UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM C

UNDER THE SECURITIES ACT OF 1933

(Mark one.)

☐ **Form C: Offering Statement**

☐ **Form C-U: Progress Update:**

☐

Form C/A: Amendment to Offering Statement:

☐ **Check box if Amendment is material and investors must reconfirm within five business days.**

☒ **Form C-AR: Annual Report**

☐ **Form C-AR/A: Amendment to Annual Report**

☐ **Form C-TR: Termination of Reporting**

Name of issuer: Beta Bionics, Inc

Legal status of issuer:

Form: Corporation

Jurisdiction of Incorporation/Organization: MA

Date of organization: 10-21-2015

Physical address of issuer: 300 Baker Ave., Suite 301, Concord, Massachusetts 01742

Website of issuer: www.betabionics.com

Is there a Co-Issuer: N

Name of intermediary through which the offering will be conducted:

CIK number of the intermediary:

SEC file number of intermediary:

CRD number, if applicable, of intermediary:

Amount of compensation to be paid to the intermediary, whether as a dollar amount or a percentage of the offering amount, or a good faith estimate if the exact amount is not available at the time of the filing, for conducting the offering, including the amount of referral and any other fees associated with the offering:

Any other direct or indirect interest in the issuer held by the intermediary, or any arrangement for the intermediary to acquire such an interest:

Type of security offered:

Target number of securities to be offered:

Price (or method for determining price): -

Target offering amount:

Oversubscriptions accepted: ☐ Yes ☐ No

If yes, disclose how oversubscriptions will be allocated: ☐ Pro-rata basis ☐ First-come, first-served basis

☐ Other – provide a description:

Maximum offering amount (if different from target offering amount):

Deadline to reach the target offering amount:

NOTE: If the sum of the investment commitments does not equal or exceed the target offering amount at the offering deadline, no securities will be sold in the offering, investment commitments will be cancelled and committed funds will be returned.

Current number of employees: 108.00

Total Assets:	Most recent fiscal year-end:	35528000.00	Prior fiscal year-end:	37050000.00
Cash & Cash Equivalents:	Most recent fiscal year-end:	27775000.00	Prior fiscal year-end:	31870000.00
Accounts Receivable:	Most recent fiscal year-end:	0.00	Prior fiscal year-end:	0.00
Short-term Debt:	Most recent fiscal year-end:	8873000.00	Prior fiscal year-end:	9058000.00
Long-term Debt:	Most recent fiscal year-end:	13655000.00	Prior fiscal year-end:	1715000.00
Revenues/Sales:	Most recent fiscal year-end:	179000.00	Prior fiscal year-end:	610000.00
Cost of Goods Sold:	Most recent fiscal year-end:	0.00	Prior fiscal year-end:	0.00

Taxes Paid:	Most recent fiscal year-end:	0.00	Prior fiscal year-end:	0.00
Net Income:	Most recent fiscal year-end:	-64751000.00	Prior fiscal year-end:	-54832000.00

Using the list below, select the jurisdictions in which the issuer intends to offer the securities:

	Jurisdiction	Code		Jurisdiction	Code		Jurisdiction	Code
	Alabama	AL		Montana	MT		District of Columbia	DC
	Alaska	AK		Nebraska	NE		Puerto Rico	PR
	Arizona	AZ		Nevada	NV			
	Arkansas	AR		New Hampshire	NH		Alberta	A0
	California	CA		New Jersey	NJ		British Columbia	A1
	Colorado	CO		New Mexico	NM		Manitoba	A2
	Connecticut	CT		New York	NY		New Brunswick	A3
	Delaware	DE		North Carolina	NC		Newfoundland	A4
	Florida	FL		North Dakota	ND		Nova Scotia	A5
	Georgia	GA		Ohio	OH		Ontario	A6
	Hawaii	HI		Oklahoma	OK		Prince Edward Island	A7
	Idaho	ID		Oregon	OR		Quebec	A8
	Illinois	IL		Pennsylvania	PA		Saskatchewan	A9
	Indiana	IN		Rhode Island	RI		Yukon	B0
	Iowa	IA		South Carolina	SC		Canada (Federal Level)	Z4
	Kansas	KS		South Dakota	SD			
	Kentucky	KY		Tennessee	TN			
	Louisiana	LA		Texas	TX			
	Maine	ME		Utah	UT			
	Maryland	MD		Vermont	VT			
	Massachusetts	MA		Virginia	VA			
	Michigan	MI		Washington	WA			
	Minnesota	MN		West Virginia	WV			
	Mississippi	MS		Wisconsin	WI			
	Missouri	MO		Wyoming	WY			

SIGNATURE

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C and has duly caused this Form to be signed on its behalf by the duly authorized undersigned.

Beta Bionics, Inc.
(Issuer)

/s/ Sean Saint, Chief Executive Officer and Director
(Signature and Title)

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 et seq.), this Form C has been signed by the following persons in the capacities and on the dates indicated.

/s/ Stephen Feider
(Signature)

Chief Financial Officer
(Title)

4/26/2023
(Date)

/s/ Edward Damiano
(Signature)

Executive Chair and Board Member
(Title)

4/26/2023
(Date)

/s/ Maria Palasis

(Signature)

Board Member
(Title)

4/26/2023
(Date)

/s/ Sean D. Carney
(Signature)

Board Member
(Title)

4/26/2023
(Date)

/s/ Mads Dall
(Signature)

Board Member
(Title)

4/26/2023
(Date)

/s/ Beth A. Brooke
(Signature)

Board Member
(Title)

4/26/2023
(Date)

/s/ Christy Jones
(Signature)

Board Member
(Title)

4/26/2023
(Date)

/s/ Gilad Glick
(Signature)

Board Member
(Title)

4/26/2023
(Date)

Beta Bionics

A Massachusetts Public Benefit Corporation

Certified B Corporation

ANNUAL REPORT

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

Corporate headquarters:
300 Baker Ave., Suite 301
Concord, MA 01742

www.betabionics.com

This Annual Report is dated April 30, 2023

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, 2022. A copy of this Report may be found on our website at www.betabionics.com/about-us.

This Annual Report (the "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.

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

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

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 April 30, 2023 are identified in the following tables.

Directors	Principal Occupation	Main Employer(s)	Year Joined as Director
Edward R. Damiano[(1)]	Founder and Executive Chair	Beta Bionics, Inc.	2015
Sean Saint	Chief Executive Officer and Director	Beta Bionics, Inc	2022

Directors	Principal Occupation	Main Employer(s)	Year Joined as Director
Maria Palasis, PhD	President and Chief Executive Officer	Lyra Therapeutics, Inc.	2022
Sean D. Carney	Investor/Consultant	Hillhouse Capital; Care Capital	2020
Beth A. Brooke	Board Director	eHealth, Inc.	2020
Christy Jones	Managing Director	Richmond Capital Partners	2021
Mads Dall	Consultant	Dall & Co.	2022
Gilad Glick	President	ZOLL ITAMAR Division	2022

(1) Previously served as Chief Executive Officer from October 2015-February 2022.

Officers and Significant Employees

Name	Principal Occupation	Start date	Term of Office
Sean Saint[(1)]	Chief Executive Officer	August 2022	Indefinite
Edward R. Damiano[(2)]	Founder and Executive Chair	October 2015	Indefinite
Stephen Feider[(3)]	Chief Financial Offer	August 2022	Indefinite
Steven J. Russell	Chief Medical Officer	November 2022	Indefinite
Marcie Cain	Chief People Officer	March 2021	November 2022

(1) Was appointed to Chief Executive Officer in August 2022.

(2) Previously served as Chief Executive Officer from October 2015-February 2022.

(3) Was appointed to Chief Financial Officer in September 2022.

Non-Employee Directors

Maria Palasis, PhD

Maria Palasis has served as a member of our board of directors since August 2022. Dr. Palasis is the President and Chief Executive Officer for Lyra Therapeutics, Inc., a position she has held since January 2015, and she sits on the board of directors for PanTher Therapeutics and on the advisory board for MedExecWomen. From 2011 to 2015 at Lyra Therapeutics, Dr. Palasis served as the Executive Vice President and Chief Technology Officer. Prior to Lyra Therapeutics, Dr. Palasis was the President and Chief Executive Officer of both Arsenal Medical and 480 Biomedical. As an engineer, she was elected into the National Academy of Engineering in 2021 for contributions to the design of medical devices and drug delivery systems. Dr. Palasis holds a B.S. and Ph.D. in Chemical Engineering from the University of Cincinnati and completed her postdoctoral fellowship in Molecular Biology at the University of Cincinnati School of Medicine.

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 and as a director of the New York Times Company since March 2021. Ms. Brooke received a BS from Purdue University and is a certified public accountant.

Christy Jones, MBA

Christy Jones has served as a member of our board of directors since April 2021. Ms. Jones currently serves as Managing Director of Richmond Capital Partners and as a member of the board of directors of Extend Fertility, LLC, which she founded. She previously served on the board of Optiva, Inc. She is also the co-founder of Trilogy Software and served as the President and Founder of pcOrder, which she successfully led from start-up to a Nasdaq- listed public corporation. Ms. Jones received a BA in economics from Stanford University and an MBA from Harvard Business School.

Gilad Glick, MBA

Gilad Glick has served as a member of our board of directors since April 2022. Mr. Glick has more than 20 years of medical device experience across multiple countries in Europe and the US, and a variety of functional areas including sales, marketing, service, and research and development. Mr. Glick is the President of ZOLL ITAMAR Division. Prior to joining Itamar Medical as the Chief Executive Officer, Mr. Glick was worldwide vice president of sales and marketing at Biosense Webster, a Johnson & Johnson company, overseeing all strategic and commercial activities. Mr. Glick is a member of Israel's 8400 Heath Network, a founder of the MedTech Commercialization Institute and a Board of Directors member at Almeda Venture MedTech Fund. Mr. Glick earned an MBA from the Maastricht School of Management in the Netherlands, majoring in General and Strategic Management. He is also a graduate of the Strategic Marketing Management Executive Program at the Stanford Graduate School of Business.

Mads Dall

Mads Dall has served as a member of our board of directors since October 2022. Mr. Dall owns Dall & Company ApS, a strategic business development boutique working globally with private and public clients, mainly within life sciences. Mr. Dall brings significant international diabetes industry experience and has operated in US, Europe and Asia with pharma, biotech and med-tech companies in executive, advisory and board positions. Prior to founding Dall & Company in 2006, Mr, Dall held various management positions at Novo Nordisk A/S across R&D, business development and commercial functions.

Officers and Significant Employees

Sean Saint, Chief Executive Officer; Director

Sean Saint, P.E. is an engineer, entrepreneur, diabetes technologist and innovator, and person with type 1 diabetes. After his diagnosis with type 1 diabetes, he founded Companion Medical, where they developed and launched the InPen system, the first FDA-cleared smart pen. Medtronic acquired Companion Medical in 2020. Prior to Companion Medical, Sean was an early employee at Dexcom and Tandem Diabetes Care. In addition to his role as Chief Executive Officer of Beta Bionics, Sean sits on the board of directors of Luna Diabetes. Sean earned a Bachelor of Science degree in Mechanical Engineering from California Polytechnic State University – San Luis Obispo and is a registered Professional Engineer in California. He has over 175 issued and pending patent applications.

Edward R. Damiano, PhD, Founder and Executive Chair; Director

Ed Damiano is our co-Founder and Executive Chair and has served as a member of our board of directors since October 2015. Previously, he served as our Chief Executive Officer from October 2015 to February 2022. 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 PhD 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.

Stephen Feider, Chief Financial Officer; Treasurer and Secretary

Stephen Feider has served as our Chief Financial Officer and Treasurer and Secretary since August 2022. Mr. Feider previously served as the Finance Director at Medtronic from September 2020 to August 2022 and as the Vice President of Finance at Companion Medical, which was acquired by Medtronic, from April 2019 to September 2022. From January 2014 to April 2019, he was the Corporate Controller at OurHealth. Mr. Feider holds a Bachelor's and Master's of Accountancy from Butler University.

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) 3,800,000 shares of Class B Common Stock;

(iii) 500,000 shares of Class C Common Stock;

(iv) 50,000 shares of Series A Preferred Stock;

(v) 50,000 shares of Series A-2 Preferred Stock;

(vi) 420,000 shares of Series B Preferred Stock;

(vii) 450,000 shares of Series B-2 Preferred Stock; and

(viii) 550,000 shares of Series C 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 as of March 31, 2023	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 antidilution 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	1.04785 votes 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 antidilution protection
Series B-2 Preferred	450,000	396,000	1.05670 votes 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

Series C Preferred	550,000	410,186	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	589,000	One vote per share	None
Class B	3,800,000	391,910	One vote per share	None
Class C	500,000	9,691	No voting rights	None

Class of Security	**Securities Reserved for Issuance upon Exercise or Conversion**
Warrants	Warrants to purchase up to 102,539 shares of Series C Preferred Stock
Options	818,156 Class B Common Stock issuable upon exercise of stock options (Employee Incentive Option Pool) 144,871 Class B Common Stock available for future issuance (Employee Incentive Option Pool)
Antidilution	42,518 Class B Common Stock issuable upon conversion of Series B and Series B-2 Preferred Stock to Common Stock
Other rights	None, other than as provided for in the terms of the Preferred Stock

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, Series C 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.

On February 9, 2022, 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 843,372.

Principal Security Holders

The following table lists as of March 31, 2023, 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)	589,000	-	-	999(1)	25.5%

(1) The Series B Preferred Stock votes on a 1.04785 votes-per-share, as-converted basis.

The above calculation is based on the number of shares of voting securities owned as of March 31, 2023. Each share of Class A and Class B Common Stock has 1 vote per share. Class C Common Stock is non-voting. Series A, A-2, B, B-2 and C Preferred Stock vote on an as converted basis to Class B Common Stock.

Risks associated with being a minority shareholder

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 stock 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 stock 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.

Transfer agent and registrar

Townshend Venture Advisors, LLP, 12463 Rancho Bernardo Road #209, San Diego, CA 92128, 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 innovative drug delivery solutions for people with diabetes on intensive insulin therapy. Our first product, currently an 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 ("CGM"), to autonomously compute and administer all doses of insulin, glucagon, or both, 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 single hormone insulin configuration was evaluated in a pivotal trial involving 440 participants with type 1 diabetes ages six and older. In December 2021, we announced the completion of the randomized controlled and data lock of the trial results. In April 2022, the sponsor and clinical investigators of the pivotal trial released the results of the pivotal trial at a public presentation at the International Conference on Advanced Technologies & Treatments for Diabetes (ATTD). The Insulin-only Bionic Pancreas pivotal trial showed consistent mean HbA1c reductions across a variety of subgroups. We are 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.

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 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.

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 2022.

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. Diagnosis of type 1, particularly among youth in diverse populations, is expected to sharply increase[2].

Current treatment options

There are two primary means for insulin delivery: subcutaneous insulin injections by syringes or pens and subcutaneous 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 four 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 2.9 million people in the United States with diabetes are MDI users, consisting of approximately 1.3 million people, or approximately 71% 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 more burdensome option for people with diabetes. In addition to requiring multiple daily injections, MDI requires the user to self-calculate doses and therefore can result 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.

[2]https://www.jdrf.org/blog/2020/02/18/more-people-being-diagnosed-type-1-diabetes/

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 Pancreas 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, 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.

- ***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 is designed to take 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 is designed to automatically adjust 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 is designed to automatically modulate basal insulin delivery over multiple time scales, and an additional algorithm that is designed to automatically adapt 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 designed to govern 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 are designed to 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 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 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 of the iLet 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 soluble-stable glucagon analog, dasiglucagon, designed to meet this requirement. Dasiglucagon received FDA approval for an acute rescue pen setting[3].

  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. We also intend to pursue development of the insulin configuration of our iLet system in people living with type 2 diabetes who require intensive insulin therapy.

[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214231s000lbl.pdf

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 agreements.

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

Pivotal Trial of Our Insulin-Only iLet Configuration

In December 2021, our iLet insulin-only configuration completed 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 was 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 also provided partial financial support for the trials through a grant to Boston University. Trial enrollment successfully included 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, acted as sponsor and was also the contract research organization conducting the trial. Steven Russell, M.D., who is affiliated with the Massachusetts General Hospital, was the principal investigator on this trial.

This pivotal trial was designed to evaluate the safety and effectiveness of our iLet system in its insulin-only configuration. 440 participants completed the trial. The trial groups were 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 evaluated was 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). In December 2021, we announced the completion of the randomized controlled and data lock of the trial results. In April 2022, the sponsor and clinical investigators of the pivotal trial released the results of the pivotal trial at a public presentation at the International Conference on Advanced Technologies & Treatments for Diabetes (ATTD).). The Insulin-only Bionic Pancreas pivotal trial showed consistent mean HbA1c reductions across a variety of subgroups.

Manufacturing, suppliers, and quality assurance

We currently manufacture our iLet system and its accompanying ready-to-fill insulin cartridges at our facility 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 key suppliers including Unomedical, an affiliate of ConvaTec, to produce the infusion sets and with Maxon Motors for the pump motors used in our iLet system.

In 2020, we occupied and set up production at our leased Hughes building 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.

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.

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, assuming we receive FDA clearance, we intend to pursue expanded use of our iLet system by people living with type 2 diabetes who require intensive insulin therapy.

Government grants

From time to time, the Company has entered 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, 2021, the Company recognized reductions of research and development expenses of $0.3 million in the statement of operations and comprehensive loss and reductions of the carrying amount of qualifying equipment purchases of $0.3 million. The Company did not enter into any arrangements with government agencies for qualifying research and development activities during the year ended December 31, 2022.

NUMBER OF CURRENT EMPLOYEES

As of March 31, 2023, we employed 108 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.

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, 2021 and 2022 were $54.8 million and $64.8 million, respectively. As of December 31, 2022, we had an accumulated deficit of $185.6 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:

- 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;
- 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.

As of March 31, 2023, we have no products approved by the FDA or any other regulatory body 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, 2022, 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. 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, 2022, we had U.S. federal net operating loss carryforwards, or NOLs, of $137.3 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 $125.8 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, 2022, we had state NOLs of $23.4 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.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability due to the ongoing military conflict between Russia and Ukraine. Our business, financial condition and results of operations could be materially adversely affected by any negative impact on the global economy and capital markets resulting from the conflict in Ukraine or any other geopolitical tensions.

Although the length and impact of the ongoing military conflict is highly unpredictable, the conflict in Ukraine could lead to market disruptions, including significant volatility in commodity prices, credit and capital markets, as well as supply chain interruptions. We are continuing to monitor the situation in Ukraine and globally and assessing its potential impact on our business. Russian military actions and the resulting sanctions could adversely affect the global economy and financial markets and lead to instability and lack of liquidity in capital markets, potentially making it more difficult for us to obtain additional funds.

Although our business has not been materially impacted by the ongoing military conflict between Russian and Ukraine to date, it is impossible to predict the extent to which our operations, or those of our suppliers and manufacturers, will be impacted in the short and long term, or the ways in which the conflict may impact our business. The extent and duration of the military action, sanctions and resulting market disruptions are impossible to predict, but could be substantial. Any such disruptions may also magnify the impact of other risks described in this Annual Report.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our liquidity, business, financial condition and results of operations by increasing our overall cost structure. The existence of inflation in the economy has resulted in, and may continue to result in, higher interest rates and capital costs, shipping costs, supply shortages, increased costs of labor, weakening exchange rates and other similar effects. As a result of inflation, we have experienced and may continue to experience, cost increases. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective our business, financial condition, results of operations and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost inflation is incurred.

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

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. As of March 31, 2023, the iLet system has not received FDA approval. 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 in both the insulin-only and bihormonal configurations. Although we believe we have FDA concurrence with this approach, particularly for the insulin-only configuration, they may ultimately disagree that the 510(k) pathway is appropriate for the iLet system for the treatment of type 1 diabetes, or any other indications we may pursue, and may require us to file a de novo submission or even 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 can generally take more than a year 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 may have to market the iLet without its full functionality if one 510(k) is very delayed.

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. This office had previously paused review of certain non-COVID submissions, but FDA has indicated that it is working to transition back to its Medical Device User Fee Agreement (MDUFA) timelines. However, FDA has stated that an increase of applications and the agency's reallocation of resources during the ongoing COVID-19 pandemic has affected FDA's ability to meet its MDUFA review timelines, and the agency may continue to experience delays. 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, such as the iLet system.

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.

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 ongoing 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 our 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 in our planned or future trials 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 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.

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 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, we will bear the risk of warranty claims on our iLet.

If our iLet system is cleared 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, 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, 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.

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 pump is in late-stage development, and Insulet's Omnipod 5 has been granted FDA clearance and is currently in limited launch.

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 has received FDA clearance for 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, 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 have begun to, and 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 may 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. While we will be the sponsor on our bihormonal trial, we will rely on the Jaeb Center to act as the contract research organization. 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 rely on third parties to manufacture product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We rely on third parties for supply of our product candidates, and our strategy is to outsource all manufacturing of our product candidates and products to third parties.

In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities. Our third-party manufacturers (or contract manufacturers, or CMOs) may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. Any inability to manufacture our product candidates or future approved drugs in sufficient quantities when needed would seriously harm our business. For example, recent global supply chain constraints have led to a risk of shortages in lab supplies. If there is a shortage of lab supplies which are critical for our clinical programs, there can be no assurance that we would be able to find alternative suppliers for certain critical materials.

In addition, quality issues may arise during scale-up activities and at any other time. For example, ongoing data on the stability of our product candidates may shorten the expiry of our product candidates and lead to clinical trial material supply shortages, and potentially clinical trial delays. If these third-party manufacturers are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business.

Our use of new third-party manufacturers increases the risk of delays in production or insufficient supplies of our product candidates as we transfer our manufacturing technology to these manufacturers and as they gain experience manufacturing our product candidates. Changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating comparability of clinical supplies which could require the conduct of additional clinical trials.

Even after a third-party manufacturer has gained significant experience in manufacturing our product candidates or even if we believe we have succeeded in optimizing the manufacturing process, there can be no assurance that such manufacturer will produce sufficient quantities of our product candidates in a timely manner or continuously over time, or at all.

We may be delayed if we need to change the manufacturing process used by a third party. Further, if we change an approved manufacturing process, then we may be delayed if the FDA or a comparable foreign authority needs to review the new manufacturing process before it may be used. Additionally, we will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates.

We do not currently have any agreements with third-party manufacturers for long-term commercial supply. In the future, we may be unable to enter into agreements with third-party manufacturers for commercial supplies of any product candidate that we develop, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers entails risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and/or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and potentially cause delays to our ongoing clinical trials.

Our future product candidates and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP requirements particularly for the development of monoclonal antibodies, and that might be capable of manufacturing for us.

If the third parties that we engage to supply any materials or manufacture product for our preclinical tests and clinical trials should cease to continue to do so for any reason, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Our third-party manufacturers and clinical reagent suppliers may be subject to damage or interruption from, among other things, fire, natural or man-made disaster, power loss, telecommunications failure, unauthorized entry, computer viruses, denial-of-service attacks, acts of terrorism, human error, vandalism or sabotage, financial insolvency, bankruptcy and similar events. For example, we are monitoring the global response to the ongoing COVID-19 pandemic closely and our response continues to evolve, including the recent labor market and global supply chain constraints. The extent to which the novel coronavirus may impact our third-party manufacturers and suppliers going forward will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop product candidates and commercialize any products that receive marketing approval on a timely and competitive basis.

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.

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. On January 1, 2017, we entered into a co-development agreement with the Zealand, or the Co- Development Agreement, to develop our iLet system in its bihormonal configuration in conjunction with Zealand's investigational multiple-dose version of dasiglucagon. 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. Pursuant to the Co-Development Agreement, we rely on the supply of dasiglucagon for the continued clinical development of our bihormonal configuration. 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 development 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 cleared, 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.

Cyber-attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, contract research organizations, third-party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations.

We, our collaborators, our CROs, third-party logistics providers, distributors and other contractors and consultants utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators', our CROs', third-party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable U.S. and international privacy, data protection and other laws, and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, and could have a material adverse effect on our business and prospects. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

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, 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 nor 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.

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 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

Any future products we may develop will be subject to ongoing and extensive regulatory requirements, and our failure to comply with these requirements could substantially harm our business.

As of March 31, 2023, we do not have FDA approval for the iLet system. If we obtain FDA approval, 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.

As of March 31, 2023, our iLet system does not have FDA clearance. If our iLet system is cleared for the treatment of type 1 diabetes, either in its insulin-only or bihormonal configuration, the regulatory clearance will be limited by the FDA to the specific indication for which clearance 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 uncleared 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 have been extended 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 significantly modified 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 Executive Chair, Firas El-Khatib, our co-founder, VP, Research and Innovation and Sean Saint, our Chief Executive Officer. We have entered into employment agreements with each of Messrs. Damiano, El-Khatib and Saint, 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. In August, 2022 we initiated a reduction in force which may have negative impact on our future ability to recruit employees. 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, legal and compliance, 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 not remediated as of December 31, 2022. 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 $194.4 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	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	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	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	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	General business operations and further iLet bionic pancreas development

July 2019 and September 2020	Private offering exempt from registration under Securities Act §4(2)	Class B Common Stock	$0	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.
Various accredited investors (February 16, 2022)	Private offering exempt from registration under Securities Act §4(2) or Regulation D under the Securities Act	Series C Preferred Stock	$57,049,911	General business operations and further iLet bionic pancreas development

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% 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, 2022 and 2021 can be found in Exhibit A to this report.

Overview

We are a medical device company focused on the design, development, and commercialization of the iLet bionic pancreas. As of March 31, 2023, the iLet bionic pancreas has not received FDA approval. Our only revenues through 2022 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. Since our inception, we have 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,	2021	2022
Total Assets	$ 37,050,000	$ 35,528,000
Cash & Cash Equivalents	31,870,000	27,675,000
Account Receivable	-	-
Current Liabilities/ Short-Term Debt	9,058,000	8,873,000
Long-term Liabilities	1,715,000	13,655,000
Revenues/Sales	610,000	179,000
Cost of Goods Sold	-	-
Net Income (Loss)	$(54,832,000)	$(64,751,000)

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 $54.8 million and $64.8 million for the years ended December 31, 2021 and 2022, respectively. As of December 31, 2022, we had an accumulated deficit of $185.6 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 March 31, 2023, we had received gross proceeds of $194.4 million from sales of our equity securities and $6.1 million from payments received in connection with collaboration arrangements and government grants. As of December 31, 2022, we had cash, cash equivalents of $27.8 million.

As of March 31, 2023, we expect that our existing cash, cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into October 2023. Beyond that point, we will need to raise additional capital to finance our operations, which cannot be assured. We concluded as of March 31, 2023 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.

Additionally, we will need to raise significant amounts of capital or other funds to fund our operating expenses and capital expenditure requirements beyond October 2023. 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 for fiscal year 2020 initially filed on April 30, 2021 and for fiscal year 2021 initially filed on April 29, 2022, 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

COMPANY CERTIFIED FINANCIALS

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

/s/ Sean Saint
Sean Saint
Beta Bionics, Inc.
Chief Executive Officer

Beta Bionics, Inc.

Financial Statements

December 31, 2022 and 2021

INDEX TO FINANCIAL STATEMENTS

BETA BIONICS, INC.

BALANCE SHEETS
(In thousands, except share amounts)

	December 31, 2021	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 31,870	$ 27,675
Prepaid expenses and other current assets	911	792
Total current assets	32,781	28,467
Property and equipment, net	3,976	3,320
Operating lease right-of-use asset	—	3,548
Restricted cash	100	100
Deferred offering costs	14	—
Other long-term assets	179	93
Total assets	$ 37,050	$ 35,528
Liabilities, Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 569	$ 430
Accrued expenses and other current liabilities	8,310	6,327
Funded R&D liability—related party	—	1,140
Operating lease liabilities	—	976
Deferred revenue	179	—
Total current liabilities	9,058	8,873
Funded R&D liability—related party	1,140	—
Operating lease liabities, net of current portion	—	3,157
Deferred rent	575	—
Preferred stock warrant liability	—	10,498
Total liabilities	10,773	22,528
Commitments and contingencies (Note 14)		
Convertible preferred stock (Series A, A-2, B, B-2 and C), no par value; 970,000 and 1,520,000 shares authorized at December 31, 2021 and 2022, respectively; 915,793 and 1,325,979 shares issued and outstanding at December 31, 2021 and 2022, respectively; liquidation preference of $136,413 and $193,462 at December 31, 2021 and 2022, respectively	138,049	183,034
Stockholders' deficit:		
Class A common stock, no par value; 1,000,000 shares authorized at December 31, 2021 and 2022; 600,000 and 589,000 shares issued and outstanding at December 31, 2021 and 2022, respectively	12	12
Class B common stock, no par value; 2,000,000 and 3,800,000 shares authorized at December 31, 2021 and 2022 respectively; 356,813 shares and 391,910 issued and outstanding at December 31, 2021 and 2022, respectively	939	939
Class C common stock, no par value; 500,000 shares authorized at December 31, 2021 and 2022; 9,691 shares issued and outstanding at December 31, 2021 and 2022	950	950
Additional paid-in capital	7,141	13,630
Accumulated deficit	(120,814)	(185,565)
Total stockholders' deficit	(111,772)	(170,034)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 37,050	$ 35,528

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,	
	2021	**2022**
Collaboration revenue	$ 610	$ 179
Operating expenses:		
Research and development	26,191	31,428
Sales and marketing	9,347	8,827
General and administrative	20,103	25,768
Total operating expenses	55,641	66,023
Loss from operations	(55,031)	(65,844)
Other income (expense):		
Interest income	224	196
Interest and other expense	(25)	(14)
Change in fair value of preferred stock warrants	—	911
Total other income, net	199	1,093
Net loss and comprehensive loss	(54,832)	(64,751)
Net loss per share attributable to common stockholders, basic and diluted	$ (56.73)	$ (65.77)
Weighted-average common shares outstanding, basic and diluted	966,504	984,459

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 Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2020	915,793	$138,049	966,504	$ 1,901	$ 2,810	$ (65,982)	$ (61,271)
Stock-based compensation expense	—	—	—	—	4,331	—	4,331
Net loss	—	—	—	—	—	(54,832)	(54,832)
Balance at December 31, 2021	915,793	138,049	966,504	1,901	7,141	(120,814)	(111,772)
Issuance of Series C preferred stock, net of issuance costs of $656 and net of warrant liability of $11,408	410,186	44,985	—	—	—	—	—
Transfer of Class A common stock to Class B common stock	—	—	(11,000)	—	—	—	—
Transfer of Class B common stock between stockholders	—	—	11,000	—	—	—	—
Stock option exercises	—	—	24,097	—	389	—	389
Stock-based compensation expense	—	—	—	—	6,100	—	6,100
Net loss	—	—	—	—	—	(64,751)	(64,751)
Balance at December 31, 2022	1,325,979	$183,034	990,601	$ 1,901	$ 13,630	$ (185,565)	$ (170,034)

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

BETA BIONICS, INC.

STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2021	**2022**
Cash flows from operating activities:		
Net loss	$ (54,832)	$ (64,751)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,205	1,345
Stock-based compensation expense	4,331	6,100
Change in fair value of preferred stock warrant liability	—	(911)
Non-cash lease expense	—	742
Loss on disposal of property and equipment	358	43
Write-off of deferred offering costs	2,146	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	572	119
Other long-term assets	191	86
Deferred offering costs	—	14
Accounts payable	(564)	(77)
Accrued expenses and other current liabilities	4,771	(2,007)
Operating lease liability	—	(732)
Deferred rent	243	—
Deferred revenue	(45)	(179)
Net cash used in operating activities	(41,624)	(60,208)
Cash flows from investing activities:		
Proceeds from maturities of short-term investments	10,000	—
Proceeds on disposal of property and equipment	—	3
Purchases of property and equipment	(1,693)	(772)
Net cash provided by (used in) investing activities	8,307	(769)
Cash flows from financing activities:		
Proceeds from the issuance of convertible preferred stock, net of issuance costs	—	56,393
Proceeds from stock option exercises	—	389
Payments of issuance costs of convertible preferred stock	(14)	—
Payments of offering costs	(2,096)	—
Net cash (used in) provided by financing activities	(2,110)	56,782
Net decrease in cash, cash equivalents and restricted cash	(35,427)	(4,195)
Cash, cash equivalents and restricted cash at beginning of period	67,397	31,970
Cash, cash equivalents and restricted cash at end of period	$ 31,970	$ 27,775
Supplemental disclosure of non-cash investing and financing information:		
Purchases of property and equipment included in accounts payable	$ 62	$ —
Purchases of property and equipment included in accrued expenses	$ —	$ 24
Series C convertible preferred stock warrants included in issuance costs	$ —	$ 11,408
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 31,870	$ 27,675
Restricted cash	100	100
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	$ 31,970	$ 27,775

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").

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 available to be issued.

Through December 31, 2022, 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 $54.8 million and $64.8 million for the years ended December 31, 2021 and 2022, respectively. In addition, as of December 31, 2022, the Company had an accumulated deficit of $185.6 million. The Company expects to continue to generate operating losses for the foreseeable future. As of April 30, 2023, the issuance date of the financial statements for the year ended December 31, 2022, the Company expects that its existing cash and cash equivalents, will be sufficient to fund its operating expenses and capital expenditure requirements into October 2023. 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 private 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 30, 2023, the issuance date of the financial statements for the year ended December 31, 2022, 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 are available to be 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 global COVID-19 pandemic has had, and may continue to have, an impact on our business. The full extent to which COVID-19 continues to impact the Company's operations or those of its third-party partners, including its clinical trial operations, will depend on future developments, that are highly uncertain and cannot be predicted with confidence, including new variants or additional resurgences as a result of mutations.

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, the valuation of common stock and stock-based awards, and convertible preferred stock warrants. 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.

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 stockholders' 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 would be expensed immediately as a charge to operating expenses in the statement of operations and comprehensive loss.

The Company recorded $0.2 million of deferred offering costs on the balance sheet as of December 31, 2020 related to a planned financing transaction, and during the first half of 2021, the Company capitalized additional deferred offering costs. As of December 31, 2021, the Company determined to no longer pursue the financing transaction. As a result, for the year ended December 31, 2021, the Company recognized general and administrative expense of $2.1 million related to the write-off of all previously capitalized deferred offering costs.

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 and short-term investments. The Company maintains its cash and cash equivalents in accounts at multiple 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, 2021 and 2022, this amount was guaranteed by a deposit in a money market fund and classified as restricted cash on the balance sheets.

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, 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

The Company's accounts receivable consists of amounts billed and due from its collaboration partner, Novo Nordisk A/S ("Novo Nordisk"). No amounts were due from Novo Nordisk as of December 31, 2021 or 2022.

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, 2021 and 2022, the Company had no allowance for doubtful accounts. During the years ended December 31, 2021 and 2022, 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, 2021 or 2022.

Deferred Rent

The Company's lease agreements include payment escalations, which were 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, were recorded as deferred rent and amortized over the respective lease terms.

Leases

Prior to January 1, 2022, the Company accounted for leases under Accounting Standards Codification ("ASC") 840, Leases ("ASC 840"). The Company recorded monthly rent expense on a straight-line basis, equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between rent expense recorded and the amount paid was charged to deferred rent.

Effective January 1, 2022, the Company adopted Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842) ("ASC 842"), using the modified retrospective transition method. Under this method, financial statements for reporting periods after adoption are presented in accordance with ASC 842 and prior-period financial statements continue to be presented in accordance with ASC 840, the accounting standard originally in effect for such periods. Under ASC 842, leases include all agreements in which the Company obtains control of an identified asset. Leases are classified as either operating or finance leases at the lease commencement and are captured on the balance sheet as both a right-of-use asset and associated lease liability, valued based on the present value of the future lease payments over the lease term at commencement date. The operating lease right-of-use asset includes any lease payments related to initial direct cost and prepayments and is reduced by the amount of any lease incentives. The present value of future lease payments are discounted using the interest rate implicit in lease contracts if that rate is readily determinable; otherwise the Company utilizes its incremental borrowing rate ("IBR"), which reflects the fixed rate at which the Company could borrow on a collateralized basis over a similar term, the amount of the lease payments in a similar economic environment. An analysis is performed annually, or upon the measurement or remeasurement of any individually material lease agreement, to ensure that the discount rate being applied is appropriate.

If a lease includes options to extend the lease term, the Company does not assume the option will be exercised in its initial lease term assessment unless there is reasonable certainty that the Company will renew based on an assessment of economic factors present as of the lease commencement date. The Company monitors its plans to renew its material leases each reporting period. Our lease portfolio is made up entirely of operating leases for office, laboratory, and manufacturing space.

All of the Company's leases are classified as operating leases, and therefore the expense is captured in income from operations each period.

The Company elected to exclude all leases of twelve months or less from the balance sheet presentation. The Company also elected a policy in which the lease components will not be segregated from associated non-lease components for all classes of underlying assets. This policy will be applied to all classifications of leases. Variable costs associated with the lease, such as maintenance and utilities, are not included in the measurement of right-to-use assets and lease liabilities but rather are expensed when the events determining the amount of variable consideration to be paid have occurred.

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, Series B-2 and Series C 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 of the convertible preferred stock would be made only when a deemed liquidation event becomes probable.

Preferred Stock Warrants

The Company has classified warrants to purchase its Series C convertible preferred stock as a liability on the balance sheets as these warrants are freestanding financial instruments that could require the Company to transfer assets upon exercise (see Note 3).

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, 2021 and 2022, no liabilities were recorded for loss contingencies (see Note 14).

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 ("CEO").

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.

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.

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, 2021 and 2022, 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 for the years ended December 31, 2021 and 2022 (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 years ended December 31, 2021, the Company recognized reductions of research and development expenses of $0.3 million in the statement of operations and comprehensive loss and reductions of the carrying amount of qualifying equipment purchases of $0.3 million related to government grants. The Company did not enter into any arrangements with government agencies for qualifying research and development activities during the year ended December 31, 2022.

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, 2021 and 2022, 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, 2021 and 2022.

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 August 2018, the FASB issued Accounting Standards Update ("ASU") No. 2018-15*, Intangibles—Goodwill and Other-Internal—Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract* ("ASU 2018-15"), which aligns the requirements for capitalizing implementation costs incurred in a cloud computing arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use-software. The Company adopted this standard on January 1, 2021, using the prospective method, and the adoption did not have a material impact on the Company's financial statements and disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), 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 further delayed the adoption date of ASU 2016-02 for nonpublic entities. For nonpublic entities and emerging growth companies, ASU 2016-02 is effective for annual periods beginning after December 15, 2021. Early adoption is permitted.

ASU 2016-02 became effective on January 1, 2022, and the Company adopted the standard using the modified retrospective transition method, which impacted all leases existing at, or entered into after, the period of adoption. For all leases existing at the time of adoption the Company recognized a right-of-use asset and lease liability on the balance sheet. The Company elected the relief package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company not to reassess whether any expired or existing contracts are or contain leases, the lease classification for any expired or existing leases and initial direct costs for any existing leases. The reported results for 2022 reflect the application of ASC 842 guidance, while the reported results for prior periods presented were prepared under the guidance of ASC 840. For existing leases at adoption, the Company elected to apply the discount rate to determine the present value of future payments using the remaining lease term at the date of adoption. The adoption of this standard resulted in a cumulative-effect transition adjustment for the recognition of right-of-use leased assets of approximately $4.3 million and corresponding lease liabilities of approximately $4.9 million on the balance sheet as of January 1, 2022. Deferred rent of $0.6 million as of January 1, 2022 was reclassified from deferred rent to a reduction of the right-of-use leased assets in connection with the adoption of the standard. The adoption of ASC 842 did not have a material impact on its statements of operations and comprehensive loss or its statements of cash flows. See Note 13 "Leases" for additional information.

Recently Issued Accounting Pronouncements

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.

In August 2020, the FASB issued ASU 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40). The standard address issues identified as a result of the complexity associated with applying U.S. GAAP for certain financial instruments with characteristics of liabilities and equity. The standard reduces the number of accounting models for convertible debt instruments and convertible preferred stock resulting in fewer embedded conversion features being separately recognized from the host contract. The standard is effective for public companies, excluding entities eligible to be smaller reporting companies, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The FASB specified that an entity should adopt the guidance as of the beginning of its annual fiscal year. The Company is assessing the impact of this guidance and is continuing to evaluate the impact on its financial statements.

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, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$ 28,545	$ —	$ —	$ 28,545
Restricted cash:				
Money market fund	100	—	—	100
	$ 28,645	$ —	$ —	$ 28,645

	Fair Value Measurements at December 31, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$ 24,651	$ —	$ —	$ 24,651
Restricted cash:				
Money market fund	100	—	—	100
	$ 24,751	$ —	$ —	$ 24,751

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, 2021 and 2022. 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, 2021 and 2022.

Preferred stock warrant liability

In connection with the February 16, 2022 Series C Preferred Stock and Warrant Purchase Agreement (see Note 7), the Company granted warrants to purchase up to 102,539 shares of Series C convertible preferred stock at a price per share equal to $0.01 and with a term ending on the earliest to occur of (i) February 16, 2032, (ii) immediately prior to the sale of the Company or a transaction that qualifies as a Deemed Liquidation Event, or (iii) immediately prior to the consummation of a qualifying initial public offering or a SPAC transaction. As the warrants are for preferred stock, which do not qualify for equity classification, the warrants have been recorded as a liability and are required to be remeasured to fair value at each reporting date.

As there are significant inputs that are not observable in the market, the warrant valuation represents a Level 3 measurement within the fair value hierarchy. The Company's valuation of the preferred stock warrant utilized the Black-Scholes option-pricing model, which incorporates assumptions and estimates to value the preferred stock warrant.

The quantitative elements associated with the Company's Level 3 inputs impacting the fair value measurement of the preferred stock warrant liability include the fair value per share of the underlying Series C convertible preferred stock, the remaining contractual term of the warrant, risk-free interest rate, expected dividend yield and expected volatility of the price of the underlying preferred stock. The most significant assumption in the Black-Scholes option-pricing model impacting the fair value of the preferred stock warrant is the fair value of the Company's Series C convertible preferred stock as of each remeasurement date. The Company determines the fair value per share of the underlying preferred stock by taking into consideration its most recent sales of its convertible preferred stock. The Company historically has been a private company and lacks company-specific historical and implied volatility information of its stock. Therefore, it estimates its expected stock volatility based on the historical volatility of publicly traded peer companies for a term equal to the remaining contractual term of the warrant. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the warrant. The Company has estimated a 0% dividend yield based on the expected dividend yield and the fact that the Company has never paid or declared dividends.

The Company recognizes changes in the fair value of the warrant liability as a component of other income (expense) in its statements of operations and comprehensive loss. The Company will continue to recognize changes in the fair value of the warrant liability until the warrant is exercised, expires, or qualifies for equity classification.

A reconciliation of the Level 3 warrant liability is as follows (in thousands):

	Series C Preferred Stock Warrant Liability
Balance as of December 31, 2021	$ —
Issuance of Series C preferred stock warrants	11,408
Change in fair value	(911)
Balance as of December 31, 2022	$ 10,497

4. Prepaid Expenses and Other Current Assets

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

	December 31,	
	2021	2022
Prepaid expenses	$ 789	$ 542
Other current assets	122	250
	$ 911	$ 792

5. Property and Equipment, Net

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

	December 31, 2021	December 31, 2022
Manufacturing and medical equipment	$ 3,809	$ 4,008
Leasehold improvements	805	951
Furniture	875	924
Computer equipment	560	628
Construction in progress	62	182
	6,111	6,693
Less: Accumulated depreciation and amorization	(2,135)	(3,374)
	$ 3,976	$ 3,319

Depreciation and amortization expense for the years ended December 31, 2021 and 2022 was $1.2 million and $1.3 million, respectively.

6. Accrued Expenses and Other Current Liabilities

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

	December 31, 2021	December 31, 2022
Accrued employee compensation and benefits	$ 4,752	$ 5,381
Accrued professional services fees	2,452	658
Accrued consulting fees	875	104
Other current liabilities	231	184
	$ 8,310	$ 6,327

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"), Series B-2 convertible preferred stock (the "Series B-2 Preferred Stock"), and Series C convertible preferred stock (the "Series C Preferred Stock") and collectively with the Series A Preferred Stock, the Series A-2 Preferred Stock, the Series B Preferred Stock and the Series C Preferred Stock (the "Preferred Stock").

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.

In February 2022, the Company issued and sold 410,186 shares of Series C convertible preferred stock, at a price of $139.0802 per share, for gross proceeds of $57.0 million. The Company incurred issuance costs in connection with this transaction of $0.7 million. Each purchaser of the Series C Preferred Stock also received a warrant to purchase additional shares of Series C Preferred stock equal to 25% of the shares of Series C Preferred Stock purchased by the purchaser, which in the aggregate permits the purchase of up to 102,539 shares of Series C Preferred stock (the "Series C Warrants"). The Series C Warrants are exercisable at any time, at an exercise price of $0.01 per share (subject to appropriate adjustment in the event of any stock split, stock dividend, combination or other similar recapitalization) and expire on the earliest to occur of (i) February 16, 2032, (ii) immediately prior to the sale of the Company or a transaction that qualifies as a Deemed Liquidation Event, or (iii) immediately prior to the consummation of a qualifying initial public offering or a SPAC transaction. The terms of the Series C Preferred Stock are substantially the same as the terms of the Series B Preferred Stock and Series B-2 Preferred Stock, except that the Original Issue Price per share and Conversion Price per share of the Series C Preferred Stock is $139.0802.

As part of the Series C Preferred Stock issuance, the Company increased the number of shares of Class B common stock authorized for issuance from 2,000,000 shares to 3,800,000 shares and increased the number of shares of preferred stock authorized for issuance from 970,000 shares to 1,520,000 shares, of which 550,000 shares were designated as Series C Preferred Stock.

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

	December 31, 2021				
	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

	December 31, 2022				
	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	439,861
Series B-2 Preferred Stock	450,000	396,000	63,228	63,360	418,447
Series C Preferred Stock	550,000	410,186	44,985	57,049	410,186
	1,520,000	1,325,979	$183,034	$ 193,462	1,368,494

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 record of the shares of Series C Preferred Stock, exclusively and as a separate class, shall be entitled to elect two directors of the Corporation.

The holders of record of the shares of Series B Preferred Stock, Series B-2 Preferred Stock, and Series C Preferred Stock, voting together as a single class, on an as-converted basis, shall be entitled to elect one director of the Corporation. The holders of record of the shares of Class A Common Stock, exclusively and as a separate class, shall be entitled to elect three directors of the Corporation.

The CEO shall also serve as a director.

Conversion

Each series of Preferred Stock will automatically convert into shares of Class B Common Stock at the then applicable conversion rate in the event of (i) the closing of the sale of common stock to the public at a price per share equal to at least $180.8042 (subject to adjustments for stock dividends, splits, combinations and similar events) and gross proceeds to the Company of not less than $75 million (a "Qualified IPO"); (ii) the closing of a Qualified SPAC Transaction; or (iii) upon the written consent of the Requisite Holders. 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 and $139.08 per share for Series C 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 articles of organization, as amended and restated. As a result, as of December 31, 2021, 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.

The Series C Preferred Stock issuance triggered down round protections for existing holders of Series B Preferred Stock and Series B-2 Preferred Stock, as set forth in the Company's articles of organization, as amended and restated. As a result, as of December 31, 2022, each outstanding share of Series B Preferred Stock was convertible into Class B common stock on a 1.04785:1 basis and each outstanding share of Series B-2 Preferred Stock was convertible into Class B common stock on a 1.0567:1 basis. As of December 31, 2022, each outstanding share of Series A Preferred Stock, Series A-2 Preferred Stock, and Series C Preferred Stock was convertible into Class B common stock on a one-for-one basis.

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, B-2 Preferred Stock and Series C 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, 2022, 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 Series B-2 Preferred Stock and Series C 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.

In connection with the Series C Preferred Stock financing (see Note 7), the Company's articles of organization were amended and restated. As amended, the holders of Class A common stock and Class B common stock are entitled to one vote for each share of Class A common stock and Class B common stock held.

In addition, the events requiring the automatic conversion of all shares of outstanding preferred stock into Class B common stock were amended to be (i) the closing of a firm-commitment underwritten public offering of common stock at a price of at least $180.8042 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization), resulting in at least $75.0 million of gross proceeds to the Company, (ii) the closing of a qualifying SPAC transaction or (iii) the vote or written consent of the holders of at least a majority of the then-outstanding shares of Preferred Stock and Series C Preferred Stock, voting together as a single class on an as-converted basis.

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

As of December 31, 2022, the Company had reserved 2,338,156 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 818,156 shares as of December 31, 2022, of which 144,871 shares remained available for future issuance as of December 31, 2022. 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.

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,	
	2021	2022
Fair value of common stock	$78.07	$79.21
Risk-free interest rate	1.31%	2.96%
Expected term (in years)	5.88	6.01
Expected volatility	67.20%	79.40%
Expected dividend yield	0%	0%

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2020	467,530	$47.81	8.5	$ 15,441
Granted	107,425	78.07		
Exercised	—	—		
Forfeited or cancelled	(67,142)	57.24		
Outstanding at December 31, 2021	507,813	$52.97	7.6	$ 12,703
Granted	345,216	79.21		
Exercised	(25,216)	18.93		
Forfeited or cancelled	(154,528)	68.99		
Outstanding at December 31, 2022	673,285	$64.02	7.4	$ 1,870
Vested and expected to vest at December 31, 2022	673,285	$64.02	7.4	$ 1,870
Options exercisable at December 31, 2022	330,074	$50.82	5.5	$ 1,870

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.

The weighted-average grant-date fair value of stock options granted during the years ended December 31, 2021 and 2022 was $47.42 per share and $27.27 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,	
	2021	2022
Sales and marketing	$ 550	$ 384
Research and development	1,279	1,554
General and administrative	2,502	4,162
	$ 4,331	$ 6,100

For the year ended December 31, 2021, stock-based compensation expense included $0.3 million related to the modification of stock options held by two former employees and $0.9 million related to a share transfer agreement with the same former employees, included in general and administrative expense (see Note 14).

For the year ended December 31, 2022, stock-based compensation expense included $1.1 million related to the modification of stock options held by two executives in connection with separation agreements, included in general and administrative expense.

As of December 31, 2022, total unrecognized stock-based compensation expense related to the unvested stock-based awards was $9.2 million, which is expected to be recognized over a weighted-average period of 3.2 years.

10. Income Taxes

During the years ended December 31, 2021 and 2022, 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,	
	2021	2022
Federal statutory income tax rate	(21.0) %	(21.0) %
State income tax, net of federal benefit	(0.8)	(0.7)
Federal and state research and development tax credits	(2.6)	(2.1)
Non-deductible items	0.6	0.1
Other	(0.6)	(0.5)
Change in deferred tax asset valuation allowance	24.4	24.2
Effective income tax rate	0.0 %	0.0 %

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

	December 31, 2021	December 31, 2022
Deferred tax assets:		
Net operating loss carryforwards	$ 22,604	$ 30,305
Capitalized research and development expenditures	—	5,918
Research and development tax credit carryforwards	3,200	4,635
Deferred revenue	39	899
Accruals and other temporary differences	2,620	3,117
Total deferred tax assets	28,463	44,874
Deferred tax liabilities:		
Depreciation and intangibles	(36)	(27)
Operating lease right-of-use asset	—	(772)
Total deferred tax liabilities	(36)	(799)
Valuation allowance	(28,427)	(44,075)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had U.S. federal net operating loss carryforwards of $137.3 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 $125.8 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, 2022, the Company had state net operating loss carryforwards of $23.4 million, which may be available to reduce future taxable income and expire at various dates beginning in 2029. As of December 31, 2022, the Company also had U.S. federal and state research and development tax credit carryforwards of $2.7 million and $2.5 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2036 and 2032, respectively, with $2.1 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, 2021 and 2022. 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,	
	2021	2022
Valuation allowance as of beginning of year	$ 15,067	$ 28,427
Increases recorded to income tax provision	13,360	15,648
Valuation allowance as of end of year	$ 28,427	$ 44,075

As of December 31, 2021 and 2022, 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, 2021 and 2022, 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, 2021 and 2022, there were no pending tax examinations. The Company is open to future tax examination under statute from 2019 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,	
	2021	2022
Numerator:		
Net loss attributable to common stockholders	$ (54,832)	$ (64,751)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	966,504	984,459
Net loss per share attributable to common stockholders, basic and diluted	$ (56.73)	$ (65.77)

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 anti- dilutive effect:

	Years Ended December 31,	
	2021	2022
Convertible preferred stock (as converted to common stock)	915,793	1,368,494
Stock options to purchase common stock	507,813	673,285
Warrants to purchase convertible preferred stock	—	102,539
	1,423,606	2,144,318

12. Revenue

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, 2021 and 2022, all of the Company's revenue was derived from its collaboration agreement with Novo Nordisk.

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. In April 2021, the agreement was further amended to include additional supplies to be provided by Novo Nordisk to the Company to support testing. As of December 31, 2021, the Company estimated that the period of performance under the agreement would extend through September 30, 2022.

The work as described under the Novo Collaboration Agreement was completed in 2022.

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. In 2021, the second clinical milestone was achieved and the Company received a milestone payment of $0.6 million.

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 first clinical milestone and earning the related milestone payment of $0.6 million in 2020.

During the year ended December 31, 2021, the Company recognized revenue of $0.6 million under the Novo Collaboration Agreement, which included $0.5 million recognized as a catch-up adjustment upon achieving the second clinical milestone and earning the related milestone payment of $0.6 million in 2021.

During the year ended December 31, 2022, the Company recognized revenue of $0.2 million under the Novo Collaboration Agreement.

As of December 31, 2021, no amounts were due as accounts receivable and deferred revenue of $0.2 million was recorded in connection with the Novo Collaboration Agreement. As of December 31, 2022, no amounts were due as accounts receivable and there was no deferred revenue 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. Leases

The Company leased office, laboratory and manufacturing space in Irvine, California (Myford location) under an operating lease that was due to expire in March 2023. In June 2021, the Company entered into a Lease Termination Agreement with its landlord related to the lease for office, laboratory and manufacturing space in Irvine, California. As a result of the Lease Termination Agreement, rental payments under the lease ceased on May 31, 2021. The Lease Termination Agreement required the Company to pay an early termination fee of $45,000, which was recorded as a component of rent expense on the statement of operations and comprehensive loss for the year ended December 31, 2021. In addition, the remaining deferred rent balance of $20,842 related to the lease was recognized in full as a reduction of rent expense on the statement of operations and comprehensive loss for the year ended December 31, 2021.

The Company leases office space in Concord, Massachusetts under an operating lease that expires in October 2026. The lease provides for fixed rental payments with annual rent escalations. The Company pays for its proportionate share of building operating costs such as maintenance, real estate taxes, and insurance that are treated as variable costs and excluded from the measurement of the lease. The Company is entitled to one option to extend the lease term for an additional five years. The option to extend the lease term was not included in the right-of-use asset and lease liability as it was not reasonably certain of being exercised.

The Company leases office, laboratory and manufacturing space in Irvine, California (Hughes location) under an operating lease that expires in May 2027. The lease provides for fixed rental payments with annual rent escalations and a fixed management fee. The Company pays for its proportionate share of building operating costs such as maintenance, real estate taxes, and insurance that are treated as variable costs and excluded from the measurement of the lease. The Company is entitled to one option to extend the lease term for an additional five years. The option to extend the lease term was not included in the right-of-use asset and lease liability as it was not reasonably certain of being exercised.

The Company does not have any leases that are classified as financing leases.

The components of lease expense were as follows (in thousands):

	Years Ended December 31,	
	2021	2022
Operating lease cost – fixed	$ 997	$ 916
Operating lease cost – variable	—	143
Short-term lease expense	—	6
Total lease expense	$ 997	$ 1,065

Supplemental disclosure of cash flow information related to leases was as follows (in thousands):

	December 31, 2022
Cash paid for amounts included in the measurement of operating lease liabilities	$ 907

The weighted-average remaining lease term and discount rate were as follows (in thousands):

	December 31, 2022
Weighted-average remaining lease term	4.25 years
Weighted-average discount rate	4.04%

Future lease payments under non-cancellable leases as of December 31, 2022 were as follows:

Year Ending December 31,	
2023	$ 997
2024	1,038
2025	1,079
2026	1,060
2027	327
Total future lease payments	4,501
Less: imputed interest	(369)
Total lease liabilities	$ 4,132

14. Commitments and Contingencies

Purchase Commitments

Under its hardware and software license agreements, as amended, with Boston University (“BU”), a related party (see Note 15), the Company is obligated to pay BU royalties and other amounts.

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.

In June 2021, the agreement was further amended to provide additional funding for the pivotal trial. During the year ended December 31, 2021, the Company paid the Jaeb Center $1.4 million. Based on a reconciliation by the Jaeb Center of the funding received from the Company and the incurred and expected remaining costs of the trial, the Jaeb Center returned $0.3 million to the Company in December 2021. As of December 31, 2021, the Company did not have any remaining purchase commitments under the research supply agreement.

In April 2022, the agreement was further amended to provide additional funding for the pivotal trial. During the year ended December 31, 2022, the Company paid the Jaeb Center $0.3 million. As of December 31, 2022, the Company did not have any remaining purchase commitments under the research supply agreement.

Consulting Agreement

In 2020, the Company entered into a three-year, non-cancellable consulting agreement for investor relations services. As of December 31, 2022, the Company had a remaining purchase commitment of $0.3 million, payable over the remaining term of the agreement.

Separation Agreements

In May 2021, the Company terminated employment of two employees. In June 2021, in connection with the terminations of employment, the Company and Company's CEO entered into a confidential separation agreement and mutual general release with each of the former employees, which became effective in July 2021 (the "Separation Agreements"). The Separation Agreements provided for each of the former employees to each receive: (i) continuation of their base salary for 12 months and their 2021 Target Bonus payable in substantially equal installments over the severance period (equal to $0.8 million in total), (ii) payment of the Company portion of health insurance premiums for up to 12 months, (iii) reimbursement of up to $5,000 each for legal expenses incurred and (iv) an extended post-termination exercise period for certain vested stock options held by them from six months to two years. The stock-based compensation expense related to the modification of the stock options of the former employees was $0.3 million and was recognized as general and administrative expense during the year ended December 31, 2021. In addition, the Separation Agreements provided for the transfer of 5,500 shares of Class B common stock from the Company's CEO and his spouse to each of the former employees, the terms of which transfer are governed by a separate Share Transfer Agreement (the "Transfer Agreement").

In order to satisfy the transfer of the Class B common stock under the terms of the Separation Agreements, the Company entered into a Share Exchange Agreement with the Company's CEO and his spouse to exchange 11,000 shares of their Class A common stock for 11,000 shares of Class B common stock (the "Exchange Agreement"). Upon the effectiveness of the Exchange Agreement in February 2022, the Company's CEO and his spouse surrendered for cancellation the original stock certificates for Class A common stock and the Company delivered a certificate to the CEO and his spouse representing 11,000 shares of Class B common stock.

In order to effect the stock transfer to the former employees, in February 2022, the Company entered into the Transfer Agreement with the Company's CEO and his spouse and the former employees, pursuant to which the Company cancelled the stock certificates issued to the CEO and his spouse for 11,000 shares of Class B common stock and issued a stock certificate for 5,500 shares of Class B common stock to each of the former employees. The stock-based compensation expense related to the transfer of these shares was $0.9 million and was recognized as general and administrative expense during the year ended December 31, 2021. The amount of that expense was based on the fair value of the Company's common stock per share as of July 2021, the effective date of the Separation Agreements. As part of the Transfer Agreement, the Company agreed to pay $0.5 million to cover the tax withholdings for the former employees resulting from the share transfer, which has been recognized as additional general and administrative expense during the year ended December 31, 2021.

The remaining liability for accrued severance costs under the Separation Agreements was $0.9 million, which was included in accrued expenses and other current liabilities in the balance sheet as of December 31, 2021. The liability for the accrued severance costs under the Separation Agreements was paid in full as of December 31, 2022.

In August 2022, the Company terminated employment of two executives. In connection with the termination of employment, the Company extended the post-termination exercise period of all stock options. The stock-based compensation expense related to the modification of the stock options of the former executives was $1.1 million and was recognized as general and administrative expense during the year ended December 31, 2022.

In August 2022, the Company undertook a restructuring program, including a reduction in force. The Company incurred a charge totaling $4.2 million, representing employee severance and benefit-related costs to be paid over the next 12 months. The remaining liability for accrued severance costs under the restructuring program was $2.1 million, which was included in accrued expenses and other current liabilities in the balance sheet as of December 31, 2022.

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 April 30, 2023, the date that these financial statements were available to be issued, 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, financial condition or cash flows.

15. Related Party Transactions

Boston University

In December 2015, the Company executed 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, September 2020 and February 2022 to extend the milestone dates. Under the software agreement, the final milestone is FDA approval of the licensed products by July 2024. Under the hardware agreement, the final milestone is FDA approval of the licensed products by July 2027.

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 CEO.

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, 2021 and 2022, the Company paid BU $0.2 million and $0.1 million, respectively, for reimbursed legal costs in connection with the agreements.

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 CEO, 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, 2021 and 2022. As of December 31, 2022, the Company has concluded that the future economic benefit of the funded R&D liability will be achieved upon FDA approval during the year ended December 31, 2023, and therefore, has reclassed the funded F&D liability to current liabilities on the balance sheets.

As of December 31, 2021 and 2022, other than the amount of the funded R&D liability, $22,900 and $0.2 million, respectively, was due to BU from the Company. As of December 31, 2021 and 2022, no amounts were due from BU to the Company.

16. 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. Under the terms of the Plan, the Company matches 100% of the first 6% of employee contributions. During the years ended December 31, 2021 and 2022, the Company contributed $0.9 million and $1.1 million, respectively, to the 401(k) Plan.

17. Subsequent Events

For the financial statements as of and for the year ended December 31, 2022, the Company evaluated subsequent events through April 30, 2023, the date on which those financial statements were available to be issued.

Stock Option Cancellation and Regrant

On March 2, 2023, and in accordance with the terms of the Company's 2016 Plan, the Company's board of directors approved a stock option cancel and regrant (the "2023 Cancel and Regrant"), wherein outstanding stock options to acquire shares of the Company's common stock that were issued during the period December 2019 through December 2022 to active ("active" defined as active as of March 2, 2023) employees, members of the board of directors, and consultants of the Company were canceled and regranted at the price of the Company's common stock valuation on December 31, 2022. As of that date, the Company's common stock fair value was $38.05 per share. Aside from the reduced strike price, all regranted options kept the same terms and conditions of the canceled stock options, including vested amounts and vesting schedules. Upon the cancel and regrant, the Company recognized $0.4 million of additional stock-based compensation from vested options. As unvested options continue to vest, the Company anticipates the recognition of an additional $1.5 million of stock-based compensation expense from the date of the modification through 2027.

Grants of Stock Options under the 2016 Plan

In January 2023 and March 2023, the Company granted options for the purchase of an aggregate of 33,350 shares of Class B common stock, at an exercise price of $38.05 per share.

Sub-lease

On March 1, 2023, the Company entered into a facility sublease agreement (the "Sublease") for approximately 2,200 square feet of office space in San Diego, California (San Diego location) that expires on July 31, 2025, with no option to extend the lease term. The lease provides for fixed rental payments with annual rent escalations. The Company is not subject to any pass-through operating costs but will pays for its proportionate share of electricity, which is treated as a variable cost and excluded from the measurement of the lease. At the commencement of the lease, the Company recognized a $0.2 million right-of-use asset and associated lease liability.