expiry of the transition period on December 31, 2020,

companies will have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, which has the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. We may incur liabilities, expenses, costs, and other operational losses under the GDPR and applicable EU member states and the U.K. privacy laws in connection with any measures we take to comply with them.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients' and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business, including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. We have been subject to phishing attacks in the past, and while no sensitive or confidential information was compromised, we cannot assure you that our contractual measures and our own privacy and security- related safeguards will protect us from future attacks and from the risks associated with the third-party processing, storage and transmission of such information.

If our efforts to maintain the privacy and security of our customer, patient, third-party payor, employee, supplier or company information are not successful, we could incur substantial additional costs and become subject to litigation, enforcement actions and reputational damage.

Our business, like that of most medical device manufacturers, involves development of valuable intellectual property and trade secrets, the receipt, storage and transmission of patient information and payment and reimbursement information, as well as confidential information about third-party payors, our employees, our suppliers and us. Our information systems are vulnerable to an increasing threat of continually evolving cybersecurity risks. Unauthorized parties may attempt to gain access to our systems or information through fraud or other means of deceiving our employees or third-party service providers. Hardware, software or applications we develop or obtain from third parties may contain defects in design or manufacture, unknown security vulnerabilities, or other problems that could unexpectedly compromise information and device security. For example, the firmware, software, and open source software that we or our manufacturing partners have installed on our products may be susceptible to hacking, unauthorized manipulation, or misuse. Further, if we or our third-party providers are unable to properly secure our systems or successfully prevent breaches of security relating to our products, services, or user private information, including user videos and user personal identification information, or if these third-party systems fail for other reasons, our management could need to spend increasing amounts of time and effort in this area. The methods used to obtain unauthorized access, disable or degrade service or sabotage systems are also constantly changing and evolving, and may be difficult to anticipate or detect for long periods of time. Maintaining the security of our computer information systems and communication systems is a critical issue for us and our customers but the multitude and complexity of our computer systems may make them vulnerable to service interruption or destruction, disruption of data integrity, inadvertent errors that expose our data or systems, malicious intrusion, or random attacks. We have implemented and regularly review and update

processes and procedures to protect against unauthorized access to or use of secured data and to prevent data loss. However, the ever-evolving threats mean we must continually evaluate and adapt our systems and processes, and our efforts may not be adequate to safeguard against all data security breaches, misuse of data or sabotage of our systems. Any future significant compromise or breach of our data security, whether external or internal, or misuse of customer, third-party payor, employee, supplier or our own data, could result in additional significant costs, lost sales, fines, lawsuits and damage to our reputation. In addition, as the regulatory environment related to information security, data collection and use, and privacy becomes increasingly rigorous, with new and constantly changing requirements applicable to our business, compliance with those requirements could also result in additional costs.

Risks Related to Employee Matters and Managing Growth

We depend on the knowledge and skills of our senior management and other key employees, and if we are unable to retain and motivate them or recruit additional qualified personnel, our business may suffer.

We have benefited substantially from the leadership and performance of our senior management, as well as certain key employees. Our success depends, and will likely continue to depend, upon our ability to hire, retain the services of our current executive officers, principal consultants and others, including Edward Damiano, our co-founder and Chief Executive Officer and Firas El-Khatib, our co-founder, VP, Research and Innovation. We have entered into employment agreements with each of Messrs. Damiano and El- Khatib, but they may terminate their employment with us at any time. The loss of their services might impede the achievement of our research, development and commercialization objectives.

Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. Competition for senior management and key employees in our industry is intense and we cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. The loss of the services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements. Each member of senior management, as well as our key employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

We expect to experience significant growth over time in the number of our employees and the scope of our operations, particularly in the areas of regulatory and clinical affairs and sales, marketing and distribution, if our iLet system is cleared or approved for commercial sale. To manage our growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our

management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. As we expand our organization, we may have difficulty identifying, hiring and integrating new personnel. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of investigational devices. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow product revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our investigational devices and compete effectively will depend, in part, on our ability to effectively manage any future growth.

If we do not effectively manage our growth, our business resources may become strained and we may not be able to deliver the iLet system in a timely manner, which could harm our results of operations.

In order to market our iLet system, if cleared or approved, we will need to obtain regulatory approvals and reimbursement agreements with government agencies or private third-party payors in those countries. Failure to obtain such agreements would limit our ability to successfully penetrate those foreign, including the European, markets. In addition, the geographic expansion of our business will require additional manufacturing capacity to supply those markets as well as additional sales and marketing resources.

We expect to continue to increase our manufacturing capacity and our personnel, and we will need to develop additional capabilities to support our U.S. and international sales and marketing efforts, if the iLet system is cleared or approved by regulatory authorities. This growth, as well as any other growth that we may experience in the future, will provide challenges to our organization and may strain our management and operations resources. In order to manage future growth, we will be required to improve existing, and implement new, sales and marketing efforts and distribution channels. The form and function of our enterprise information technology systems will need to change and be improved upon as our business needs change. We will need to manage our supply chain effectively, including the development of our U.S. manufacturing, our relationship with sole source suppliers as well as other suppliers going forward. We may also need to partner with additional third-party suppliers to manufacture certain components of the iLet system and complete additional manufacturing lines in the future. A transition to new suppliers may result in additional costs or delays. We may misjudge the amount of time or resources that will be required to effectively manage any anticipated or unanticipated growth in our business, or we may not be able to manufacture sufficient inventory, or attract, hire and retain sufficient personnel to meet our needs. If we cannot scale our business appropriately, maintain control over expenses or otherwise adapt to anticipated and unanticipated growth, our business resources may

become strained, we may not be able to deliver the iLet system in a timely manner and our results of operations may be adversely affected.

We are subject to U.S. anti-corruption, export control, sanctions, and other trade laws and regulations, or, collectively, Trade Laws. We can face serious consequences for violations.

We are subject to anti-corruption laws, including the U.S. domestic bribery statute contained in 18 U.S.C. 201, the U.S. Travel Act, and the U.S. Foreign Corrupt Practices Act of 1977, as amended. These anti-corruption laws generally prohibit companies and their employees, agents, and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We may also have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or illegal activities of our agents and intermediaries, even if we do not explicitly authorize or have actual knowledge of such activities. We are also subject to other U.S. laws and regulations governing export controls, as well as economic sanctions and embargoes on certain countries and persons.

Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Likewise, any investigation of potential violations of Trade Laws could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Risks Relating to Our Status as a Public Benefit Corporation

As a public benefit corporation, our focus on a specific public benefit purpose and producing a positive effect for society may negatively impact our financial performance.

Unlike traditional corporations, which have a fiduciary duty to focus exclusively on maximizing stockholder value, our directors have a fiduciary duty to consider not only the stockholders' interests, but also the company's specific public benefit and the interests of other stakeholders affected by our actions. Therefore, we may take actions that we believe will be in the best interests of those stakeholders materially affected by our specific benefit purpose, even if those actions do not maximize our financial results. While we intend for this public benefit designation and obligation to provide an overall net benefit to us and people living with diabetes, it could instead cause us to make decisions and take actions without seeking to maximize the income generated from our business, and hence available for distribution to our stockholders. Our pursuit of longer-term or non- pecuniary benefits may not materialize within the timeframe we expect or at all, yet may have an immediate negative effect on any amounts available for distribution to our stockholders. Accordingly, being a public benefit corporation and complying with our related obligations could have a material adverse effect on our business, results of operations and financial condition.

If we lose our certification as a Certified B Corp or our publicly reported B Corp score declines, our reputation could be harmed and our business could be adversely affected.

Our business model and brand could be harmed if we were to lose our certification as a Certified B Corp. Certified B Corp status is a certification that requires us to consider the impact of our decisions on our workers, customers, suppliers, community and the environment. We believe that Certified B Corp status has allowed us to build credibility and trust among our customers. We dedicate significant resources to maintaining our Certified B Corp status, which is subject to annual audits by B Lab. Whether due to our choice or our failure to meet B Lab's certification requirements, any change in our status could create a perception that we are more focused on financial performance and no longer as committed to the values shared by Certified B Corp. Likewise, our reputation could be harmed if our publicly reported B Corp score declines and there is a perception that we are no longer committed to the Certified B Corp standards. Similarly, our reputation could be harmed if we take actions that are perceived to be misaligned with B Lab's values.

Any such harm to our reputation could have a material adverse effect on our business, financial position and results of operations.

General Risk Factors

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

In connection with the audit of our financial statements as of and for the year ended December 31, 2019, we identified material weaknesses in our internal control over financial reporting that existed during fiscal 2018 and remain unremediated as of December 31, 2020. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses we identified were as follows:

- We did not design and maintain an effective control environment as we lacked a sufficient complement of resources with an appropriate level of knowledge, experience and training commensurate with our financial reporting requirements. This material weakness contributed to the following material weaknesses:

- We did not design and maintain formal accounting policies, procedures and controls to achieve complete and accurate financial accounting and reporting.

- We did not design and maintain controls to ensure adequate segregation of duties within our financial reporting function, including the preparation and review of journal entries, account reconciliations and financial statements.

These material weaknesses resulted in misstatements to collaboration revenue and funded R&D liability due to a related party, which resulted in the restatement of our financial statements as of and for the year ended December 31, 2018 and adjustments to the accounting for a modification of the terms of certain preferred stock, affecting our preferred stock, additional paid-in capital, accumulated deficit and net loss attributable to common stockholders as of and for the year ended December 31, 2019, which were recorded prior to the issuance of the 2019 financial statements. Additionally, these material weaknesses could result in a misstatement of the aforementioned accounts or disclosures that would result in a material misstatement of our annual or interim financial statements that would not be prevented or detected.

We identified an additional material weakness as a result of the material weakness in our control environment in that we did not design and maintain effective controls over information technology, or IT, general controls for information systems that are relevant to the preparation of our financial statements. Specifically, we did not design and maintain:

(i) program change management controls for financial systems to ensure that IT program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately; and

(ii) user access controls to ensure appropriate segregation of duties and that adequately restrict user and privileged access to financial applications, programs and data to appropriate Company personnel.

These IT deficiencies did not result in a material misstatement to the financial statements; however, the deficiencies, when aggregated, could impact our ability to maintain effective segregation of duties, as well as the effectiveness of IT-dependent controls (such as automated controls that address the risk of material misstatement to one or more assertions, along with the IT controls and underlying data that support the effectiveness of system-generated data and reports) that could result in misstatements potentially impacting all financial statement accounts and disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. Accordingly, management has determined these deficiencies in the aggregate constitute a material weakness.

We have had limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. We are in the process of implementing measures designed to improve our internal control over financial reporting and remediate the control deficiencies that led to these material weaknesses, including hiring additional finance and accounting personnel, hiring a third-party accounting firm, including specialists, to assist us with the accounting for complex transactions, designing and implementing segregation of duties, designing and implementing formal accounting policies, procedures and controls, designing and implementing effective controls over IT general controls for information systems, and initiating design and implementation of our financial control environment.

We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiencies that led to these material

weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses.

Adverse changes in general economic conditions in the United States and outside of the United States, predominantly in Europe, could adversely affect us.

We are subject to the risks arising from adverse changes in general economic market conditions. A U.S. or global recession, could negatively impact our current and prospective customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our ability to pay our expenses and ability to obtain financing of our operations, cause delays or other problems with key suppliers and increase the risk of counterparty failures.

Healthcare spending in the United States, Canada and Europe could be negatively affected in the event of a downturn in economic conditions. For example, U.S. patients who have lost their jobs or healthcare coverage may no longer be covered by an employer-sponsored health insurance plan and patients reducing their overall spending may eliminate purchases requiring co-payments. Since the sale of the iLet system, if approved, to a new patient will be generally dependent on the availability of third-party reimbursement and will require the patient to make a significant co-payment, an economic downturn on our potential customers could reduce the referrals generated by our sales force and thereby reduce our customer orders. Similarly, existing customers at such time could cease purchasing the iLet system and return to other types of intensive insulin therapy, such as multiple daily injections, or other less-costly therapies, which would cause our attrition rate to increase. Any decline in new customer orders or increase in our customer attrition rate would reduce our revenue.

We may be subject to adverse legislative or regulatory changes in tax laws that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service, or IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability. Prospective investors should consult their tax advisors regarding the potential consequences of changes in tax law on our business and on the ownership and disposition of our Class B common stock.

Healthcare reform laws could adversely affect our revenue and financial condition.

During the past several years, the U.S. healthcare industry has been subject to an increase in governmental regulation at both the federal and state levels. Efforts to control healthcare costs, including limiting access to care, alternative delivery models and changes in the methods used to determine reimbursement scenarios and rates, are ongoing at the federal and state government levels. There are provisions of law that provide for the creation of a new public-private Patient-Centered Outcomes Research Institute tasked with identifying comparative effectiveness research

priorities. For example, establishing a research project agenda and contracting with entities to conduct the research in accordance with the agenda. Research findings published by this institute are publicly disseminated. It is difficult at this time to determine whether a comparative effectiveness analysis impacting our business will be done, and assuming one is, what impact that analysis will have on the iLet system or our future financial results.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries, presidential executive orders and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. For example, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives.

In addition, the ACA and related healthcare reform laws, regulations and initiatives have significantly increased regulation of managed care plans and decreased reimbursement to Medicare managed care. Some of these initiatives purport to, among other things, require that health plan members have greater access to drugs not included on a plan's formulary. Moreover, to alleviate budget shortfalls, states have reduced or frozen payments to Medicaid managed care plans. We cannot accurately predict the complete impact of these healthcare reform initiatives, but they could lead to a decreased demand for our products and other outcomes that could adversely impact our business and financial results.

There remain judicial and Congressional challenges to certain aspects of the ACA. In addition, there were efforts by the Trump administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the "individual mandate," effective January 1, 2019. On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held that the individual mandate is unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. The U.S. Supreme Court is currently reviewing this case, but it is unknown when a decision will be reached. Although the U.S. Supreme Court has yet to rule on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the U.S. Supreme Court ruling, other such litigation, and the healthcare form measures of the Biden administration will impact the

ACA and our business. Additional legislative changes, regulatory changes, and judicial challenges related to the ACA remain possible. It is possible that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have an adverse effect on our industry generally and on our ability to maintain or increase sales of any of our products and achieve profitability.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for deficit reduction of at least $1.2 trillion for the years 2013 through 2021. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction, which triggered the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of, up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless Congress takes additional action. However, the Medicare sequester reductions under the Budget Control Act are suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. In January 2013, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

At the state level, legislatures in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs.

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

As of April 9, 2021, we expect that our existing cash, cash equivalents and short-term investments will be sufficient to fund our operating expenses and capital expenditure requirements through September 30, 2021. Beyond that point, we will need to raise additional capital to finance our operations, which cannot be assured. We concluded as of April 9, 2021, the issuance date our financial statements for the year ended December 31, 2020, that this circumstance raised substantial doubt about our ability to continue as a going concern within one year of the issuance date of those financial statements. See Note 1 to our financial statements appearing at the end of this report for additional information on our assessment.

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

Except for omitting certain audited financial statements in our Form C-AR filing for fiscal year 2020 initially filed on April 30, 2021, we have not previously failed to comply with the requirements of Regulation Crowdfunding, and we are current in our ongoing reporting obligations under Regulation CF.

EXHIBIT A

FINANCIAL STATEMENTS AND REPORT OF INDEPENDENT AUDITORS

Beta Bionics, Inc.

Financial Statements

December 31, 2020 and 2019

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REPORT OF INDEPENDENT AUDITORS

To the Board of Directors of Beta Bionics, Inc.

We have audited the accompanying financial statements of Beta Bionics, Inc., which comprise the balance sheets as of December 31, 2020 and 2019, and the related statements of operations and comprehensive loss, of convertible preferred stock and stockholders' deficit and of cash flows for the years then ended.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on the financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on our judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the Company's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Beta Bionics, Inc. as of December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

Emphasis of Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred recurring losses from operations since inception, expects to continue to generate operating losses for the foreseeable future, will require additional capital to finance its future operation and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
April 9, 2021

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

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

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

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

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)

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

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 deferred 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

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

1. Nature of Business and Basis of Presentation

Beta Bionics, Inc. (the "Company") was incorporated as a Massachusetts benefit corporation on October 21, 2015. The Company is a medical device company focused on the design, development and commercialization of a solution for people with diabetes on intensive insulin therapy. The Company's investigational device, which it refers to as the iLet bionic pancreas, is designed to leverage continuous, subcutaneous, insulin-pump technology and adaptive control algorithms to administer either insulin, glucagon, or both, in an autonomous manner to mimic the body's natural ability to maintain a targeted glycemic range.

The Company is subject to risks and uncertainties common to companies in the medical device industry and of similar size, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, uncertainty of market acceptance of products, and the need to obtain additional financing to fund operations. Potential risks and uncertainties also include, without limitation, uncertainties regarding the duration and magnitude of the impact of the COVID-19 pandemic on the Company's business and the economy generally. Products currently under development will require additional research and development efforts prior to commercialization and will require additional capital and adequate personnel and infrastructure. The Company's research and development may not be successfully completed, adequate protection for the Company's technology may not be obtained, the Company may not obtain necessary government regulatory approval for its products, and approved products may not prove commercially viable. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Going Concern

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

Through December 31, 2020, the Company has funded its operations primarily with proceeds from sales of convertible preferred stock and payments received in connection with collaboration arrangements and government grants. The Company has incurred recurring losses since its inception, including net losses of $14.7 million and $29.6 million for the years ended December 31, 2019 and 2020, respectively. In addition, as of December 31, 2020, the Company had an accumulated deficit of $66.0 million. The Company expects to continue to generate operating

losses for the foreseeable future. As of April 9, 2021, the issuance date of the financial statements for the year ended December 31, 2020, the Company expects that its existing cash and short-term investments will be sufficient to fund its operating expenses and capital expenditure requirements through September 30, 2021. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company expects to seek additional funding through equity financings, debt financings, or other capital sources, which may include collaborations with other companies, government funding arrangements or other strategic transactions. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or the rights of the Company's stockholders.

If the Company is unable to obtain funding, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Based on its recurring losses from operations incurred since inception, expectation of continuing losses for the foreseeable future and need to raise additional capital to finance its future operations, as of April 9, 2021, the issuance date of the financial statements for the year ended December 31, 2020, the Company has concluded that there is substantial doubt about its ability to continue as a going concern for a period of one year from the date that these financial statements were issued.

The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

COVID-19

The outbreak of SARS-CoV-2, the novel strain of coronavirus that causes COVID-19, has evolved into a global pandemic. The extent to which COVID-19 impacts the Company's business and operating results will depend in part on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, including potential variants thereof, and the actions taken to contain COVID-19 or treat its impact, among others.

Infections and deaths related to the pandemic have disrupted and may continue to disrupt the United States' healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay review and/or approval by the U.S. Food and Drug Administration (the "FDA") with respect to, the Company's clinical trials. Any elongation or de-prioritization of clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and commercialization of the Company's iLet system.

In response to these public health directives and to help reduce the risk to its employees, the Company took precautionary measures, including implementing work-from-home policies for its employees. The Company plans to continue these measures and is assessing when and how to resume normal operations. The effects of its work-from-home policies may negatively impact productivity, disrupt its business and delay the development of its iLet system and timelines and future clinical trials, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Company's ability to conduct its business in the ordinary course. These and similar, and perhaps more severe, disruptions in the Company's operations could negatively impact our business, results of operations and financial condition, including our ability to obtain financing.

The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, has impacted the timetable for development of the Company's iLet system for the treatment of type 1 diabetes, in both its insulin-only and bi-hormonal configurations and may continue to have an adverse effect on our business. In particular, the COVID-19 pandemic impacted the Company's trial execution plans for the iLet insulin-only configuration pivotal trial and caused delays in the timeline of the clinical trial.

While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and may result in further, significant disruption of global financial markets, which may reduce the Company's ability to access capital either at all or on favorable terms. The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change.

2. Significant Accounting Policies

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, revenue recognition and the valuation of common stock, stock-based awards and a preferred stock

modification. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

The Company is monitoring the potential impact of the COVID-19 pandemic on its business and financial statements. The Company is not aware of any specific event or circumstance that would require an update to its estimates or judgments reflected in these financial statements or a revision of the carrying value of its assets or liabilities as of April 9, 2021, the issuance date of these financial statements. These estimates may change as new events occur and additional information is obtained.

Deferred Offering Costs

The Company capitalizes certain legal, accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholder's equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the statement of operations and comprehensive loss. The Company had no deferred offering costs recorded as of December 31, 2019. The Company recorded $0.2 million of deferred offering costs on the balance sheet as of December 31, 2020.

Concentrations of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash, cash equivalents, accounts receivable—related party (see Note 14) and short-term investments. The Company maintains its cash, cash equivalents and short-term investments in custodian accounts and certificates of deposit in accredited financial institutions. The Company does not believe that it is subject to unusual risk beyond the normal credit risk associated with commercial banking relationships.

The Company relies, and expects to continue to rely, on a small number of vendors to manufacture supplies and to process its investigational devices for its development programs. These programs could be adversely affected by a significant interruption in the manufacturing process or supply chain.

Cash Equivalents

The Company considers all highly liquid investments purchased with original maturities of three months or less to be cash equivalents.

Restricted Cash

In connection with the Company's lease agreement entered into May 2019 (see Note 13), the Company is required to maintain a letter of credit of $0.1 million for the benefit of the landlord. As of December 31, 2019 and 2020, this amount was guaranteed by a deposit in a money market fund and classified as restricted cash on the balance sheets.

Short-Term Investments

Short-term investments consist of certificates of deposits with a financial institution. All investments have original maturities of greater than three months and less than one year from the balance sheet date and are classified as held-to-maturity, as the Company believes it has the intent and ability to hold the securities to maturity. The investments are recorded at amortized cost, which approximates fair value.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

Level 1 — Quoted prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and restricted cash are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). The fair values of the Company's accounts receivables— related party, accounts payable and accrued expenses approximate their carrying values due to the short-term nature of these assets and liabilities. The fair value of the Company's short-term investments in certificates of deposit, which are held until maturity, approximates their aggregate carrying value at amortized cost.

Accounts Receivable

For the periods presented, all of the Company's accounts receivable consisted of amounts billed and due from its collaboration partner, Novo Nordisk A/S ("Novo Nordisk"). During the year ended December 31, 2019, Novo Nordisk was a related party (see Note 14). As a result, as of December 31, 2019, amounts due from Novo Nordisk were presented as accounts receivable— related party on the balance sheet. No amounts were due from Novo Nordisk as of December 31, 2020.

The Company has implemented an allowance for doubtful accounts for estimated losses related to accounts receivable. In determining the allowance, consideration includes the probability of recoverability based on prior experience and general economic factors. Certain accounts receivable may be fully reserved when the Company becomes aware of any specific collection issues. As of December 31, 2019 and 2020, the Company had no allowance for doubtful accounts. During the years ended December 31, 2019 and 2020, the Company did not record any provisions for doubtful accounts and did not write off any accounts receivable balances.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Manufacturing and medical equipment	5 years
Furniture	5 years
Computer equipment	2 years
Leasehold improvements	Shorter of remaining lease term or 10 years

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any

resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance that do not improve or extend the life of the respective asset are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. The Company continually evaluates long-lived assets to be held and used for potential impairment whenever events or changes in circumstances indicate the carrying value of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares the carrying values of the asset group to the expected future undiscounted cash flows that the asset group is expected to generate from the use and eventual disposition of the long-lived asset group. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. If such asset group is considered to be impaired, the impairment loss to be recognized is measured based on the excess of the carrying value of the impaired asset group over its fair value. The Company did not recognize any impairment losses during the years ended December 31, 2019 or 2020.

Deferred Rent

The Company's lease agreements include payment escalations, which are accrued or deferred as appropriate such that rent expense for each lease is recognized on a straight-line basis over the respective lease term. Adjustments for such items, consisting primarily of payment escalations, are recorded as deferred rent and amortized over the respective lease terms.

Classification and Accretion of Convertible Preferred Stock

The Company's convertible preferred stock is classified outside of stockholders' deficit on the balance sheets because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock. The Company's Series A, Series A-2, Series B and Series B-2 convertible preferred stock are not redeemable, except in the event of a deemed liquidation (see Note 7). Because the occurrence of a deemed liquidation event is not currently probable, the carrying values of the convertible preferred stock are not being accreted to their redemption values. Subsequent adjustments to the carrying values to the convertible preferred stock would be made only when a deemed liquidation event becomes probable.

Contingencies

In the normal course of business, the Company is subject to loss contingencies, such as legal proceedings and claims arising out of its business, that cover a wide range of matters. The Company records accruals for those loss contingencies when it is probable that a liability will be incurred and the amount of loss can be reasonably estimated. The Company does not recognize gain contingencies until realized. As of December 31, 2019 and 2020, no liabilities were recorded for loss contingencies (see Note 13).

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is focused on developing its iLet system for safe and effective autonomous glycemic control in type 1 diabetes. Operating segments are defined as components of an enterprise for which separate financial information is regularly evaluated by the Company's chief operating decision maker, or decision-making group, in deciding how to allocate resources and assess performance. The Company has determined that its chief operating decision maker is its Chief Executive Officer.

For the periods presented, all of the Company's long-lived assets were held in the United States, and all of the Company's collaboration revenue was derived from its collaboration partner, Novo Nordisk, headquartered in Denmark. During the year ended December 31, 2019, Novo Nordisk was a related party (see Note 14).

Revenue Recognition

The Company's primary product is not yet commercially available for sale. Until these sales begin, the Company's only source of revenue, from time to time, is from research and collaboration agreements with various pharmaceutical and biotechnology companies one of which, Novo Nordisk, was a related party during the year ended December 31, 2019 (see Note 14).

Revenue from Contracts with Customers

In accordance with ASC 606, *Revenue from Contracts with Customers* ("ASC 606"), the Company recognizes revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract and (v) recognize revenue when (or as) the entity satisfies a performance obligation. Once the contract is determined to be within the scope of ASC 606, at contract inception, the Company assesses the goods or services promised within each contract and determines those that are performance

obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

During the years ended December 31, 2019 and 2020, the Company had no arrangements accounted for and no amounts of revenue recognized under ASC 606.

Collaboration Revenue

The Company evaluates its license and/or collaboration arrangements to determine whether the arrangement (or part of the arrangement) represents a collaborative arrangement pursuant to ASC 808, *Collaborative Arrangements* ("ASC 808"). The Company considers the nature and contractual terms of collaborative arrangements and assesses whether the arrangement (or any part of the arrangement) involves joint operating activities pursuant to which the Company is an active participant in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. If the Company is an active participant and is exposed to significant risks and rewards with respect to the arrangement, the Company accounts for the arrangement as a collaboration under ASC 808.

The Company also evaluates whether the license and/or collaboration arrangements represent a contract with a customer pursuant to the scope of ASC 606. The Company accounts for collaborative arrangements (or elements within the contract that are deemed part of a collaborative arrangement) outside the scope of ASC 606 whenever the collaboration represents a collaborative relationship and not a customer relationship. In the periods presented, the Company has concluded that its collaboration agreement with Novo Nordisk does not represent a customer relationship and, accordingly, is accounted for under ASC 808 and is reflected in the statement of operations and comprehensive loss as collaboration revenue— related party for the year ended December 31, 2019 and as collaboration revenue for the year ended December 31, 2020 (see Note 12).

ASC 808 does not address recognition or measurement matters related to collaborative arrangements. Under ASC 808, payments between participants pursuant to a collaborative arrangement that are within the scope of other authoritative accounting literature on income statement classification are accounted for using the relevant provisions of that literature. If the payments are not within the scope of other authoritative accounting literature, the income statement classification for the payments is based on an analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational and consistently applied accounting policy election (see Note 12). Payments received from a collaboration partner to which this policy applies may include upfront payments in respect of a license of intellectual property, development and commercialization-based milestones, and royalties.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses consist of both internal and external costs incurred in performing research and development activities, including employee-related expenses, material expenses, consulting services, contract services and manufacturing costs associated with the development of the Company's investigational device, costs associated with licensing the technology as well as costs related to performance under collaboration arrangements, and the allocation of corporate costs, such as facility rent, utilities and depreciation.

Upfront payments under license agreements are expensed upon receipt of the license, and annual maintenance or minimum royalty fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued, with a corresponding expense being recognized, in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

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 (see Note 4).

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.

Stock-Based Compensation

The Company accounts for stock-based compensation awards in accordance with FASB ASC Topic 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires all stock-based

compensation to employees, including grants of employee stock options and restricted stock and modifications to existing stock options, to be recognized in the statement of operations and comprehensive loss based on their grant date fair values.

For stock-based awards granted to employees, non-employees and directors, the Company estimates the grant-date fair value of each award using the Black-Scholes option-pricing model. Compensation expense for awards related to employees and directors is recognized over the requisite service period, which is generally the vesting period of the respective award. Compensation expense for non-employee awards is recognized in the same manner as if the Company had paid cash in exchange for the goods or services, which is generally the vesting period of the respective award. The Company issues awards with only service-based vesting conditions and records the expense for these awards using the straight-line method. The Company accounts for forfeitures of stock options as they occur rather than applying an estimated forfeiture rate to stock-based compensation expense.

The Company classifies stock-based compensation expense in its statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2019 and 2020, there was no difference between net loss and comprehensive loss.

Net Income (Loss) per Share

The Company follows the two-class method when computing net income (loss) per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to share in undistributed earnings as if all income (loss) for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is computed by dividing net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net income (loss) per share attributable to common stockholders is computed by adjusting net income (loss) attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted-

average number of common shares outstanding for the period, including potential dilutive common shares. For purposes of this calculation, the Company's outstanding stock options and convertible preferred stock are considered potential dilutive common shares.

The Company's convertible preferred stock contractually entitles the holders of such shares to participate in dividends but does not contractually require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders, since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. The Company reported a net loss attributable to common stockholders for the years ended December 31, 2019 and 2020.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statements and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse.

Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Recently Adopted Accounting Pronouncements

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718), Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). The standard expands the scope of ASC 718 (which currently only includes share-based payments to employees) to include share based payments issued to non-employees for goods or services. Under the new guidance, the existing employee guidance will apply to non-employee share-based transactions (as long as the transaction is not effectively a form of financing), with the exception of specific guidance related to the attribution of compensation cost. The cost of non-employee awards is recorded as if the grantor had paid cash for the goods or services. For public entities, ASU 2018-07 was required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For nonpublic entities, ASU 2018-07 is effective for annual periods beginning after December 15, 2019. Early adoption is permitted for all entities but no earlier than the Company's adoption of ASU 2014-09. The Company adopted ASU 2018-07 on January 1, 2019, and the adoption did not have a material impact on the Company's financial statements.

In November 2016, the FASB issued ASU No. 2016-18, *Statement of Cash Flows (Topic 230), Restricted Cash* ("ASU 2016-18"). The amendments of ASU 2016-18 were issued to address the diversity in classification and presentation of changes in restricted cash and restricted cash equivalents on the statement of cash flows, which is currently not addressed under Topic 230. ASU 2016-18 requires an entity to include amounts generally described as restricted cash and restricted cash equivalents with cash and cash equivalents when reconciling the beginning of period and end of period total amounts on the statement of cash flows. The new accounting guidance was adopted by the Company on January 1, 2019, and the adoption did not have a material impact on the Company's financial statements.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "ASC 842"), which sets out the principles for the recognition, measurement, presentation, and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. In addition, a lessee is required to record (i) a right-of-use asset and a lease liability on its balance sheets for all leases with accounting lease terms of greater than 12 months regardless of whether it is an operating or finance lease and (ii) lease expense in its statement of operations for operating leases and amortization and interest expense in its statement of operations for finance leases. Leases with a term of 12 months or less may be accounted for similar to prior guidance for operating leases under ASC 840. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842)*, which added an optional transition method that allows companies to adopt the standard as of the beginning of the year of adoption as opposed to the earliest comparative period presented. In November 2019, the FASB issued guidance delaying the effective date for all entities, except for public business entities. For public entities, ASU 2016-02 was effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. In June 2020, the FASB issued ASU No. 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities* ("ASU 2020-05"), which delayed the adoption date of ASU 2016-02 for nonpublic entities. For nonpublic entities, ASU 2016-02 is effective for annual periods beginning after December 15, 2021. Early adoption is permitted. ASU 2016-02 will be effective for the Company as of January 1, 2022. The Company plans to adopt the new standard using the modified retrospective transition method. Under this method, financial statements for periods after the adoption date are presented in accordance with ASC 842 and prior-period financial statements continue to be presented in accordance with ASC 840, *Leases* ("ASC 840"), the accounting standard originally in effect for such periods. While its assessment is incomplete, the Company currently expects that its adoption of ASC 842, which relates to the Company's existing operating leases for office, laboratory and manufacturing space, will result in the recognition of operating lease liabilities and right-of-use assets of material amounts and the derecognition of deferred rent liabilities on its balance sheet as of the adoption date. In addition, the Company currently expects that its adoption of ASC 842 will not have a net material impact on its statements of operations and comprehensive loss or its statements of cash flows.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04 and ASU 2019-05 (collectively, "Topic 326"). Topic 326 requires measurement and recognition of expected credit losses for financial assets held. For public entities that are Securities and Exchange Commission filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. In November 2019, the FASB issued ASU No.

2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. Topic 326 is effective for the Company beginning January 1, 2023, and earlier adoption is permitted. The Company is currently evaluating the impact that Topic 326 will have on its financial position, results of operations and disclosures.

3. Financial Instruments and Fair Value Measurements

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31,2019 Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market fund	$ 18,907	$ —	$ —	$ 18,907
Restricted cash:				
Money market fund	100	—	—	100
	$ 19,007	$ —	$ —	$ 19,007

	Fair Value Measurements at December 31,2020 Using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market fund	$ 65,012	$ —	$ —	$ 65,012
Restricted cash:				
Money market fund	100	—	—	100
	$ 65,112	$ —	$ —	$ 65,112

Money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no changes to the valuation methods during the years ended December 31, 2019 and 2020. The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Level 1 or Level 2 during the years ended December 31, 2019 and 2020.

4. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2019	2020
Prepaid expenses	$ 491	$ 803
Grants receivable	277	421
Interest receivable on short-term investments	582	139
Other current assets	104	120
	$ 1,454	$ 1,483

5. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	December 31,	
	2019	2020
Manufacturing and medical equipment	$ 1,948	$ 2,449
Leasehold improvements	691	1,130
Furniture	100	674
Computer equipment	203	300
Construction in progress	98	922
	3,040	5,475
Less: Accumulated depreciation and amortization	(468)	(1,389)
	$ 2,572	$ 4,086

Depreciation and amortization expense for the years ended December 31, 2019 and 2020 was $0.5 million and $1.0 million, respectively.

6. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following (in thousands):

	December 31,	
	2019	2020
Accrued employee compensation and benefits	$ 1,271	$ 1,960
Accrued professional services fees	685	1,137
Accrued consulting fees	136	393
Other current liabilities	129	246
	$ 2,221	$ 3,736

7. Convertible Preferred Stock

The Company has issued Series A convertible preferred stock (the "Series A Preferred Stock"), Series A-2 convertible preferred stock (the "Series A-2 Preferred Stock"), Series B convertible preferred stock (the "Series B Preferred Stock"), and Series B-2 convertible preferred stock (the "Series B-2 Preferred Stock," and collectively with the Series A Preferred Stock, the Series A-2 Preferred Stock and the Series B Preferred Stock, the "Preferred Stock").

In December 2015, the Company issued and sold 50,000 shares of Series A Preferred Stock, at a price of $100.00 per share, for gross proceeds of $5.0 million.

In September 2016, the Company issued and sold 50,000 shares of Series A-2 Preferred Stock, at a price of $100.00 per share, for gross proceeds of $5.0 million.

In December 2017, the Company issued and sold 15,664 shares of Series B Preferred Stock, at a price of $150.20 per share, for gross proceeds of $2.4 million.

From June to December 2018, the Company issued and sold an additional 404,129 shares of Series B Preferred Stock, at a price of $150.20 per share, for gross proceeds of $60.7 million. In addition, as of December 31, 2018, the Company reduced the carrying value of the Series B Preferred Stock for subscriptions receivable from the sale of such stock by an amount of $6.5 million. In January 2019, the Company collected the subscriptions receivable from investors of $6.5 million and recorded that receipt as an increase to the carrying value of the Series B Preferred Stock.

In June 2019, the Company issued and sold 396,000 shares of Series B-2 Preferred Stock to new and existing investors, at a price of $160.00 per share, for gross proceeds of $63.3 million. The Company incurred issuance costs in connection with this transaction of $0.1 million.

Upon issuance of each class of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each class of Preferred Stock.

Extinguishment of Series A and Series A-2 Preferred Stock

In June 2019, in connection with the Series B-2 Preferred Stock financing and in exchange for the cancellation of certain protective anti-dilution rights by the two and only holders of the Company's Series A and Series A-2 Preferred Stock, the Company entered into an agreement (i) to issue an aggregate of 58,920 shares of its Class B common stock to the stockholders, which shares were issued in early- July 2019, and (ii) committing the Company to issue a specified number of shares of its Class B common stock if the Company had not consummated an IPO of

its common stock, on specified terms, by June 30, 2020. As a result of not having fulfilled the commitment, in September 2020, the Company issued an aggregate of 47,893 shares of its Class B common stock to the two stockholders, one of which was Novo Nordisk, which was a related party during the year ended December 31, 2019 (see Note 14).

The agreement with the stockholders resulted in the Company amending the terms of the Series A and Series A-2 Preferred Stock to reflect the removal of the certain anti-dilution rights that had lowered the original Conversion Price (as described below) of such stock upon subsequent stock sales and issuances by the Company, prior to the modification. This amendment to the terms of the Series A and Series A-2 Preferred Stock was accounted for as an extinguishment of preferred stock based on a quantitative assessment of the change in the fair value that resulted from the modification as of the modification date, given that there was greater than a 10% change in the fair values of Series A and Series A-2 Preferred Stock measured immediately before and after the modification. The loss on extinguishment of the preferred stock, equal to $8.3 million, was treated as a deemed dividend paid on preferred stock, thereby being recognized within stockholders' deficit and affecting the calculation of net loss per share attributable to common stockholders for the period.

The deemed dividend to the Series A and Series A-2 Preferred Stock of $8.3 million consisted of the impact of three components reflected in the agreement made with the holders of such stock:

- For the 58,920 shares of Class B common stock issued to the stockholders in early-July 2019, the Company recorded the issuance of such shares at the aggregate fair value of the Class B common stock as of the agreement date, recording an increase to additional paid-in capital of $3.2 million.

- For the commitment to issue 47,893 shares of its Class B common stock if an IPO of common stock had not been consummated by June 30, 2020, the Company recorded the contingent commitment at the fair value of the commitment when made, recording an increase to additional paid-in capital of $1.8 million. The Company concluded that the contingent commitment qualified for the equity contract scope exception and accounted for the commitment as an equity instrument.

- The Company derecognized from the balance sheet the aggregate carrying value of the Series A and Series A-2 Preferred Stock as of the modification date, totaling $10.0 million. The Company then recorded the modified Series A and Series A-2 Preferred Stock on the balance sheet at the aggregate fair value of such stock immediately after its terms were modified, totaling $13.3 million.

The $8.3 million deemed dividend to the Series A and Series A-2 Preferred Stock was recognized within stockholders' deficit first by recording a $5.8 million decrease to additional paid-in capital, reducing such balance at that time to $0, and then by increasing accumulated deficit by $2.5 million for the residual amount.

The fair values of (i) the shares of Class B common stock issued in early-July 2019, (ii) the contingent commitment to issue 47,893 shares of Class B common stock if an IPO of common stock had not been consummated by June 30, 2020 and (iii) the shares Series A and Series A-2 Preferred Stock immediately before and after the modification of their terms were estimated by the Company's management taking into consideration the results obtained from third-party valuations of each item, prepared as of the modification date, that utilized methodologies and assumptions consistent with the Company's most recent common stock valuations, including on a minority, nonmarketable interest basis. In these third-party valuations, the Company's aggregate equity value was determined using an option pricing method ("OPM") backsolve approach that was based on the $160.00 price paid per share by new and existing investors in the Company's Series B-2 Preferred Stock financing that closed on the same date in June 2019 as the Series A and Series A-2 Preferred Stock modification date.

Terms of Preferred Stock

At the balance sheet dates, Preferred Stock consisted of the following (in thousands, except share amounts):

	December 31, 2019 and 2020				
	Preferred Stock Authorized	**Preferred Stock Issued and Outstanding**	**Carrying Value**	**Liquidation Preference**	**Common Stock Issuable Upon Conversion**
Series A Preferred Stock	50,000	50,000	$ 6,589	$ 5,000	50,000
Series A-2 Preferred Stock	50,000	50,000	6,626	5,000	50,000
Series B Preferred Stock	420,000	419,793	61,606	63,053	419,793
Series B-2 Preferred Stock	450,000	396,000	63,228	63,360	396,000
	970,000	915,793	$138,049	$136,413	915,793

The holders of Preferred Stock have the following rights and preferences:

Voting

The holders of the Preferred Stock are entitled to vote, together with the holders of Class A common stock and Class B common stock as a single class, on all matters submitted to stockholders for a vote. Each holder of Preferred Stock is entitled to the number of votes equal to the number of shares of Class B common stock into which each share of Preferred Stock is convertible as of the record date for determining stockholders entitled to vote on such matters. The holders of Series B Preferred Stock, exclusively and as a separate class, are entitled to elect one director of the Company.

Conversion

Each share of Preferred Stock is convertible into shares of Class B common stock at the option of the holder at any time after the date of issuance. Each share of Preferred Stock will be automatically converted into shares of common stock, at the applicable conversion ratio then in effect, upon either (i) the closing of a firm commitment public offering with at least $50.0 million of gross proceeds, net of the underwriting discount and commissions, to the Company and at an implied pre-money valuation of at least $250.0 million or (ii) the vote or written consent of at least a majority of the then-outstanding shares of Preferred Stock, voting together as a single class on an as-converted basis.

The conversion ratio of each series of Preferred Stock is determined by dividing the Original Issue Price of each series by the Conversion Price of each series. The Original Issue Price is $100.00 per share for Series A Preferred Stock, $100.00 per share for Series A-2 Preferred Stock, $150.20 per share for Series B Preferred Stock and $160.00 per share for Series B-2 Preferred Stock. The Conversion Price is $100.00 per share for Series A Preferred Stock, $100.00 per share for Series A-2 Preferred Stock, $150.20 per share for Series B Preferred Stock and $160.00 per share for Series B-2 Preferred Stock, each subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization and other adjustments as set forth in the Company's certificate of incorporation, as amended and restated. As a result, as of December 31, 2019 and 2020, each outstanding share of Preferred Stock was convertible into Class B common stock on a one-for-one basis.

In the event the Company at any time after the Preferred Stock Series B-2 original issue date issues additional shares of common stock without consideration or for a consideration per share less than the applicable Conversion Price of each series in effect immediately prior to such issuance, the applicable Conversion Price of each series of Preferred Stock will be reduced, concurrently with such issue, to the appropriate price that will effectuate anti-dilution of existing holders of Preferred Stock.

Dividends

The holders of shares of Series A Preferred Stock and Series A-2 Preferred Stock are entitled to receive, when, as and if declared by the board of directors on a *pari passu* basis, non-cumulative cash dividends of 4% per annum of each respective Original Issue Price, and the holders of Series B Preferred Stock and B-2 Preferred Stock are entitled to receive, when, as and if declared by the board of directors on a *pari passu* basis, non-cumulative cash dividends of 2% per annum of each respective Original Issue Price (the "Annual Dividend" for each respective series). The Company shall not declare, pay or set aside any dividends on shares of any other class or series of stock of the Company unless the holders of the Preferred Stock then outstanding shall first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to the Annual Dividend plus: (i) in the case of a dividend on common stock or any class or series of stock that is convertible into common stock, a dividend per share of Preferred Stock that would equal the product of (A) the dividend payable on each share of such class or series

determined, if applicable, as if all shares of such class or series had been converted into common stock and (B) the number of shares of common stock issuable upon conversion of a share of Preferred Stock; or (ii) in the case of a dividend on any class or series of stock that is not convertible into common stock, at a rate per share of Preferred Stock determined by (A) dividing the amount of the dividend payable on each share of such class or series of stock by the Original Issue Price of such class or series of stock (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to such class or series) and (B) multiplying such fraction by an amount equal to the Original Issue Price of such class or series. If the Company declares, pays or sets aside, on the same date, a dividend on shares of more than one class or series of stock of the Company, the dividend payable to the holders of the Preferred Stock will be calculated based upon the dividend on the class or series of stock that would result in the highest Preferred Stock dividend.

Through December 31, 2020, no dividends had been declared on any series or class of shares.

Liquidation

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company or Deemed Liquidation Event (as described below), the holders of shares of Preferred Stock are entitled to be paid out of the assets of the Company available for distribution to its stockholders *pari passu* before any payments are made to holders of the common stock. The holders of shares of Preferred Stock are entitled to an amount per share equal to the greater of (i) the applicable Original Issue Price per share of each respective share of Preferred Stock, plus all dividends declared but unpaid thereon, or (ii) the amount that would have been payable had all shares of the series been converted to common stock immediately prior to the liquidation, dissolution, winding-up or Deemed Liquidation Event. If upon any such liquidation event, the assets of the Company available for distribution are insufficient to pay the holders of Preferred Stock the full amount to which they are entitled, the holders of Preferred Stock will share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would be otherwise payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

Unless the holders of at least a majority of the outstanding shares of Series A Preferred Stock, Series A-2 Preferred Stock, Series B Preferred Stock and Series B-2 Preferred Stock, each voting as a separate class, elect otherwise, a Deemed Liquidation Event shall include a merger, consolidation, or share exchange (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

8. Common Stock

The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above.

The holders of Class A common stock are entitled to ten votes for each share of common stock, and the holders of Class B common stock are entitled to one vote for each share of common stock, together with the holders of the Preferred Stock, on all matters submitted to the stockholders for a vote. In the event the voting rights of the Class A common stock, voting together as a single class, cease to represent a majority of the votes represented by all outstanding shares of capital stock of the Company entitled to vote, the number of votes attributable to each share of Class A common stock shall be increased to such next whole number which would provide the Class A common stock with majority voting rights.

The holders of Class C common stock do not have voting rights.

As of December 31, 2020, the Company had reserved 1,495,000 shares of Class B common stock for the potential conversion of shares of Preferred Stock into common stock and the exercise of outstanding and available-for-grant stock options.

9. Stock-Based Compensation

2016 Stock Incentive Plan

The Company's 2016 Stock Incentive Plan, as amended (the "2016 Plan"), provides for the Company to grant stock options and restricted stock awards to employees, officers, directors and consultants of the Company. The 2016 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee if so delegated.

Stock options granted under the 2016 Plan with service-based vesting conditions typically vest over four years and expire after ten years. The total number of shares of Class B common stock that may be issued under the 2016 Plan was 525,000 shares as of December 31, 2020, of which 57,470 shares remained available for future issuance as of December 31, 2020. Shares that are expired, terminated, surrendered or canceled without having been fully exercised will be available for future grant under the 2016 Plan.

The exercise price for stock options granted may not be less than the fair value of Class B common stock as determined by the board of directors as of the date of grant. The Company's board of directors values the Company's Class B common stock taking into consideration the most recent sales of the Company's preferred stock, results obtained from third-party valuations and additional factors the Company deems relevant and which may have changed since the date of the most recent contemporaneous valuation through the date of grant.

Common Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted:

	Years Ended December 31,	
	2019	**2020**
Fair value of common stock	$ 50.05	$ 58.84
Risk-free interest rate	1.86 %	0.47 %
Expected term (in years)	5.99	5.92
Expected volatility	72.56 %	67.42%
Expected dividend yield	0 %	0 %

Stock Option Activity

The following table summarizes the stock option activity since December 31, 2018:

	Number of Shares	**Weighted-Average Exercise Price**	**Weighted-Average Remaining Contractual Term (in years)**	**Aggregate Intrinsic Value (in thousands)**
Outstanding at December 31, 2018	100,000	$ 18.23	7.9	$ 2,317
Granted	207,125	53.79		
Exercised	—	—		
Forfeited or cancelled	—	—		
Outstanding at December 31, 2019	307,125	$ 42.21	8.9	$ 3,900
Granted	168,680	58.37		
Exercised	—	—		
Forfeited or cancelled	(8,275)	54.91		
Outstanding at December 31, 2020	467,530	$ 47.81	8.5	$ 15,441

Vested and expected to vest at December 31, 2020	467,530	$ 47.81	8.5	$	15,441
Options exercisable at December 31, 2020	164,950	$ 32.87	7.2	$	7,913

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's Class B common stock for those stock options that had exercise prices lower than the fair value of the Company's Class B common stock. There was no aggregate intrinsic value of stock options exercised during the years ended December 31, 2019 and 2020.

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2019 and 2020 was $35.14 per share and $35.00 per share, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense related to the stock options was included in the Company's statement of operations and comprehensive loss as follows (in thousands):

	Years Ended December 31,	
	2019	**2020**
Sales and marketing	$ 20	$ 285
Research and development	426	1,196
General and administrative	167	1,021
	$ 613	$ 2,502

As of December 31, 2020, total unrecognized stock-based compensation expense related to the unvested stock-based awards was $10.1 million, which is expected to be recognized over a weighted-average period of 3.1 years.

10. Income Taxes

During the years ended December 31, 2019 and 2020, the Company did not record income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each year, due to its uncertainty of realizing a benefit from those items. The Company does not have any foreign operations and therefore has not provided for any foreign income taxes.

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

	Years Ended December 31,	
	2019	**2020**
Federal statutory income tax rate	(21.0) %	(21.0) %

State income tax, net of federal benefit	(0.4)	(0.7)
Federal and state research and development tax credits	(1.9)	(2.6)
Non-deductible items	0.5	0.8
Other	(0.1)	—
Change in deferred tax asset valuation allowance	22.9	23.5
Effective income tax rate	0.0%	0.0%

The Company's net deferred tax assets consisted of the following (in thousands):

	December 31,	
	2019	**2020**
Deferred tax assets:		
Net operating loss carryforwards	$ 6,736	$ 12,585
Research and development tax credit carryforwards	1,006	1,756
Deferred revenue	29	29
Accruals and other temporary differences	381	716
Total deferred tax assets	8,152	15,086
Deferred tax liabilities:		
Depreciation and intangibles	(42)	(19)
Total deferred tax liabilities	(42)	(19)
Valuation allowance	(8,110)	(15,067)
Net deferred tax assets	$ —	$ —

As of December 31, 2020, the Company had U.S. federal net operating loss carryforwards of $55.9 million, which may be available to reduce future taxable income, of which $11.5 million expire at various dates beginning in 2035 while the remaining $44.4 million do not expire but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2020, the Company had state net operating loss carryforwards of $13.2 million, which may be available to reduce future taxable income and expire at various dates beginning in 2029. As of December 31, 2020, the Company also had U.S. federal and state research and development tax credit carryforwards $0.9 million and $1.1 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2036 and 2032, with $0.8 million of state research and development tax credits carrying forward indefinitely.

Utilization of the U.S. federal and state net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has

not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before their utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2019 and 2020. Management reevaluates the positive and negative evidence at each reporting period.

Changes in the valuation allowance for deferred tax assets related primarily to the increase in net operating loss carryforwards and research and development tax credit carryforwards and were as follows (in thousands):

	Years Ended December 31,	
	2019	**2020**
Valuation allowance as of beginning of year	$ 4,760	$ 8,110
Increases recorded to income tax provision	3,350	6,957
Valuation allowance as of end of year	$ 8,110	$ 15,067

The Coronavirus Aid, Relief, and Economic Security ("CARES") Act was enacted on March 27, 2020. Among the business provisions, the CARES Act provided for various payroll tax incentives, changes to net operating loss carryback and carryforward rules, business interest expense limitation increases, and bonus depreciation on qualified improvement property. Additionally, the Consolidated Appropriations Act of 2021 was enacted on December 27, 2020, which provided additional COVID relief provisions for businesses. The Company evaluated the impact of both Acts and determined that any impact is not material to its financial statements.

As of December 31, 2019 and 2020, the Company had not recorded any amounts for unrecognized tax benefits. The Company's policy is to record interest and penalties related to

income taxes as part of its income tax provision. As of December 31, 2019 and 2020, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's statements of operations and comprehensive loss. The Company files income tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. As of December 31, 2019 and 2020, there were no pending tax examinations. The Company is open to future tax examination under statute from 2016 to present.

11. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Years Ended December 31,	
	2019	2020
Numerator:		
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)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	889,232	941,642
Net loss per share attributable to common stockholders, basic and diluted	$ (25.81)	$ (31.43)

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the period indicated because including them would have had an antidilutive effect:

	Years Ended December 31,	
	2019	2020
Convertible preferred stock (as converted to common stock)	915,793	915,793
Stock options to purchase common stock	307,125	467,530
	1,222,918	1,383,323

12. Revenue

The Company's primary product is not yet commercially available for sale. The Company's source of revenue to date is from research, clinical and collaboration agreements with various academic, pharmaceutical and biotechnology companies.

During the years ended December 31, 2019 and 2020, all of the Company's revenue was derived from its collaboration agreement with Novo Nordisk, which was a related party during the year ended December 31, 2019 (see Note 14).

Collaboration Agreement with Novo Nordisk

In September 2017, the Company entered into a collaboration agreement with Novo Nordisk (as amended, the "Novo Collaboration Agreement"). The purpose of the collaboration agreement is to produce clinical data using Novo Nordisk's fast-acting insulin to support its compatibility and integration with the Company's iLet bionic pancreas system. Under the agreement, both parties have shared responsibilities, and each party is an active participant in the development of its products utilizing its own resources.

In September 2017, the Company received a nonrefundable, upfront cash payment of $0.6 million upon the execution of the Novo Collaboration Agreement. Under the agreement before amended, the Company was entitled to receive aggregate milestone payments of up to $1.1 million upon the achievement of specified clinical and regulatory milestones, which together with the $0.6 million upfront payment, resulted in total potential payments under the agreement of $1.7 million. The milestone payments represent consideration that will only be earned by the Company if and when the specified conditions for each are met.

In December 2019, the Novo Collaboration Agreement was amended to modify the amounts of the existing milestone payments and include a new set of specified clinical and regulatory milestones and payments, which increased the total potential payments under the agreement to $3.5 million, including the $0.6 million upfront cash payment previously received. In February 2021, the agreement was further amended to extend the estimated milestone achievement dates of the agreement.

The Novo Collaboration Agreement will remain in effect until all work described under the agreement is complete. As of December 31, 2019, the Company estimated that the period of performance under the agreement would extend into the second quarter of 2021. As of December 31, 2020, the Company estimated that the period of performance under the agreement would extend through September 30, 2022. Novo Nordisk has the right to terminate the agreement upon notice to the Company. In the event of early termination, Novo Nordisk is obligated to pay all costs incurred, including all non-cancellable obligations, prior to the date of termination. The Company or Novo Nordisk may terminate the agreement if the other party fails to cure its material breach within a specified period after receiving notice of such breach.

The Company accounts for this arrangement under ASC 808 and has determined there is one unit of accounting. Under ASC 808, the Company has determined that it cannot analogize to other accounting literature for recognition under ASC 808, and thus has used a reasonable and rational method and recognized collaboration revenue ratably over the estimated period of performance because the Company's efforts to satisfy its obligation have been, and are expected to be, incurred evenly throughout the period of performance. The upfront payment of $0.6 million received in 2017 is being recognized on a ratable basis over the estimated period of performance of the work described in the collaboration agreement. As each milestone is achieved, a cumulative catch-up adjustment is recorded as revenue for the elapsed portion of the period of performance, and the remaining amount of the milestone payment is recognized ratably over the remaining estimated period of performance.

In 2018, the first regulatory milestone was achieved and the Company received a milestone payment of $0.2 million. In 2019, the second regulatory milestone was achieved, at which time the Company became entitled to receive a milestone payment of $0.5 million, which was received by the Company in January 2020. In 2020, the first clinical milestone was achieved and the Company received a milestone payment of $0.6 million.

During the year ended December 31, 2019, the Company recognized revenue of $0.5 million under the Novo Collaboration Agreement, which included $0.3 million recognized as a catch-up adjustment upon achieving the second milestone and earning the related milestone payment of $0.5 million in 2019.

During the year ended December 31, 2020, the Company recognized revenue of $0.7 million under the Novo Collaboration Agreement, which included $0.5 million recognized as a catch-up adjustment upon achieving the third milestone and earning the related milestone payment of $0.6 million in 2020.

As of December 31, 2019, the Company had recorded accounts receivable—related party of $0.5 million and deferred revenue—related party of $0.3 million in connection with the Novo Collaboration Agreement. As of December 31, 2020, no amounts were due as accounts receivable and deferred revenue of $0.2 million was recorded in connection with the Novo Collaboration Agreement. Deferred revenue is recorded when consideration is received from the collaboration partner in advance of the Company's satisfaction of the contract's obligations.

13. Commitments and Contingencies

Purchase Commitments

Under its hardware and software license agreements, as amended, with Boston University ("BU"), a related party (see Note 14), the Company is obligated to pay BU royalties and other amounts.

Operating Leases

The Company leased incubator office space from BU (see Note 14) under an operating lease that expired in May 2020. In addition, the Company leases office, laboratory and manufacturing space in Irvine, California under an operating lease that expires in March 2023 and office space in Concord, Massachusetts under an operating lease that expires in October 2026. In February 2020, the Company entered into a lease for office, laboratory and manufacturing space in Irvine, California under an operating lease that expires in May 2027. Total rent expense for the years ended December 31, 2019 and 2020 was $0.3 million and $0.8 million, respectively.

As of December 31, 2020, the minimum aggregate future lease commitments under the Company's operating leases were as follows (in thousands):

Year Ending December 31	
2021	$ 817
2022	1,097
2023	1,029
2024	1,017
2025	1,057
Thereafter	1,355
	$ 6,372

Research Supply Agreement

In March 2020, the Company entered into a research supply agreement with the Jaeb Center for Health Research Foundation (the "Jaeb Center"), a contract research organization, for the regulatory sponsorship and coordination of the iLet insulin-only configuration pivotal trial. The agreement was amended in May and December 2020 and includes minimum purchase commitments to fund a portion of the total costs of the pivotal trial. During the year ended December 31, 2020, the Company paid the Jaeb Center $2.9 million, fulfilling the first minimum purchase commitment. As of December 31, 2020, the Company had remaining purchase commitments under the agreement of up to $0.7 million primarily for certain trial expenses incurred beyond January 31, 2021.

Consulting Agreement

In 2020, the Company entered into a three-year, non-cancellable consulting agreement for investor relations services. As of December 31, 2020, the Company had a remaining purchase commitment of $1.6 million, payable over the remaining term of the agreement.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, contract research organizations, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and some of its executive officers that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

Legal Proceedings

From time to time, the Company may become involved in various legal proceedings, including those that may arise in the ordinary course of business. As of December 31, 2019, the Company was engaged in litigation with a former research scientist at BU, a related party (see Note 14). In October 2018, the former research scientist at BU filed a lawsuit against the Company, its Chief Executive Officer, its VP Clinical & Regulatory Affairs and BU. In September 2019, the complaint was amended to state additional causes of action.

The amended complaint asserts that the plaintiff was promised an equity stake in the Company in exchange for his work on the bionic pancreas related technology in the BU lab. The plaintiff also asserts that his patent rights have been interfered with and he has thereby been deprived of his rights to certain royalties. The plaintiff seeks actual damages, consequential damages, compensatory damages, exemplary damages, punitive damages, double or treble damages and attorneys' fees and costs.

The Company denies that it or any of its officers or employees ever promised the plaintiff any equity in the Company in exchange for the work he performed at BU or that it or its officers or employees engaged in any of the other alleged unlawful activities.

In June 2020, the Company and its VP Clinical & Regulatory Affairs were dismissed from the case, leaving the Company's Chief Executive Officer and BU as defendants.

As of April 9, 2021, the issuance date of these financial statements, the Company believes there is no litigation pending that could have, individually, or in the aggregate, a material adverse effect on the results of its operations or financial condition.

14. Related Party Transactions

Novo Nordisk

For the year ended December 31, 2019, the Company concluded that Novo Nordisk was a related party because a representative of Novo Nordisk was a member of the Company's board of directors until June 2019. For the year ended December 31, 2020, the Company concluded that Novo Nordisk was no longer a related party as a result of (i) the Novo Nordisk representative resigning from the board of directors in 2019 and (ii) Novo Nordisk owning an insignificant percentage of the total voting interests of the Company.

In September 2017, the Company entered into a collaboration agreement with Novo Nordisk (see Note 12). For the years ended December 31, 2019 and 2020, the Company recognized collaboration revenue of $0.5 million and $0.7 million, respectively, under the Novo Collaboration Agreement.

Boston University

In December 2015, the Company executed a hardware and software license agreements with BU under which the Company received exclusive, non-transferable, sublicensable, worldwide, royalty-bearing licenses to certain patent rights and copyrights. The Company is obligated to use commercially reasonable efforts to develop and commercialize the licensed products. These agreements stipulate a series of milestones for the development and commercialization of the licensed products. The milestones are a mechanism for tracking the development and commercialization progress of the licensed products and are not attached to any form of financial payment. The agreements were subsequently amended in December 2017 and September 2020 to extend the milestone dates. Under the agreements, the final milestone is FDA approval of the licensed products by June 2022.

In consideration for the licensed patent rights and other rights under the license agreement, the Company issued BU 50,000 shares of its Class B common stock, which were valued at $0.9 million. Under the agreements, the Company is obligated to pay BU royalties of a mid-single-digit percentage based on net sales of any products licensed under the agreements and royalties in the range of 15 to 25% of any sublicense income received by the Company. In addition, the Company is obligated to pay BU annual minimum royalties of an insignificant amount. Pursuant to the BU patent policy, BU is obligated to pay a specified percentage of royalties received from the Company on net sales of products licensed under the agreements to the inventors of the patentable inventions, one of which is the Company's Chief Executive Officer.

The Company has the right to terminate the license agreements with notice. BU may terminate the license agreements upon specified events of breach or default, including failure of the Company to pay and the bankruptcy of the Company.

Under the license agreements, the Company is responsible for all costs related to the amendment, prosecution and maintenance of the licensed patent rights. During the years ended December 31, 2019 and 2020, the Company paid BU $0.3 million and $0.1 million, respectively, for reimbursed legal costs in connection with the agreements. In addition, during the year ended December 31, 2019, the Company paid BU $0.1 million for subcontracting fees.

In 2017 and 2018, BU ordered a number of pre-commercial iLet bionic pancreas devices from the Company that were and are being used in BU's collaborative clinical trials program. The orders were subsequently invoiced in 2018 in an aggregate amount of $1.1 million, which was received by the Company in 2018.

The Company has determined that these BU transactions related to the clinical trials program are within the scope of ASC 730-20, Research and Development Arrangements. The Company concluded that there has not been a substantive and genuine transfer of risk related to the consideration received as there is a presumption that the Company is obligated to repay BU based on the significant related party relationship that existed at the time the parties entered into the transactions. The Company deems BU to have a significant related party relationship with the Company based on (i) the dual employment relationship of certain Company officers and employees, including its Chief Executive Officer, which provided BU representation on the Company's board of directors, (ii) BU's stock ownership level at the time of the transactions, (iii) the provisions of the license agreements described above and (iv) the joint development efforts between the parties, among other qualitative factors. Therefore, the aggregate amount of $1.1 million received from BU was recorded by the Company as funded R&D liability—related party on the balance sheets of December 31, 2019 and 2020.

In addition, the Company leased office and laboratory space from BU. Total rent expense in respect of this lease in the years ended December 31, 2019 and 2020 was $17,000 and $6,250, respectively. The lease expired in May 2020 and was not renewed. As of December 31, 2019 and 2020, other than the amount of the funded R&D liability, $0 and $40,190, respectively, was due to BU by the Company. As of December 31, 2019 and 2020, no amounts were due from BU to the Company.

15. Employee Benefit Plan

The Company maintains a 401(k) retirement plan (the "401(k) Plan") for the benefit of eligible employees. Each participant may elect to contribute up to 100% of his or her compensation to the 401(k) Plan each year, subject to certain Internal Revenue Service limitations. On January 1, 2019, the Company began an employer 401(k) match, which was effective for any funds contributed after January 1, 2019 at a rate of 100% of the first 6% of

employee contributions. During the years ended December 31, 2019 and 2020, the Company contributed $0.2 million and $0.5 million, respectively, to the 401(k) Plan.

16. Subsequent Events

For the financial statements as of and for the year ended December 31, 2020, the Company evaluated subsequent events through April 9, 2021, the date on which those financial statements were issued.