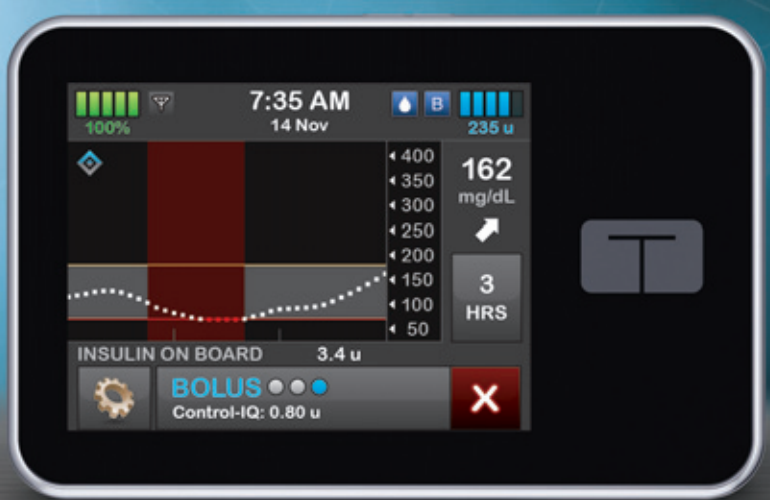
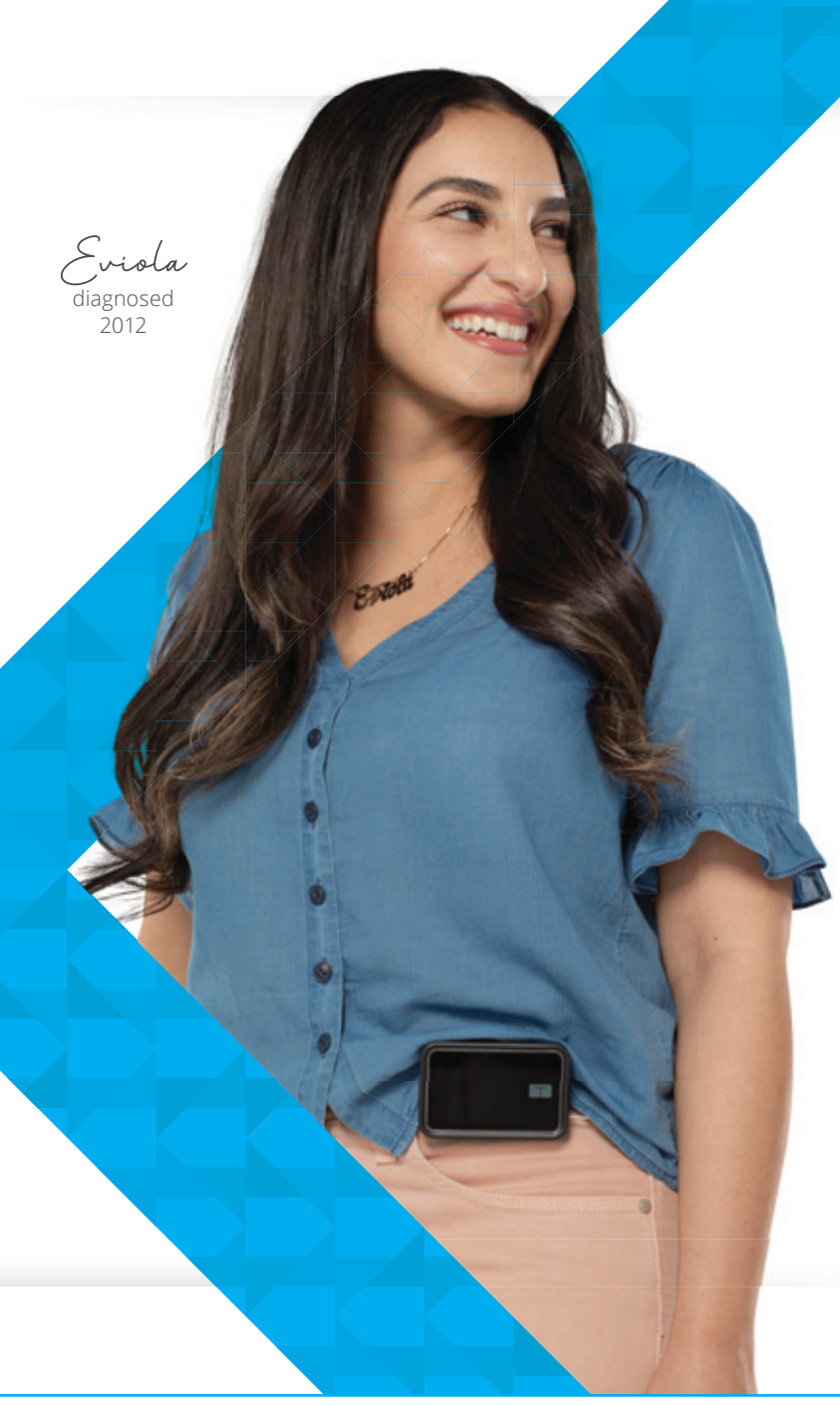
TANDEM®
DIABETES CARE

2019 ANNUAL REPORT

t:slim X2™
Insulin Pump

with Control-IQ™ Technology





Eviola
diagnosed
2012

See How Easy **Control** Can Be

t:slim X2 Insulin Pump
WITH Control-IQ TECHNOLOGY

- Adjusts basal insulin delivery to help prevent highs and lows
- Delivers automatic correction boluses (up to one per hour)
- Dedicated Exercise and Sleep Activities for more targeted control

Control-IQ technology does not prevent all highs and lows. You must still bolus for meals and actively manage your diabetes. For more information, please visit tandemdiabetes.com/tslimX2-use.

Important Safety Information: Caution: Federal (USA) law restricts the t:slim X2 insulin pump and Control-IQ technology to sale by or on the order of a physician. The t:slim X2 pump and Control-IQ technology are intended for single patient use. The t:slim X2 pump and Control-IQ technology are indicated for use with NovoLog or Humalog U-100 insulin. t:slim X2 insulin pump: The t:slim X2 insulin pump with interoperable technology is an alternate controller enabled (ACE) pump that is intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in people requiring insulin. The pump is able to reliably and securely communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. The t:slim X2 pump is indicated for use in individuals 6 years of age and greater. Control-IQ technology: Control-IQ technology is intended for use with a compatible integrated continuous glucose monitor (iCGM, sold separately) and ACE pump to automatically increase, decrease, and suspend delivery of basal insulin based on iCGM readings and predicted glucose values. It can also deliver correction boluses when the glucose value is predicted to exceed a predefined threshold. **Control-IQ technology is intended for the management of Type 1 diabetes mellitus in persons 14 years of age and greater.**

Control-IQ technology is not indicated for use in pregnant women, people on dialysis, or critically ill patients. Do not use Control-IQ technology if using hydroxyurea. Users of the t:slim X2 pump and Control-IQ technology must: use the insulin pump, CGM, and all other system components in accordance with their respective instructions for use; test blood glucose levels as recommended by their healthcare provider; demonstrate adequate carb-counting skills; maintain sufficient diabetes self-care skills; see healthcare provider(s) regularly; and have adequate vision and/or hearing to recognize all functions of the pump, including alerts, alarms, and reminders. The t:slim X2 pump, transmitter, and sensor must be removed before MRI, CT, or diathermy treatment. Visit tandemdiabetes.com/safetyinfo for additional important safety information.

WARNING: Control-IQ technology should not be used by anyone under the age of six years old. It should also not be used in patients who require less than 10 units of insulin per day or who weigh less than 55 pounds.

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DEAR FELLOW STOCKHOLDERS,

"In Tandem" means together and at Tandem Diabetes Care, we strive to embody that in every aspect of our business. We believe that working together is the best way to continually exceed expectations. In 2019, this approach allowed us to set records throughout our business, add to our growing list of first-time achievements, and execute on key scalability initiatives that position us well for longer-term success.

Bringing the benefits of pump therapy to more people with diabetes has been a longer-term goal for our Company, and we believe that we are a meaningful contributor to the expansion of the insulin pump market. We first began offering our modern, easy-to-use insulin pump in the United States in 2012. Since that time, we estimate that the U.S. insulin pump market has grown by 40% to 600,000 people and at the end of 2019, Tandem customers represented nearly 20% of this expanded pump market.

2019 was also our first full year of sales outside the United States. We are transforming into a global enterprise with approximately 24,000 people using a t:slim X2 pump in more than 13 countries outside the United States, which is an incredible accomplishment following our first full year of international sales.

Importantly, each year since launch we've demonstrated meaningful growth, and our performance in 2019 was our strongest yet. It was a record-setting year for us in many ways, including our:

- nearly doubling of year-over-year sales,
- shipping more pumps in 2019 than the past 3 years combined,
- driving a 5-point year-over-year gross margin improvement, and
- generating nearly $50 million in cash.

These achievements have helped to redefine the financial profile of the Company, putting us in the strongest position since our inception. Much of this success can be attributed to the rapid adoption of the t:slim X2 insulin pump with Basal-IQ technology, which took place domestically throughout the year, and internationally beginning in the third quarter. The response from customers has been very positive and for the first time our insulin pump system gained attention for its clinical offerings in addition to its consumer-oriented features.

Building upon this clinical momentum was the June 2019 unveiling of clinical trial results featuring our next-generation automated insulin delivery system, the t:slim X2 insulin pump with Control-IQ technology. The results were overwhelmingly positive. All primary and secondary outcomes were met with statistical significance, and the quality of life metrics were outstanding. In October 2019, these results were published in the *New England Journal of Medicine,* which further validated the rigor of the landmark study and the robustness of the safety and efficacy data, followed by the FDA's clearance of our t:slim X2 with Control-IQ technology in December 2019.

We now offer the most advanced automated insulin dosing system commercially available in the world today. This is a testament to our Company's commitment to working together to improve the lives of people with diabetes by offering simple-to-use products that deliver superior performance.

Scalability was a primary focus in 2019 to keep up with the unprecedented growth, particularly in areas such as manufacturing where we tripled our output. We began making meaningful investments throughout our business to not only support the increased volumes, but also create efficiencies in our operations to help support

our next phase of growth and drive long-term margin expansion. We began by investing in new manufacturing lines to create significant increased capacity, partnering with a key third party contract manufacturer and opening a new warehouse facility.

Customer support was also an area of continued expansion, as we believe the service we provide our customers is equally as important as our insulin delivery systems. With this philosophy in mind, in the summer of 2019 we opened a parallel customer service facility in Boise, Idaho that is dedicated to supporting many of the positions that scale with our customer base.

Another key investment area in 2019 was in information technology. Customer facing systems, as well as internal systems that help our business run more efficiently, were included in this effort. These initiatives are important to support our longer-term growth, and with the more recent global threat of the Coronavirus, they've also shown to have an immediate benefit of providing many employees the flexibility to successfully work outside of the office. As a result, our team has stayed adaptable during recent uncertain times, and we are prioritizing the safety of our customers, employees, and communities, while working to further our business.

Over the past few years, we've worked to transform our Company from a domestic venture-backed insulin pump start-up to a self-sustained, global diabetes technology company. We have been successful in recruiting a diverse group of new talented leaders, many from more mature global organizations, and have also expanded the responsibilities of many of our tenured members of management. In combination, I believe our leadership team has the strategic vision and operational skills to thoughtfully execute our business plan and prepare the organization for our next phase of growth.

Throughout every phase of our company, Kim Blickenstaff has played in integral role. He led Tandem as our President and CEO until last year when he transitioned to Executive Chairman, and then recently transitioned to our Chairman. Tandem's story is a success because of Kim's leadership and unwavering personal and financial support. We appreciate his guidance through the years and look forward to continuing working closely with him as our Chairman.

In 2020, we are excited that nearly all of the catalysts that drove our growth in 2018 and 2019 are still in place: our differentiated insulin pump platform, our best-in-class automated insulin delivery algorithms, meaningfully underpenetrated domestic and international insulin pump markets, significant competitive capture opportunities, and a growing renewal base. What underlays our excitement is the passion of our employees to improve the lives of people with diabetes.

These growth catalysts, combined with our robust product pipeline, give us confidence that we will reach our goal of 500,000 people using our products worldwide within the next five years. To achieve this, we'll be working to lead in insulin therapy management by building a robust ecosystem and portfolio of data-driven products and services around our flagship insulin pumps. We'll also be continuing to invest in our customer service and support to live up to the world-class standard we set for ourselves.

We appreciate the confidence of our investors during this exciting time for Tandem Diabetes Care. We'd also like to extend our sincere thanks and appreciation to our more than 1,000 employees as we continue to support people with diabetes through relentless innovation and revolutionary customer experience.

John Sheridan
President & CEO

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

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2019
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____
Commission File Number 001-36189

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**20-4327508**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11075 Roselle Street	**92121**
San Diego California	**(Zip Code)**
(Address of principal executive offices)	

(858) 366-6900
Registrant's telephone number, including area code
Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	**TNDM**	**NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☐
Indicate by check if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☐
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☐ No ☐
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See definitions of "large accelerated filer, "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☐
As of June 28, 2019, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $3.6 billion based on the closing price for the common stock of $64.52 on that date. Shares of common stock held by each executive officer, director, and their affiliated stockholders have been excluded from this calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.
As of February 14, 2020, there were 59,726,471 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2020 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K. Except for the portions of the Proxy Statement specifically incorporated by reference in this Form 10-K, the Proxy Statement shall not be deemed to be filed as part hereof.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2019, or this Annual Report, contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to considerable risks and uncertainties. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Annual Report, other than statements of historical fact, are forward-looking statements. You can identify forward-looking statements by the use of words such as "may," "will," "could," "anticipate," "expect," "intend," "believe," "continue" or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements. In particular, forward-looking statements contained in this Annual Report relate to, among other things, our future or assumed financial condition, results of operations, liquidity, trends impacting our financial results, business forecasts and plans, research and product development plans, manufacturing plans, strategic plans and objectives, capital needs and financing plans, product launches, regulatory approvals, the impact of changes in the competitive environment, and the application of accounting guidance. We caution you that the foregoing list may not include all of the forward-looking statements made in this Annual Report.

Our forward-looking statements are based on our management's current assumptions and expectations about future events and trends, which affect or may affect our business, strategy, operations or financial performance. Although we believe that these forward-looking statements are based upon reasonable assumptions, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Our actual financial condition and results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption "Risk Factors" in Part I, Item 1A and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7, and elsewhere in this Annual Report, as well as in the other reports we file with the Securities and Exchange Commission, or the SEC. You should read this Annual Report with the understanding that our actual future results may be materially different from and worse than what we expect.

Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Forward-looking statements speak only as of the date they were made, and, except to the extent required by law or the rules of the NASDAQ Global Market, we undertake no obligation to update or review any forward-looking statement because of new information, future events or other factors.

We qualify all of our forward-looking statements by these cautionary statements.

PART I

Item 1. Business

Overview

We are a medical device company with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. Our goal is to lead in insulin therapy management by building a robust ecosystem and portfolio of data-driven products and services around our flagship insulin pumps. We believe our competitive advantage is rooted in our consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing, sales and support activities principally focus on our flagship pump platform, the t:slim X2 Insulin Delivery System (t:slim X2), and our complementary product offerings. The simple-to-use t:slim X2 is based on our proprietary technology platform and is the smallest durable insulin pump available. It is the only pump currently available in the United States that is capable of remote feature updates, which positions us well to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. We aim to improve and simplify the lives of people with diabetes and those of their healthcare providers, by delivering innovative hardware and software solutions, as well as best-in-class customer support.

Since our initial commercial launch, we have been able to rapidly innovate and bring more products to market than our competitors. We have commercially launched seven insulin pumps in the United States since 2012 and two pumps outside the United States since 2018. Four of our insulin pumps have featured integration with continuous glucose monitoring (CGM) technology, and two have featured an automated insulin delivery (AID) algorithm. We believe that the three new classifications defined by the United States Food and Drug Administration (FDA) for the interoperability of devices for AID will help support continued rapid innovation by streamlining the regulatory pathway for integrated products. In June 2018, the t:slim X2 was the first insulin pump designated as compatible with integrated continuous glucose monitoring (known as iCGM) devices; in February 2019, the t:slim X2 was the first in a new device category called Alternate Controller Enabled Infusion Pumps (ACE pumps); and in December 2019, Control-IQ technology for the t:slim X2 insulin pump was the first automated insulin dosing software in a new interoperable automated glycemic controller category.

Today, our t:slim X2 hardware platform represents 100% of our new pump shipments. It is the only commercial insulin pump that allows users to update their pumps' software quickly and easily from a personal computer. We have offered in-warranty t:slim customers in the United States four different software updates for no-cost using the Tandem Device Updater, including our two AID algorithms, Basal-IQ technology and Control-IQ technology. Basal-IQ technology launched in August 2018 and is a predictive low glucose suspend feature that is designed to temporarily suspend insulin delivery to help reduce the frequency and duration of hypoglycemic events. Control-IQ technology launched in January 2020 and is an advanced hybrid-closed loop feature, designed to help increase a user's time in targeted glycemic range. It is the first and only system cleared to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. Outside the United States we began selling efforts with t:slim X2 with Dexcom G5 integration in the third quarter of 2018, offering no-cost software updates for Basal-IQ technology in the third quarter of 2019, and intend to begin offering Control-IQ technology updates in select geographies in the second half of 2020.

Our insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, we sell disposable products that are used together with our pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body.

In the four-year period ended December 31, 2019, we shipped approximately 142,000 insulin pumps, which is representative of our estimated global installed customer base on the typical four-year reimbursement cycle. Approximately 118,000 of these pumps were shipped to customers in the United States and approximately 24,000 were shipped to international markets.

For the years ended December 31, 2019, 2018 and 2017, our consolidated sales were $362.3 million, $183.9 million, and $107.6 million, respectively. For the years ended December 31, 2019, 2018 and 2017, our net loss was $24.8 million, $122.6 million, and $73.0 million, respectively. Worldwide pump sales accounted for 68%, 67%, and 66% of our total sales, respectively, for the years ended December 31, 2019, 2018 and 2017, while pump-related supplies and accessories accounted for the remainder in each year. Our accumulated deficit as of December 31, 2019 and December 31, 2018 was $624.8 million and $600.1 million, respectively. This included $216.6 million and $147.4 million of non-cash stock-based compensation charges and non-cash changes in the fair value of common stock warrants as of December 31, 2019 and 2018, respectively.

Our headquarters and our manufacturing facility are located in San Diego, California. We also have an office in Boise, Idaho. We employed 1,043 full-time employees as of December 31, 2019.

Diabetes and the Insulin Therapy Management Market

Diabetes is a chronic, life-threatening disease for which there is no known cure. The disease is categorized by improper function of the pancreas when it either does not produce enough insulin or the body cannot effectively use the insulin it produces. If not closely monitored and properly treated, diabetes can lead to serious medical complications, including damage to various tissues and organs, seizures, coma and death.

Diabetes is typically classified as either type 1 or type 2:

- Type 1 diabetes is characterized by the body's nearly complete inability to produce insulin. It is frequently diagnosed during childhood or adolescence. Individuals with type 1 diabetes require daily insulin therapy to survive.

- Type 2 diabetes represents 90% to 95% of all individuals diagnosed with diabetes and is characterized by the body's inability to either properly utilize insulin or produce enough insulin. Initially, many people with type 2 diabetes attempt to manage their diabetes with improvements in diet, exercise and oral medications. However, as their diabetes advances, some patients progress to requiring injectable therapies, such as long-acting insulin, and a subset of this population will require daily rapid-acting insulin therapy.

The International Diabetes Federation estimates that 463 million people have diabetes worldwide, approximately half of which are undiagnosed. In the United States, the Centers for Disease Control and Prevention estimates that in 2018 approximately 34 million people were living with diabetes of which approximately 27 million had diagnosed diabetes. We consider our addressable market to be people diagnosed with diabetes who are living with either type 1 diabetes, or with type 2 diabetes who require daily rapid acting insulin. Throughout this Annual Report, we refer to these individuals as people with insulin-dependent diabetes.

Estimated Diagnosed Diabetes Prevalence[(1)]

	Worldwide	Domestic
Type 1	24.2 million	1.6 million
Type 2 (all therapies)	206.8 million	25.4 million
Type 2 (insulin only)	*5 million*	*1.5 million*

(1) Internal estimates based on data from the International Diabetes Federation and the Centers for Disease Control and Prevention (CDC)

Diabetes Management Challenges

Diabetes can be difficult for patients to manage. Unlike most therapies, daily insulin requirements can vary greatly and can be affected by many factors, such as type or quantity of food eaten, illness, stress and exercise. People with diabetes have to be diligent in working to prevent their blood glucose from fluctuating outside of a targeted range. Hypoglycemia, or low blood glucose levels, can cause a variety of long-term effects or complications, including damage to various tissues and organs, seizures, coma or death. Hyperglycemia, or high blood glucose levels, can also cause a variety of long-term effects or complications, including cardiovascular disease and damage to various tissues and organs. Preventing and managing fluctuations in blood glucose levels, particularly when someone is outside their target blood glucose range is often time consuming and stressful to people with diabetes and their loved ones.

Insulin Therapy Management

There are two primary therapies used by people with insulin-dependent diabetes, insulin injections and insulin pumps. The use of insulin injections is often referred to as Multiple Daily Injection, or MDI, therapy. Insulin pumps are intended to more closely resemble the physiologic function of a healthy pancreas and use rapid-acting insulin to fulfill both mealtime (bolus) and background (basal) requirements. Insulin pump systems are most commonly comprised of a programmable hardware device, a cartridge filled with insulin by the user, and an infusion set to administer insulin into the person's body. This system is known as a durable pump. By comparison, patch insulin pumps are disposable and adhere to the body without an infusion set.

Insulin pump therapy can provide benefit to a person with insulin-dependent diabetes when used independently or in conjunction with CGM, which is a therapy that provides users with real-time access to their glucose levels as well as trend information. In addition, insulin pumps may feature an AID algorithm that is designed to automatically adjust a person's insulin delivery based on their CGM trends and other factors to help minimize the frequency and/or duration of hypoglycemia and/or hyperglycemic events. Insulin pumps may also feature connectivity with mobile apps and data management applications, which are used by the pump user, their caregivers and their healthcare providers, to quickly and easily identify meaningful insights and trends, allowing them to refine therapy and lifestyle choices for better management of their diabetes.

The American Diabetes Association estimated that in 2015, between 750,000 and 1 million people worldwide used an insulin pump. Domestically, we estimate that 600,000 people in the United States use an insulin pump. There are a variety of insulin pump manufacturers worldwide, while domestically, we are currently one of only two commercial durable insulin pump manufacturers and there is one programmable commercial patch insulin pump manufacturer.

We believe that the distinct advantages and increased awareness of insulin pump therapy as compared to other available insulin therapies will continue to generate demand for insulin pump devices and pump-related supplies. We further believe that recent and ongoing developments in the use of CGM technology and AID algorithms in conjunction with insulin pump therapy will continue to provide people with insulin-dependent diabetes benefits that will make insulin pump therapy an even more attractive treatment alternative.

Our Technology: Improving the Lives of People with Diabetes

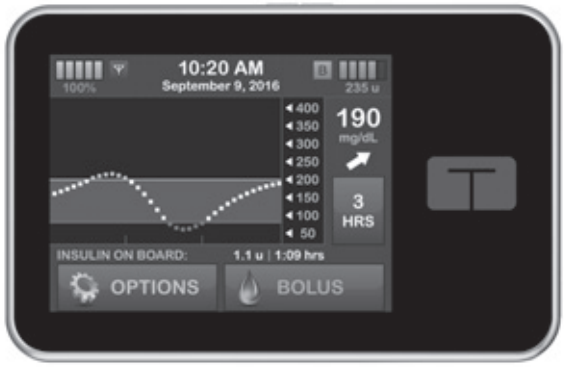
We develop our insulin pump technology and related product offerings using a consumer-focused approach. We initially rely on the use of behavioral sciences, including extensive research to ascertain what people with insulin-dependent diabetes require and prefer from their diabetes therapy. We then look to modern consumer technology for inspiration and design our hardware and software solutions to meet the specific demands of people with diabetes. This multi-step approach has resulted in products that provide users with the distinct features and functionality they seek and in a manner that makes the features usable and intuitive.

Since our initial commercial launch, we have been able to rapidly innovate and bring more products to market than our competitors. We have commercially launched seven insulin pumps since inception, all of which have been developed using our proprietary technology platform. The following table provides information regarding the commercial availability of our insulin pump products:

Product	U.S. Commercial Availability	OUS Commercial Availability
t:slim	August 2012 - October 2016	N/A
t:flex	May 2015 - June 2018	N/A
t:slim G4	September 2015 - August 2017	N/A
t:slim X2	October 2016 - September 2017	N/A
t:slim X2 with G5	September 2017 - August 2018	September 2018 - present (varies by geography)
t:slim X2 with Basal-IQ technology	August 2018 - present	September 2019 - present (varies by geography)
t:slim X2 with Control-IQ technology	January 2020 - present	Launch goal: 2H 2020* (to vary by geography)

*Subject to regulatory approvals and other factors

Today, our commercial efforts exclusively focus on the manufacturing, sale and support of our flagship pump platform, the t:slim X2 insulin delivery system, but we continue to provide ongoing service and support to existing t:slim, t:slim G4 and t:flex customers. The t:slim X2 insulin delivery system is comprised of a t:slim X2 pump, its 300-unit disposable insulin cartridge and an infusion set. It is also the only commercially available insulin pump featuring optional integration with Dexcom's CGM.



Our t:slim X2 Insulin Pump Form Factor (Actual Size)

t:slim X2 Insulin Pump: Our t:slim X2 was designed to offer greater ease of use and look more like other modern consumer technology, such as a smart phone, as compared to other traditional insulin pumps. Key features include:

- Color touchscreen - The large color touchscreen is easy to read, simple to learn, and intuitive to use for anyone familiar with a smartphone or tablet.
- Small and discreet - The t:slim X2 pump is up to 38 percent smaller than other pumps, yet can hold up to 300-units of insulin.

t:slim X2 Profile (Actual Size)

- Flexible technology - Can be used with or without automated insulin delivery or CGM - When advanced features are turned off, the t:slim X2 pump removes the CGM chart from the screen and puts the Bolus and Option buttons front and center for easy access. We currently offer integration with Dexcom's G5 or G6 sensor, depending on geography.
- AID features (availability varies by geography) - We have commercially launched two different AID algorithms on our t:slim X2 platform - Basal-IQ technology and Control-IQ technology.
    - Basal-IQ technology: This predictive low glucose suspend feature is designed to temporarily suspend insulin delivery to help reduce the frequency and duration of hypoglycemic events. With Dexcom G6 CGM integration, this feature works with no fingersticks required for mealtime dosing or calibration.
    - Control-IQ technology: This advanced hybrid-closed loop feature is designed to help increase a user's time in targeted glycemic range (70-180 mg/dL). It is the first and only system cleared to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. Control-IQ technology is integrated with Dexcom's G6 CGM and offers optional settings for sleep and exercise that change the treatment values to better match the different physiological needs during these activities.
- Connectivity - Features a two-way Bluetooth wireless technology radio for communicating with more than one external device at a time. It also features a micro-USB connection that supports charging the lithium-polymer battery, software updates and rapid data uploads.

Tandem Device Updater: A revolutionary tool that allows pump users to update their pumps' software quickly and easily from a personal computer. It is PC- and Mac- compatible and designed to work with the t:slim X2 in a manner similar to software updates on a smartphone. Because remote updatability for insulin pump software is a unique feature not available in competitive pump offerings, the Tandem Device Updater provides our customers with the capability to access new and enhanced features and functionality faster than the industry has been able to in the past. It was cleared by the FDA in the third quarter of 2016 and launched outside the United States in the third quarter of 2019. We have used this technology to offer in-warranty t:slim customers in the United States four different software updates for no-cost, including Basal-IQ technology, and most recently Control-IQ technology. Outside the United States we began offering no-cost software updates for Basal-IQ technology in the third quarter of 2019 and intend to begin offering Control-IQ technology updates in select geographies in the second half of 2020, subject to regulatory approvals and other factors.

t:connect: Our web-based data management application provides users, their caregivers and their healthcare providers with a fast, easy and visual way to display diabetes therapy management data from our pumps and supported blood glucose meters. This application empowers people with diabetes, as well as their caregivers and healthcare providers, to quickly and easily identify meaningful insights and trends, allowing them to refine therapy and lifestyle choices for better management of their diabetes. It also provides us with valuable data that we can analyze computationally to reveal patterns, trends and associations that can be used in continuous product improvements, and identification of clinical outcomes data. t:connect launched in the United States in the third quarter of 2013. In 2017, we launched t:connect HCP, which is an enhanced version of t:connect designed to simplify the ability of pump users to share t:connect data with their healthcare providers. We also plan to launch our new mobile application that when used with Control-IQ technology, is designed to wirelessly upload pump data to t:connect, receive notification of pump alerts and alarms, and provide a discrete, secondary display of glucose and insulin data. We believe t:connect can serve as a key component of additional mobile health applications that are currently under development. t:connect and t:connect HCP are currently not available to users or healthcare providers outside the United States.

Our Strategy

Enabled by our singular focus on diabetes management, our goal is to lead in insulin therapy management by building a robust ecosystem and portfolio of data-driven products and services around our flagship insulin pumps. We believe we are uniquely positioned to significantly expand and further penetrate the insulin-dependent diabetes market by focusing on the needs of our customers and their caregivers, and by supporting healthcare providers and payors with real world insights.

To achieve our goal, we intend to pursue the following business strategies:

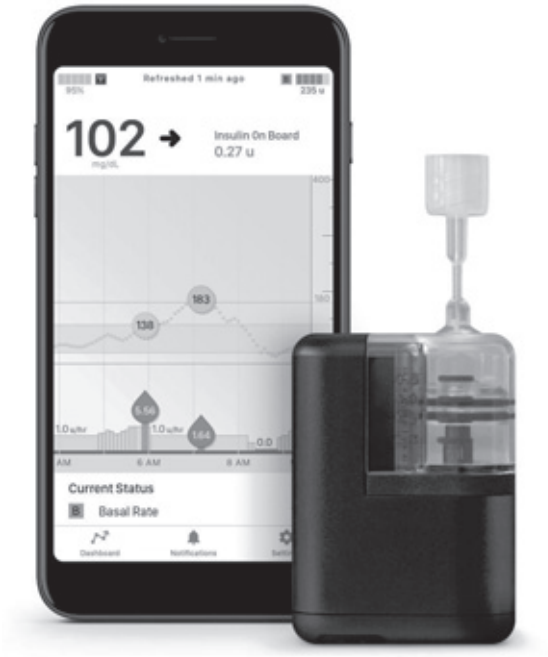
- drive worldwide adoption of our products by offering the best insulin delivery systems;
- deliver a portfolio of therapy management solutions designed to improve patient outcomes;
- expand the value provided by our portfolio through an ecosystem approach to diabetes management;
- build deeper relationships with all stakeholders across multiple channels, including virtual and tele-health platforms;
- leverage our manufacturing operations to achieve cost and production efficiencies;
- use data in new ways that deliver real-world insights and that promote better outcomes; and
- identify new offerings that support our mission to improve the lives of people with diabetes.

Products Under Development

Our products under development support our strategy of developing insulin delivery systems as part of a therapy management portfolio designed to improve patient outcomes, and include AID system enhancements, a next-generation hardware platform, and connected (mobile) health offerings.

t:sport Insulin Delivery System: Our Next-Generation Hardware Platform

Our next-generation hardware platform is referred to under its development name, the t:sport Insulin Delivery System, or t:sport. The t:sport pump is half the size of t:slim X2 and is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. We anticipate that t:sport will feature a 200-unit cartridge, an on-pump bolus button, a rechargeable battery, an AID algorithm, and a Bluetooth radio. t:sport is being designed for use with leading U-100 insulins, and we are evaluating the use of insulin concentrates for people with greater insulin needs. t:sport will utilize a pumping mechanism that differs from our current Micro-Delivery technology used in the t:slim pump platform.



t:sport Shown with Mobile App Controller

Based on the FDA's feedback, we are designing the product so that it will have the technical capability to be controlled using either a dedicated controller or our mobile device application. We expect that each of these functionalities will require separate regulatory reviews by the FDA. We plan to first pursue FDA authorization for t:sport as an ACE pump in 2020 and to thereafter submit for regulatory approvals outside the United States. We are designing t:sport to be compatible with our AID algorithms and any available iCGM.

Connected (Mobile) Health Offerings

We are preparing for the launch of a mobile application that has been designed to wirelessly upload pump data to our t:connect database management application, receive notification of pump alerts and alarms, and provide a discrete, secondary display of pump therapy data. Future updates of this app are expected to integrate other health-related information from third party sources and, subject to future regulatory approvals, support future pump-control capabilities for t:slim X2 and other products under development. The launch of the first generation of this app in the United States follows the availability of our Control-IQ technology. We also expect the wireless upload of data to the t:connect database will reduce patient burden and increase healthcare provider office efficiency by reducing the manual steps historically required for data extraction.

Sales, Marketing and Customer Care

In 2019, we expanded the number of territories in our U.S. sales organization from approximately 70 to approximately 90 by year-end. The vast majority of these territories are supported by a sales representative and a clinical diabetes specialist who, as a team, call on domestic endocrinologists, nurse practitioners, primary care physicians, certified diabetes educators and potential customers. Where appropriate, some territories are supported by multiple clinical diabetes specialists. Our U.S. sales team is augmented by individuals in our internal customer sales support organization, who follow up on leads generated through promotional activities and educate people on the benefits of our proprietary technology and products.

Our internal customer sales support organization also contacts existing customers who are approaching their insurance renewal date to aid in the renewal process. Our goal is for at least 70% of our existing customers to purchase a new pump from us when making their next pump purchasing decision. Typically, domestic customers are eligible for insurance reimbursement to purchase a new insulin pump once every four years; however, some plans may be limited to once every five years or have additional restrictions or requirements. Insurance reimbursement processes outside the United States vary by geography. As our market penetration continues to build momentum, and as we launch new products into the market, we plan to further expand our sales, clinical and marketing infrastructure in the United States. However, only modest territory optimizations and expansions are anticipated in 2020.

In Canada, we established a small direct sales and clinical infrastructure, and commenced marketing and sales efforts following Health Canada approval of the t:slim X2 with G5 integration in October 2018. In November 2019, we received Health Canada approval for the t:slim X2 with Basal-IQ technology. Throughout 2019, we also secured reimbursement in the majority of Canadian provinces, and these efforts will continue in 2020.

In other select geographies outside the United States, our initial efforts focused on the identification and contracting of distributors in areas where we believe there is a meaningful opportunity to achieve market acceptance of our t:slim X2 insulin pump. We began our scaled launch in the third quarter of 2018 after obtaining the right to affix the CE Mark to the t:slim X2 with G5 integration and following the completion of pre-launch activities, such as translating our pump software and user manual, and completing distributor sales and customer service trainings. Unlike our domestic operations, our international distributors (other than in Canada) have substantially greater responsibility for sales, marketing and customer support efforts. Our international distributors in 2019 covered several geographies including: Australia, Italy, New Zealand, Scandinavia (Denmark, Norway and Sweden), South Africa, Spain, and the United Kingdom. In 2020, our international distributors will also cover Germany, France, Belgium, Luxembourg and the Netherlands.

Revenue Concentrations and Significant Customers. A small number of independent domestic distributors have historically accounted for a significant portion of our revenues. During the year ended December 31, 2019, we made sales to approximately 43 independent distributors in the United States, and 12 independent distributors internationally. In fiscal 2019, sales to Byram Healthcare and RGH Enterprises, Inc. accounted for 15.4% and 14.8% of consolidated sales, respectively. In fiscal 2018, sales to RGH Enterprises, Inc. and Byram Healthcare accounted for 19.4% and 15.6% of consolidated sales, respectively. None of our independent distributors in the United States are required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements in the United States generally have one-year initial terms with automatic one-year renewal terms and are terminable in connection with a party's material breach. Our distributor agreements outside the United States generally have longer initial terms and, in addition to being terminable in connection with a party's material breach, include provisions that allow us to terminate those agreements prior to their ordinary expiration in exceptional circumstances. We believe our domestic distributors carry minimal inventory at any given time. Internationally, there may be variability in inventory levels among our distributors, particularly when they first commence product sales or surrounding the launch of new products.

Animas. In October 2017, Johnson & Johnson announced that it was discontinuing the operations of Animas, and exiting the insulin pump business entirely, and, in connection with these activities, designated Medtronic as a preferred partner to facilitate the transition of Animas insulin pump customers. Throughout 2018 and 2019 we experienced an increase in our percentage of sales to people who reported converting from using an Animas pump. Animas pump supplies were no longer available for customers to purchase after September 2019. Accordingly, we believe that the vast majority of Animas pump users have transitioned to an alternative pump, and that remaining Animas pump users will likely switch in 2020 as they use up their remaining supplies.

Outside the United States, many of our international distributors had existing relationships with Animas customers and were motivated to keep those individuals as existing customers by replacing Animas pumps with our t:slim X2 as opportunities arose. We believe the benefit from the Animas opportunity outside the U.S. was substantially realized by end of the second quarter of 2019.

Training and Customer Care. Our customer care infrastructure, which services the United States and Canada, consists of individuals focused on training, insurance verification and 24/7 technical services. Our goal is to offer best-in-class customer support and services as these offerings are often viewed by people with diabetes and their healthcare providers equally as important as the products we offer. In 2019, we opened a facility in Boise, Idaho to begin scaling our customer care organization outside of San Diego. This has allowed us to hire talented service employees more quickly than we would have been able to in San Diego at a lower cost of operations, which provides further leverage to our infrastructure. During 2020 we expect to expand our customer care infrastructure, including investments in facilities, technology and personnel, to meet the needs of our larger base of in-warranty customers. We also provide training to our distribution partners who fulfill their customer care responsibilities outside the United States.

Third-Party Reimbursement

In the United States, customer orders are typically fulfilled by billing third-party payors on behalf of our customers, or by utilizing our network of distributors who then bill third-party payors on our customers' behalf. Our fulfillment and reimbursement systems are fully integrated such that our products are shipped only after receipt of a valid physician's order and verification of current health insurance information.

We are accredited by the Community Health Accreditation Program and are an approved Medicare provider. Over the last ten years, Medicare reimbursement rates for insulin pumps and disposable cartridges have remained relatively unchanged. Domestically, we primarily bill for our insulin pump products and associated supplies using existing Healthcare Common Procedure Coding System codes for which Medicare reimbursement is well established. However, pump eligibility criteria for people with type 2 diabetes can be different and often requires additional documentation and laboratory testing to gain in-network insurance reimbursement benefits.

We enter into contracts with national and regional third-party payors to establish reimbursement for our insulin pump products, disposable cartridges and other related supplies. We employ a team of managed care managers who are responsible for negotiating and securing contracts with third-party payors throughout the United States. For the year ended December 31, 2019, approximately 27% of our sales in the United States were generated through our direct third-party payor contracts.

If we are not contracted with a person's third-party payor and in-network status cannot be otherwise obtained, then to the extent possible we utilize distribution channels so our customers' orders can be serviced. As of December 31, 2019, we had executed distributor agreements with approximately 43 independent distributors in the United States. In some cases, but not all, this network of distributors allows us to access people who are covered by commercial payors with whom we are not contracted, at in-network rates that are generally more affordable for our customers. However, UnitedHealthcare designated one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over seven years of age. Unless UnitedHealthcare implements a change to its coverage policies for insulin pumps, we expect this decision will prevent a majority of UnitedHealthcare members from purchasing our insulin pump , whether directly from us or through our network of distributors.

Our distribution partners outside the United States and Canada are responsible for all reimbursement, tender application and fulfillment activities.

Manufacturing and Quality Assurance

Historically, we have manufactured our pump and disposable cartridge products at our Barnes Canyon facility in San Diego, California. In 2020, we anticipate outsourcing a portion of our cartridge manufacturing to an experienced third-party contract manufacturer to provide us additional flexibility in scaling our business while creating additional leverage. In 2019, we made capital expenditure investments for the expansion of warehousing capacity and ordered additional manufacturing equipment for implementation in 2020. We anticipate these investments will allow us to double our cartridge manufacturing capacity from 2019 to 2020, without meaningfully increasing the cost of overhead associated with our manufacturing facilities. We believe these investments position us well to achieve our long-term gross margin targets.

We currently utilize a semi-automated manufacturing process for our pump products and disposable cartridges. The pump production line reaches a maximum output of approximately 30,000 pumps per year on a single shift. In 2019, we scaled from two to three pump manufacturing lines and currently have the capacity to produce approximately 180,000 pumps annually. Disposable cartridges are manufactured on a production line that reaches a maximum output of approximately one million cartridges per year on a single standard eight-hour shift. In 2019, we had four cartridge manufacturing lines and improved the efficiency of our disposable cartridge manufacturing process, which provided us capacity to build 16 million units annually. We also began investing in three additional cartridge manufacturing lines that will become operational at our third-party manufacturing location. When fully operational, we believe our seven cartridge manufacturing lines can support an installed base of more than 250,000 customers.

Outside suppliers are the source for most of the components and some sub-assemblies in the production of our insulin pumps. Any sole and single source supplier is managed through our supplier management program that is focused on reducing supply chain risk. Our suppliers are evaluated, approved and monitored periodically by our quality department to ensure conformity with the specifications, policies and procedures applicable to our devices. Members of our quality department also inspect our devices at various steps during the manufacturing cycle to facilitate compliance with our devices' stringent specifications.

We have received certification from BSI Group, a Notified Body to the International Standards Organization, or ISO, of our quality system. Certain processes utilized in the manufacturing and testing of our devices have been verified and validated as required by the FDA and other regulatory bodies. As a medical device manufacturer, our manufacturing facility and the facilities of our sterilization and other critical suppliers are subject to periodic inspection by the FDA and certain corresponding state agencies.

Research and Development

Our research and development team includes employees who specialize in software engineering, mechanical engineering, electrical engineering, fluid dynamics, mobile connectivity and graphical user interface design, many of whom have considerable experience in diabetes-related products. Our research and development team focuses on the continuous improvement and support of current product offerings, as well as our products under development.

In June 2015, we entered into non-exclusive agreements with Dexcom to allow the integration of our insulin pump products with the Dexcom G5 and G6 CGM systems worldwide. Each agreement has an initial term of five years, and thereafter renew automatically for additional one-year terms unless either party provides advance notice to the other party that they do not wish to extend the agreement. The agreements do not require any licensing fees, milestone payments or royalty obligations to Dexcom. The agreements contain customary provisions for termination in the event of an uncured material breach or in the event of a dissolution of the other party, and prohibit our assignment of the agreements to a Dexcom competitor without Dexcom's prior consent.

In 2016, we entered into a worldwide, non-exclusive, royalty-bearing license agreement with TypeZero to allow the integration of our insulin pump products with TypeZero's inControl AID technology. The agreement also provides us access to TypeZero's future AID innovations for five years following the date of the agreement. In addition, the license agreement contemplated that our insulin pump products would be used alongside TypeZero's AID technology in certain studies under the International Diabetes Closed Loop (IDCL) Trial, which are now completed. In August 2018, TypeZero was acquired by Dexcom. Nevertheless, the terms of our agreement with TypeZero remain effective until the patents covered by the agreement have expired, subject to customary provisions for termination in the event of an uncured material breach.

In October 2019, we and Abbott Laboratories, or Abbott, announced that we intend to develop and commercialize integrated diabetes solutions that combine Abbott's glucose sensing technology with Tandem's innovative insulin delivery systems to provide additional treatment options for people with insulin-dependence to manage their diabetes. These development and commercialization plans are contingent on the negotiation of a definitive agreement, and while the parties are currently exploring a business relationship, there can be no assurance that an agreement will be reached or that any agreement will be on the terms that are currently being discussed.

Intellectual Property

We have made protection of our intellectual property a strategic priority. We rely on a combination of copyright, patent, trademark, trade secret and other intellectual property laws, non-disclosure agreements and other measures to protect our proprietary rights.

As of December 31, 2019, our patent portfolio consisted of approximately 86 issued U.S. patents and 68 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2036. We are also seeking patent protection for our proprietary technology in other countries throughout the world. In addition, we also have 39 trademark registrations, including 16 U.S. trademark registrations and 23 foreign trademark registrations.

In July 2012, we entered into an agreement with Smiths Medical, Inc. pursuant to which we were granted, through certain assignments and certain non-exclusive and exclusive, worldwide, fully paid-up, royalty-free licenses, certain rights to patents and patent applications related to ambulatory infusion pumps and related software and accessories for the treatment of diabetes. We agreed to pay $5.0 million in license fees and to share equally any associated sublicense revenues we may receive. As of December 31, 2019, we had paid the initial license fees in full and have not entered into any sublicense agreements.

Competition

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 in domestic and international markets with a number of companies that manufacture insulin delivery devices, such as Medtronic MiniMed, a division of Medtronic, and Insulet Corporation. In late 2017, Eli Lilly & Co. announced that it was developing an insulin pump with AID technology, and there are several other companies that are currently marketing insulin pump products in international markets. In addition, we face competition from a number of companies, medical researchers and existing pharmaceutical companies that are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and prevention of diabetes.

For additional information, see the section of this Annual Report under the caption "Risk Factors" in Part I, Item 1A.

Government Regulation

Our products are medical devices subject to extensive regulation by the FDA in the United States, corresponding state regulatory authorities and other regulatory bodies in other countries. The U.S. Federal Food, Drug, and Cosmetic Act, (FDCA) and the FDA's implementing regulations govern:

- product design and development;
- pre-clinical and clinical testing;
- establishment registration and product listing;
- product manufacturing;
- labeling and storage;
- pre-market clearance or approval;
- advertising and promotion;
- product sales and distribution;
- recalls and field safety corrective actions; and
- servicing and post-market surveillance.

FDA's Pre-Market Clearance and Approval Requirements. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a pre-market notification under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA through the Premarket Approval, or PMA, process. Both the 510(k) clearance and PMA processes can be expensive, lengthy and require payment of significant user fees, unless an exemption is available.

The FDA classifies medical devices into one of three classes. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are subject to general controls such as labeling, pre-market notification and adherence to the FDA's Quality System Regulation, or QSR, which cover manufacturers' methods and documentation of the design, testing, production, control quality assurance, labeling, packaging, sterilization, storage and shipping of products. Class II devices are subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling, as well as general controls. Some Class I and Class II devices are exempted by regulation from the 510(k) clearance requirement, and the requirement of compliance with substantially all of the QSR. t:slim, t:flex, t:slim X2, t:slim X2 with Control-IQ technology and t:connect received FDA clearance as Class II devices. However, t:connect was subsequently down-classified to a Class I device. A PMA application is required for devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or those that are "not substantially equivalent" either to a device previously cleared through the 510(k) process or to a "preamendment" Class III device in commercial distribution before May 28, 1976 when PMA applications were not required. t:slim G4 and t:slim X2 with G5 integration, and t:slim X2 with Basal-IQ technology received FDA approval as Class III devices.

There are three new Class II categories classified by the FDA for the interoperability of devices as a complete AID system that are intended to help support continued rapid innovation by streamlining the regulatory pathway for integrated products approved by the FDA. In June 2018, our t:slim X2 with Basal-IQ technology was the first insulin pump to receive approval for iCGM compatibility. In February 2019, we received FDA approval of our De Novo application to classify the t:slim X2 to a Class II device, under the new insulin pump classification referred to as ACE pumps. Most recently, in December 2019 we received FDA approval of our De Novo application to classify our Control-IQ technology as the first automated insulin dosing software in a new interoperable automated glycemic controller category that automatically adjusts insulin delivery to a person with diabetes by connecting to an ACE pump and iCGM. In connection with the De Novo applications for both the ACE pump and the interoperable automated glycemic controller category the FDA also established certain special controls that we will need to continue to satisfy. If we are not able to satisfy those special controls, we would be required to seek approval for those products under the traditional PMA submission process.

For Class III devices a PMA application must be supported by valid scientific evidence that typically includes extensive technical, pre-clinical, clinical, manufacturing and labeling data to demonstrate to the FDA's satisfaction the safety and efficacy of the device. A PMA application also must include a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA. In addition, the FDA generally will conduct a pre-approval inspection of the manufacturing facility to evaluate compliance with QSR, which requires manufacturers to implement and follow design, testing, control, documentation and other quality assurance procedures.

FDA review of a PMA application generally takes approximately one year but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- systems may not be safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If an FDA evaluation of a PMA application is favorable, the FDA will issue either an approval letter, or approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of a device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not-approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel.

Clinical trials are typically required to support a PMA application and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an Investigational Device Exemption, or IDE, to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. The FDA's approval of an IDE allows clinical testing to go forward, but it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to the products that are part of our trial;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to us or our study that the FDA deems to make the study results unreliable, or the company or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

Other Regulatory Requirements. Even after a device receives clearance or approval and is placed in commercial distribution, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations that prohibit the promotion of products for uncleared, unapproved or "off-label" uses, and impose other restrictions on labeling, advertising and promotion;
- the FDA's Medical Device Reporting, or MDR regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- voluntary and mandatory device recalls to address problems when a device is defective and could be a risk to health; and
- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

Also, the FDA may require us to conduct post-market surveillance studies or establish and maintain a system for tracking our products through the chain of distribution to the patient level. We are currently in the planning phases for a post-market surveillance study for our t:slim X2 with Control-IQ technology. The FDA and the Food and Drug Branch of the California Department of Health Services enforce regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

In general, failure to comply with applicable regulatory requirements can result in enforcement actions by the FDA and other regulatory agencies. These may include any of the following sanctions or consequences:

- warning letters or untitled letters that require corrective action;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve future products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA clearance or approval;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

We and our contract manufacturers, specification developers and some suppliers of components or device accessories, are required to manufacture our products in compliance with current Good Manufacturing Practice, or GMP, requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and it includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components or services, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing, and record keeping. The FDA evaluates compliance with the QSR through periodic unannounced inspections that may include the manufacturing facilities of our subcontractors. If the FDA believes that we or any of our contract manufacturers, or regulated suppliers, are not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees.

Licensure. In the United States, several states require that durable medical equipment, or DME, providers be licensed in order to sell products to patients in that state. Some of these states require that DME providers maintain an in-state location or retain a licensed pharmacist, and in those states, we sell our products through a third-party distributor. Although we believe we are in material compliance with applicable state regulations regarding licensure requirements, if we were found to be noncompliant, we could be subject to fines and penalties or lose our licensure in that state, which could prohibit us from selling our current or future products to patients in that state. In addition, we are subject to certain state laws regarding professional licensure. We believe that our certified diabetes educators are in material compliance with such state laws. However, if our educators or we were to be found non-compliant in a given state, we may need to modify our approach to providing education, clinical support and customer service.

Fraud and Abuse Laws. There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including the federal Anti-Kickback Statute and the Physician Self-Referral Law, or the Stark Law, the federal civil False Claims Acts, the federal criminal Health Care Fraud Statute, as well as various state laws regulating healthcare. Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

Federal Anti-Kickback Statue. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid.

We provide the initial training to customers necessary for appropriate use of our products either through our own diabetes educators or by contracting with outside diabetes educators who have completed a Tandem pump-training course. Outside diabetes educators are reimbursed for their services at fair market value. Although we believe that these arrangements do not violate the Anti-Kickback Statute, regulatory authorities may determine otherwise, especially as enforcement of this law historically has been a high priority for the federal government. Noncompliance with the federal Anti-Kickback Statute could result in our exclusion from Medicare, Medicaid or other governmental programs (which could adversely affect our revenues to a material extent), restrictions on our ability to operate in certain jurisdictions, and civil and criminal penalties.

Physician Self-Referral Law. The Stark Law prohibits a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, if the physician has a financial relationship with the company. In addition to statutory exceptions, the Centers for Medicare and Medicaid Services (CMS), has issued numerous regulatory exceptions to the Stark Law. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these arrangements may not expressly meet the requirements for applicable exception from the law.

Federal False Claims Act. The federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits under the act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines and/or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

We submit reimbursement claims to federal healthcare programs, and we also may provide some coding and billing information to purchasers of our devices. These activities, if inappropriate, could result in liability under the False Claims Act. Further, claims arising from relationships which violate the Anti-Kickback Statute are considered to be false claims under the False Claims Act. Liability under the False Claims Act may also attach to claims arising from financial relationships which violate the Stark Law. We believe that we currently are in material compliance with the federal government's laws and regulations concerning the submission of claims and the provision of coding and billing information. However, because we cannot guarantee that the government or qui tam relators will regard any billing errors that may be made as inadvertent, or our provider relationships as compliant, we may have exposure under the False Claims Act.

Federal Health Care Fraud Statutes. We are also subject to a federal health care fraud statute that, among other things, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program including non-governmental programs, and prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false or fraudulent statement or representation, or making or using any false writing or document with knowledge that it contains a materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

State Fraud and Abuse Provisions. Many states have also adopted some form of anti-kickback and anti-referral laws and false claims acts. We believe that we are in material conformance to such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Data Privacy and Information Security Laws and Regulations. t:connect data is hosted on secure servers and our use of t:connect data is subject to internal policies and procedures that are designed to comply with the federal U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, as well as applicable U.S state privacy laws (including, but not limited to, the California Consumer Privacy Act). Although t:connect and t:connect HCP are not currently available to users or healthcare providers outside the United States, we are also mindful of requirements under Canada's Personal Information Protection and Electronic Documents Act, referred to as PIPEDA, and similar provincial laws, and the E.U. General Data Protection Regulation, commonly known as GDPR, and similar E.U. member state laws. Collectively, these laws and regulations set standards for safeguarding the confidentiality, integrity, and availability of the personal information we collect and use from customers and healthcare providers. These laws also require, among other things, that we are transparent about how we collect and share personal data and that we give t:connect users the ability to know what data we are collecting about them, to obtain a copy of that data, to correct or amend that data, and to request we restrict use of that data.

Healthcare Fraud. In addition to information security and data privacy obligations, HIPAA also created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment. We believe we are in substantial compliance with these provisions of HIPAA.

Physician Payments Sunshine Act. The Physician Payments Sunshine Act requires certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians. Manufacturers may be subject to audit for their compliance with this law. Failure to submit the required data in an accurate and timely manner may result in the imposition of civil monetary penalties. We believe we are in substantial compliance with the Physician Payments Sunshine Act.

Anti-Bribery and Anti-Corruption Laws. The U.S. Foreign Corrupt Practices Act, or the FCPA, and similar laws in foreign jurisdictions generally prohibit U.S. corporations and their representatives from offering, promising, authorizing or making improper payments, gifts or transfers to any foreign government official in order to obtain or retain business. The scope of the FCPA would include interactions with certain healthcare professionals and hospital administrators in many countries. We believe we are in substantial compliance with the FCPA and similar foreign regulations.

International Regulation

International sales of medical devices are subject to local government regulations, which vary substantially from country to country. The time required to obtain approval in another country may be longer or shorter than that required for FDA approval, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, United States, Canada and various other industrialized countries.

The primary regulatory body in Europe is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. Additional local requirements may apply on a country-by-country basis. Outside of the European Union, regulatory approval would need to be sought on a country-by-country basis in order for us to market our products.

Employees

As of December 31, 2019, we had 1,043 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

Executive Officers

Kim D. Blickenstaff (age 67) has served as Executive Chairman of our board of directors since March 2019, and previously served as President and Chief Executive Officer from September 2007 to March 2019. Mr. Blickenstaff has served as one of our directors since September 2007. We recently announced that Mr. Blickenstaff will transition to the role of Chairman of our board of directors in March 2020. Prior to joining our company, he served as Chairman and Chief Executive Officer of Biosite Incorporated, or Biosite, a provider of medical diagnostic products, from 1988 until its acquisition by Inverness Medical Innovations, Inc. in June 2007. Mr. Blickenstaff previously served as a director of Medivation, Inc. (NASDAQ: MDVN), a biotechnology company, from 2005 to 2016, until its acquisition by Pfizer, and as a director of DexCom, Inc. (NASDAQ: DXCM), a provider of CGM systems, from June 2001 to September 2007. Mr. Blickenstaff was formerly a certified public accountant and has more than 20 years of experience overseeing the preparation of financial statements. He received a B.A. in Political Science from Loyola University, Chicago, and an M.B.A. from the Graduate School of Business, Loyola University, Chicago.

John F. Sheridan (age 64) has served as our President and Chief Executive Officer since March 2019 and as a member of our board of directors since June 2019. Mr. Sheridan previously served as Executive Vice President and Chief Operating Officer since April 2013. Prior to joining our company, Mr. Sheridan served as Chief Operating Officer of Rapiscan Systems, Inc., a provider of security equipment and systems, from March 2012 to February 2013. Mr. Sheridan served as Executive Vice President of Research and Development and Operations for Volcano Corporation, a medical technology company, from November 2004 to March 2010. From May 2002 to May 2004, Mr. Sheridan served as Executive Vice President of Operations at CardioNet, Inc., a medical technology company, now operating as BioTelemetry, Inc. (NASDAQ: BEAT). From March 1998 to May 2002, he served as Vice President of Operations at Digirad Corporation, a medical imaging company. Mr. Sheridan holds a B.S. in Chemistry from the University of West Florida and an M.B.A. from Boston University.

David B. Berger (age 50) has served as our Chief Legal and Compliance Officer since April 2019, as General Counsel since August 2013, as our Corporate Secretary since January 2015, and as our Executive Vice President since January 2016. From January 2008 until August 2013, Mr. Berger was employed at Senomyx, Inc., a taste science company, where he most recently served as Senior Vice President and General Counsel. He also served as Corporate Secretary of Senomyx from January 2008 until May 2014. From April 2003 until October 2007, Mr. Berger was responsible for all commercial aspects of legal affairs at Biosite, most recently serving as Vice President, Legal Affairs. Previously, Mr. Berger was an attorney at Cooley Godward LLP and Amylin Pharmaceuticals, Inc. Mr. Berger holds a B.A. in Economics from the University of California, Berkeley and a J.D. from Stanford Law School.

Brian B. Hansen (age 52) has served as our Executive Vice President and Chief Commercial Officer since February 2016. Prior to joining our company, Mr. Hansen served from September 2014 as Chief Commercial Officer of Adaptive Biotechnologies Corp. From May 2013 to September 2014, Mr. Hansen served as Head of Commercial, Sales and Marketing, of Genoptix, a Novartis Company. From December 2005 to February 2013, he served in various roles of increasing responsibility at Gen-Probe, Inc., a medical diagnostics company, most recently serving as Senior Vice President, Global Sales and Services from January 2012 to February 2013. Mr. Hansen received a B.S. in Business Administration from the University of Missouri-Columbia, and an M.B.A. from the School of Business at San Diego State University.

Elizabeth A. Gasser (age 44) has served as our Executive Vice President of Strategy and Corporate Development since January 2020. Prior to joining our company, Ms. Gasser served from June 2017 as an independent adviser providing strategic and corporate development solutions to boards and executive teams. From January 2016 to June 2017 she was Vice President of Corporate Strategy at QUALCOMM Technologies, Inc. (QTI), a subsidiary of QUALCOMM Incorporated (NASDAQ: QCOM), a global leader in the development and commercialization of technologies and products used in mobile devices and other wireless products. Prior to that, from November 2012 to January 2016 she was Vice President of Strategic Development at QTI, after serving in other strategic related roles of increasing responsibility beginning in 2006. Ms. Gasser holds a B.A. and an M.A. in Economics from the University of Cambridge.

Susan M. Morrison (age 40) has served as our Chief Administrative Officer since September 2013 and as an Executive Vice President since December 2017. From April 2013 until September 2013, she served as our Vice President, Human Resources, Corporate and Investor Relations. Ms. Morrison served as our Director, Corporate and Investor Relations, from January 2009 to March 2013, and was our Director, Corporate Services from November 2007 to December 2008. Prior to joining our company, Ms. Morrison held various positions in Corporate and Investor Relations at Biosite from August 2003 through November 2007. Ms. Morrison holds a B.A. in Public Relations from Western Michigan University.

Leigh A. Vosseller (age 47) has served as our Executive Vice President, Chief Financial Officer, and Treasurer since June 2018, and served as Senior Vice President, Chief Financial Officer and Treasurer from January 2018 to May 2018. Ms. Vosseller is our principal financial and accounting officer. She joined us as Vice President of Finance in 2013 and was promoted to Senior Vice President of Finance in August 2017. Prior to that time, she served as Vice President and Chief Financial Officer at Genoptix, beginning in 2011, after initially joining Genoptix in 2008. Prior to that she held a senior finance position at Biosite where she played a key role in developing the financial and administrative infrastructure for international expansion. Ms. Vosseller is a certified public accountant (inactive) and holds a B.S. in Accounting from Missouri State University.

Family Relationships

Mr. Sheridan, our President and Chief Executive Officer, and Ms. Vosseller, our Executive Vice President, Chief Financial Officer and Treasurer, are involved in a personal relationship and share a primary residence. Ms. Vosseller reports directly to Mr. Sheridan. Our board of directors is informed of the relationship and due to the direct reporting arrangement, we have taken appropriate actions to ensure compliance with Company policies and procedures. Mr. Sheridan and Ms. Vosseller will not be involved in setting compensation or benefits for one another, which will continue to be determined by our Compensation Committee. In addition, our Audit Committee of the Board of Directors considered whether additional internal disclosure controls and procedures are appropriate in light of the circumstances and, as a result, certain additional internal controls were implemented during the year ended December 31, 2019.

Except as described above, there are no family relationships between any of our directors and executive officers.

Additional Information

We were incorporated in Colorado in January 2006 and reincorporated in Delaware in January 2008. Our website address is *www.tandemdiabetes.com*. We post links to our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, information statements, beneficial ownership reports and any amendments to those reports or statements filed or furnished pursuant to Sections 13(a), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All such filings are available through our website free of charge. However, the information contained on or accessed through our website does not constitute part of this Annual Report, and references to our website address in this Annual Report are inactive textual references only.

Item 1A. Risk Factors

An investment in our common stock involves risks. You should carefully consider the risks described below, together with all of the other information included in this Annual Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results and prospects. Certain statements below are forward-looking statements. For additional information, see the section of this Annual Report under the caption "Cautionary Note Regarding Forward-Looking Statements."

Risks Related to our Business and our Industry

We have incurred significant operating losses since inception and cannot assure you that we will achieve sustained profitability.

Since our inception in January 2006, we have incurred a significant net loss. As of December 31, 2019, we had an accumulated deficit of $624.8 million. To date, we have funded our operations primarily through private and public offerings of our equity securities, cash collected from sales of our products, and debt financing which has since been fully repaid. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing operations and commercial organization, the research and development of our current products and products under development, and the assembly of a management team to manage our business.

We began commercial sales of our first product, t:slim, in August 2012 and our flagship pump platform, t:slim X2, in October 2016. The t:slim X2 hardware platform now represents 100% of new pump shipments. Until the third quarter of 2018 we were only selling our products in the United States.

Since the first quarter of 2013, we have been able to manufacture and sell our insulin pump products at a cost and in volumes sufficient to allow us to achieve a positive overall gross margin. For the years ended December 31, 2019 and 2018, our gross profit was $194.2 million and $89.8 million, respectively. Although we have achieved a positive overall gross margin and have substantially reduced our operating loss, we still operate at a net loss on an annual basis and expect that we may continue to do so for the foreseeable future.

To implement our business strategy and achieve consistent profitability, we need to, among other things, increase sales of our products and the gross profit associated with those sales, maintain an appropriate customer service and support infrastructure, fund ongoing research and development activities, create additional efficiencies in our manufacturing processes while adding to our capacity, and obtain regulatory clearance or approval to commercialize our products currently under development both domestically and internationally. We expect our expenses will continue to increase as we pursue these objectives and make investments in our business. Additional increases in our expenses without commensurate increases in sales could significantly increase our operating losses.

The extent of our future operating losses and the timing of our profitability are highly uncertain in light of a number of factors, including the timing of the launch of new products and product features by us and our competitors, market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers, and the timing of regulatory approval of our products and the products of our competitors. Any additional operating losses will have an adverse effect on our stockholders' equity, and we cannot assure you that we will be able to sustain profitability.

We currently rely on sales of insulin pump products to generate a significant portion of our revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.

We generate nearly all of our revenue from the sale of t:slim X2 insulin pumps and the related insulin cartridges and infusion sets. Sales of these products may be negatively impacted by many factors, including:

- market acceptance of the insulin pumps and related products manufactured and sold by our key competitors, including Medtronic MiniMed, a division of Medtronic plc;
- the potential that breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pumps obsolete or less desirable;
- adverse regulatory or legal actions relating to our products, or similar products or technologies of our competitors;
- failure of our Tandem Device Updater to accurately and timely provide customers with remote access to new product features and functionality as anticipated, or our failure to obtain regulatory approval for any such updates;
- changes in reimbursement rates or policies relating to insulin pumps or similar products or technologies by third-party payors, such as the decision by UnitedHealthcare that restricts a majority of its members from accessing our pumps;
- our inability to enter into contracts with third-party payors on a timely basis and on acceptable terms;
- problems arising from the expansion of our manufacturing capabilities and commercial operations, or destruction, loss, or temporary shutdown of our manufacturing facilities;
- concerns regarding the perceived safety or reliability of any of our products, or any component thereof; and
- claims that any of our products, or any component thereof, infringes on patent rights or other intellectual property rights of third parties.

In addition, sales of any of our current or future insulin pump products with CGM integration are subject to the continuation of our applicable agreements with Dexcom or other third parties which, under some circumstances, may be subject to termination, with or without cause, on relatively short notice. Sales of our current products may also be negatively impacted in the event of any regulatory or legal actions relating to CGM products that are compatible with our pumps, or in the event of any disruption to the availability of the applicable CGM-related supplies, such as sensors or transmitters, in a given market in which our products are sold. Sales of our products may also be adversely impacted if the CGM products that are compatible with our pumps are not viewed as superior to competing CGM products in markets where our products are sold, or if the price of these products is not competitive with similar products available in the market.

Because we currently rely on sales of our t:slim X2 insulin pump and related products to generate a significant majority of our revenue, any factors that negatively impact sales of these products, or result in sales of these products increasing at a lower rate than expected, could adversely affect our business, financial condition and operating results.

Our ability to maintain and grow our revenue depends in part on retaining a high percentage of our customer base.

A key to maintaining and growing our revenue is the retention of a high percentage of our customers due to the potentially significant revenue generated from ongoing purchases of disposable insulin cartridges and other supplies. In addition, our pumps are designed and tested to remain effective for at least four years and a satisfied customer may consider purchasing another product from us when the time comes to replace the pump. We have developed retention programs aimed at our customers, their caregivers and healthcare providers, which include training specific to our products, ongoing support by sales and clinical employees, and technical support and customer service. Demand for our products from our existing customers could decline or could fail to increase in line with our projections as a result of a number of factors, including the introduction of competitive products, breakthroughs for the monitoring, treatment or prevention of diabetes, changes in reimbursement rates or policies, manufacturing problems, perceived safety or reliability issues with our products or components or the products of our competitors, the failure to secure regulatory clearance or approvals for products or product features in a timely manner or at all, or for other reasons. The failure to retain a high percentage of our customers and increase sales to these customers consistent with our forecasts would have a material adverse effect on our business, financial condition and operating results.

We operate in a very competitive industry and if we fail to compete successfully against our existing or potential competitors, many of whom have greater resources than us, our sales and operating results may be negatively affected.

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, as well as other activities of industry participants. We believe our products compete, and will continue to compete, directly with a number of traditional insulin pumps, as well as other methods for the treatment of diabetes, including MDI therapy.

Our primary competitors are major medical device companies that are either publicly traded companies or divisions or subsidiaries of publicly traded companies, including Insulet and Medtronic MiniMed. In addition, Eli Lilly & Co. is developing an insulin pump. There are also a number of other companies developing and marketing their own insulin delivery systems and/or related software applications, including insulin pumps and Bluetooth-enabled insulin pens to support MDI therapy. While these industry changes are significant, it is difficult to know how they will impact our business or the competitive landscape in which we operate. Our key competitors, most notably Medtronic, enjoy several competitive advantages over us, including:

- greater financial and human resources for sales and marketing, product development, customer service and clinical resources;
- greater ability to respond to competitive pressures and regulatory uncertainty;
- established relationships with healthcare providers, third-party payors and regulatory agencies;
- established reputation and name recognition among healthcare providers and other key opinion leaders in the medical industry generally and the diabetes industry in particular;
- greater market share and established base of customers;
- larger and more established distribution networks;
- greater ability to cross-sell products or provide incentives to healthcare providers to use their products; and

- more experience in conducting research and development, manufacturing, clinical trials, and obtaining regulatory approval or clearance.

In some instances, our competitors offer products that include features that we do not currently offer. For instance, Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set.

In addition, the competitive environment in which we operate has resulted and may continue to result in competitive pressures on our manufacturers, suppliers, distributors, collaboration partners and other business constituents. For example, we have entered into development agreements with Dexcom, which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. In the fourth quarter of 2017, Abbott launched a new blood glucose sensing technology in the United States which competes with the Dexcom technology, and another CGM product with CE Mark approval was approved in the second quarter of 2018 for sale in the United States. While we are currently in discussions with Abbott to develop and commercialize integrated diabetes solutions, there can be no assurance that we will enter into a definitive agreement with Abbott, that such an agreement will be on terms favorable to us, or that this collaboration will be successful. Competitive pressures within our industry could negatively impact the financial condition of our business partners, impact their ability to fulfill contractual obligations to us, and result in harm to our financial condition and operating results.

For these and other reasons, we may not be able to compete successfully against our current or potential future competitors. As a result, our product sales may be negatively affected, which could have a material adverse impact on our financial condition and operating results

Competitive products or other technological developments and breakthroughs for the monitoring, treatment or prevention of diabetes may render our products obsolete or less desirable.

Our ability to achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the treatment of diabetes that offer distinct features and functionality, are easy-to-use, provide superior treatment outcomes, 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 our products obsolete altogether, which would significantly reduce our sales or cause our sales to grow at a slower rate than we currently expect. 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 products.

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 that are or claim to be superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competitive products. In addition, some of our competitors employ aggressive pricing strategies, including the use of discounts, rebates, low cost product upgrades or other financial incentives that could adversely affect sales of our products. If a competitor develops a product that competes with or is perceived to be superior to our products, or if competitors continue to utilize strategies that place downward pressure on pricing within our industry, our sales may decline, our operating margins could be reduced and we may fail to meet our financial projections, which would materially and adversely affect our business, financial condition and operating results.

Moreover, we have designed our products to resemble modern consumer electronic devices to address certain embarrassment 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.

The failure of our insulin pump and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.

Our current business strategy is highly dependent on our insulin pump and related products achieving and maintaining market acceptance. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that our products are an attractive alternative to competitive products for the treatment of diabetes, including traditional insulin pump products and MDI therapies, as well as alternative diabetes monitoring, treatment or prevention methodologies. Market acceptance and adoption of our products depends on educating people with diabetes, as well as their caregivers and healthcare providers, about the distinct features, ease-of-use, beneficial treatment outcomes, and other perceived benefits of our products as compared to competitive products. If we are not successful in convincing existing and potential customers of the benefits of our products, or if we are not able to achieve the support of caregivers and healthcare providers for our products, our sales may decline or we may achieve sales below our expectations.

Market acceptance of our products could be negatively impacted by many factors, including:

- the failure of our products to achieve and maintain wide 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 products over competitive products or other currently-available insulin treatment methodologies;
- perceived risks or uncertainties associated with the use of our products, or components thereof, or of similar products or technologies of our competitors;
- adverse regulatory or legal actions relating to our insulin pump products or similar products or technologies; and
- results of clinical studies relating to our existing products or products under development or similar competitive products.

In addition, even if we are able to convince people with insulin-dependent diabetes, their caregivers or healthcare providers that our products compare favorably to the products and treatment alternatives offered by our competitors, negative perceptions regarding our size or financial stability relative to that of our competitors could cause consumers to delay the purchase of our products or to purchase competitive products.

Furthermore, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements or breakthroughs, or the perception that advancements or breakthroughs could occur, in our products or the products offered by our competitors. It is also possible that consumers interested in purchasing any of our future products currently under development may delay the purchase of one of our current products.

If our insulin pump products do 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.

Failure to secure or retain adequate coverage or reimbursement for our current products and our potential future products by third-party payors could adversely affect our business, financial condition and operating results.

A substantial portion of the purchase price of an insulin pump is typically paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Future sales of our current and future products will be limited unless our customers can rely on third-party payors to pay for all or part of the associated purchase cost. Access to adequate coverage and reimbursement for our current and future products by third-party payors, both domestically and internationally, is essential to the acceptance of our products by customers.

As guidelines in setting their coverage and reimbursement policies, many third-party payors in the United States use coverage decisions and payment amounts determined by CMS, which administers the U.S. Medicare program. Medicare periodically reviews its reimbursement practices for diabetes-related products, and there is uncertainty as to the future Medicare reimbursement rate for our products. In addition to the currently existing reimbursement code for insulin pumps, CMS recently established an additional reimbursement code for insulin pumps with automated insulin delivery and CGM integration. The reimbursement rate for the new code is expected to be established in 2020, but is not yet known. We are unable to determine the effect of this new reimbursement code on the volume of our pump sales, pump revenues, and operating results, until the reimbursement rate is known. It is also possible that CMS may review and modify the current coverage and reimbursement of diabetes-related products in connection with anticipated changes to the regulatory approval process for insulin pumps and related products, software applications and services. In addition, third-party payors that do not follow the CMS guidelines may adopt different coverage and reimbursement policies for our current and future products. It is possible that some third-party payors will not offer any coverage for our current or future products. For instance, UnitedHealthcare has designated one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers age seven or above. Unless UnitedHealthcare changes its coverage policies regarding insulin pumps, we expect this decision will prevent a majority of UnitedHealthcare members from purchasing our products. It is possible that other third-party payors may adopt similar policies in the future, which would adversely impact our ability to sell our products.

We currently have contracts establishing reimbursement for our insulin pump products with approximately 184 national and regional third-party payors in the United States. While we may enter into additional contracts both domestically and internationally, with third-party payors and add coverage for future products under our current agreements, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis. In particular, we have limited experience securing reimbursement in international markets. In addition, existing contracts with third-party payors generally can be modified or terminated by the third-party payor without cause and with little or no notice to us. Moreover, compliance with the administrative procedures or requirements of third-party payors may result in delays in processing approvals by those third-party payors for customers to obtain coverage for our products. Failure to secure or retain adequate coverage or reimbursement for our current and future products by third-party payors, or delays in processing approvals by those payors, could result in the loss of sales, which could have a material adverse effect on our business, financial condition and operating results.

Further, the healthcare industry in the United States is increasingly focused on cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with third-party payors. If third-party payors deny coverage or reduce their current levels of payment, or if our production costs increase faster than increases in reimbursement levels, we may be unable to sell our products on a profitable basis.

We may face unexpected challenges in marketing and selling our products, and training new customers on the use of our products, which could harm our ability to achieve our sales forecasts.

We have limited experience marketing and selling our newer products as well as training new customers on their use, particularly in international markets. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have limited experience marketing and selling our products to customers with type 2 diabetes. We anticipate that selling our products to customers with higher insulin requirements, including customers with type 2 diabetes, may be even more difficult following our decision to discontinue sales of new t:flex pumps in the third quarter of 2018.

Our financial condition and operating results are and will continue to be highly dependent on our ability to adequately promote, market and sell our t:slim X2 insulin pump and related products, and the ability of our diabetes educators to train new customers on the use of our products. If our sales and marketing representatives or diabetes educators fail to achieve their objectives, our sales could decrease or may not increase at levels that are in line with our forecasts.

If we are unable to maintain our existing sales, marketing, clinical and customer service infrastructure, we may fail to increase our sales to meet our forecasts.

A key element of our business strategy involves our sales, clinical, marketing and customer service personnel driving adoption of our products. We have significantly increased the number of sales, marketing, clinical and customer service personnel employed by us since we commenced commercial sales in 2012. However, we have faced considerable challenges in growing and managing these resources, including with respect to recruiting, training and assimilation of new territories and accounts. We expect to continue to face significant challenges as we manage and grow our infrastructure in the future and work to motivate and retain the individuals who make up our existing infrastructure. These challenges may be even greater in connection with our commercial expansion outside of the United States, where we have limited experience. Unexpected turnover among our sales, marketing, clinical and customer service personnel, or unanticipated challenges in recruiting additional personnel, would have a negative impact on our ability to achieve our sales projections. Further, if a sales, marketing or clinical representative was to depart and be retained by one of our competitors, we may fail to prevent him or her from helping competitors solicit business from our existing customers, which could adversely affect our sales. Similarly, if we are not able to recruit and retain a network of diabetes educators and customer service personnel, we may not be able to successfully train and service new customers, which could delay new sales and harm our reputation.

We expect the management of our sales, marketing, clinical and customer service personnel will continue to place significant burdens on our management team. If we are unable to retain our personnel in line with our strategic plans, we may not be able to effectively commercialize our existing products or products under development, or enhance the strength of our brand, either of which could result in the failure of our sales to increase in line with our projections or cause sales to decline.

Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with our products. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

For the year ended December 31, 2019, sales to approximately 55 independent distributors represented approximately 76% of our sales. We believe a majority of our sales will continue to be to independent distributors for the foreseeable future, and it is possible that the percentage of our sales to independent distributors could increase, particularly in light of our reliance on independent distributors outside of the United States. For example, our dependence upon independent distributors domestically could increase if third-party payors decide to contract with independent distributors directly in lieu of contracting with us to supply our products to their members directly. Our dependence upon independent distributors could also increase if customers prefer to purchase all of their diabetes supplies through a single source, instead of purchasing pump-related products through us and other diabetes supplies through other suppliers. None of our independent distributors domestically has been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements in the United States generally have one-year initial terms with automatic one-year renewal terms, and are terminable in connection with a party's material breach. Our distributor agreements outside of the United States generally have longer initial terms and, in addition to being terminable in connection with a party's material breach, include provisions that allow us to terminate those agreements prior to their ordinary expiration in specified circumstances. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

For the year ended December 31, 2019, our two largest independent distributors in the United States collectively comprised approximately 31% of our worldwide sales, and our three largest independent international distributors collectively comprised approximately 60% of our international sales. If any of our key independent distributors were to cease to distribute our products or reduce their promotion of our products as compared to the products of our competitors, our sales could be adversely affected. In that case, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, the terms of the arrangements could result in our product margins being lower than if we directly marketed and sold our products.

If the third parties on which we increasingly rely to assist us with our current and anticipated pre-clinical development or clinical trials do not perform as expected, we may not be able to obtain regulatory clearance or approval or commercialize our products.

As our clinical infrastructure expands, we expect to increasingly rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our current and anticipated pre-clinical investigations and clinical trials. If we are not able to reach mutually acceptable agreements with these third parties on a timely basis, these third parties do not successfully carry out their commitments or regulatory obligations or meet expected deadlines, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to agreed upon clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

We are increasingly dependent on clinical investigators and clinical sites to enroll patients in our current and anticipated clinical trials, and the failure to successfully complete the clinical trials could prevent us from obtaining regulatory approvals for or commercializing our products.

As part of our product development efforts, we expect to increasingly rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage such trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients, fail to ensure compliance by patients with clinical protocols, or fail to comply with regulatory requirements, we may be unable to successfully complete our clinical trials, which could prevent us from obtaining regulatory approvals for our products and commercializing our products, which would have an adverse impact on our business.

If important assumptions about the potential market for our products are inaccurate, or if we have failed to understand what people with insulin-dependent diabetes are seeking in an insulin pump, our business and operating results may be adversely affected.

Our business strategy was developed based on a number of important assumptions about the diabetes industry in general, and the insulin-dependent diabetes market in particular, any one or more of which may prove to be inaccurate or may change over time. For example, we believe that the benefits of insulin pump therapy as compared to other common insulin treatment alternatives will continue to drive growth in the market for insulin pump therapy. In addition, we believe the incidence of diabetes in the United States and worldwide is increasing. However, each of these assumptions may prove to be inaccurate and limited sources exist to compare treatment alternatives and obtain reliable market data. The actual incidence of diabetes, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. In addition, our strategy of focusing exclusively on the insulin-dependent diabetes market may limit our ability to increase sales or achieve profitability.

Another key element of our business strategy is utilizing market research to understand what people with diabetes are seeking to improve their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed our current products and are pursuing the development of new products. However, our market research is based on interviews, focus groups and online surveys involving people with insulin-dependent diabetes, their caregivers and healthcare providers that represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we received may not be reflective of the broader market and may not provide us accurate insight into the desires of people with insulin-dependent diabetes. In addition, understanding the meaning and significance of the responses received during our market research necessarily requires that analysis be conducted and conclusions be drawn. We may not be able perform an analysis that yields meaningful results, or the conclusions we draw from the analysis could be misleading or incorrect. Moreover, even if our market research has allowed us to better understand the features and functionality consumers are seeking in an insulin pump to improve management of their diabetes therapy, there can be no assurance that consumers will actually purchase our products or that our competitors will not develop products with similar features.

We expect to face complexities frequently encountered by companies in competitive and rapidly-evolving markets, which may make it difficult to evaluate our business and forecast our future sales and operating results.

We operate in a competitive and rapidly-evolving market. Important industry changes, such as the FDA approval and launch of new products by our competitors, as well as changes specific to our business, such as the timing of our launch of new products currently in development and our potential expansion of commercial sales in international markets, combine to make it more difficult for us to predict our future sales and operating results, as well as our expected timeframe to achieve profitability. In assessing our business prospects, you should consider these factors as well as the various risks and difficulties frequently encountered by companies in competitive and rapidly evolving markets, particularly those companies that manufacture and sell medical devices.

These risks include our ability to:

- implement and execute our business strategy;
- manage and improve the productivity of our sales, clinical, marketing and customer service infrastructure to grow sales of our existing and proposed products, and enhance our ability to provide service and support to our customers;
- achieve and maintain market acceptance of our products and increase awareness of our brand among people with insulin-dependent diabetes, their caregivers and healthcare providers;
- comply with a broad range of regulatory requirements within a highly regulated industry;
- enhance our manufacturing capabilities, increase production of products efficiently while maintaining quality standards, and adapt our manufacturing facilities to the production of new products;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop proposed products;
- obtain and maintain regulatory clearance or approval to enhance our existing products and commercialize proposed products;
- perform clinical trials with respect to our existing products and proposed products; and
- attract, retain and motivate qualified personnel in various areas of our business.

As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer

The Technology Upgrade Program resulted in accounting complexities that may lead to confusion when comparing our historical and future financial results.

While our Technology Upgrade Program expired on September 30, 2017, it resulted in a number of accounting complexities that made comparisons of our historical and future financial results more difficult. In particular, during the term of the Technology Upgrade Program, generally accepted accounting principles in the United States prevented us from recognizing, at the time of sale, up to 100% of the sales and cost of sales associated with the sale of our insulin pumps to eligible customers. Instead, depending on the type of pump sold, we were required to defer some or all of the sales and cost of sales until a later date. In light of the expiration of the program, we are no longer subject to these accounting deferrals. However, in evaluating our 2017 financial results through December 31, 2017, as a result of the Technology Upgrade Program we recorded incremental net sales of $5.0 million that were previously deferred, with a corresponding increase of $3.1 million in gross profit. It is possible that we may offer other consumer-directed programs in the future, which may result in similar or additional accounting complexities making comparisons of historical and future results more difficult.

Despite our efforts to explain the required accounting treatment for the Technology Upgrade Program, it is possible that there may be confusion when comparing our historical and future financial results, which may cause investors to avoid investing in our common stock and adversely impact our stock price.

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit cost of our products while also increasing production volume.

We believe our ability to reduce the per unit cost of our insulin pumps and related products will have a significant impact on our ability to achieve profitability. Our cost of sales includes raw materials and component parts, labor costs, product training expenses, freight, reserves for expected warranty costs, royalties, scrap and excess and obsolete inventories. It also includes manufacturing overhead costs, including expenses relating to quality assurance, manufacturing engineering, material procurement and inventory control, facilities, equipment, information technology and operations management. Our warranty reserves require a significant amount of judgment and are primarily estimated based on historical experience. Recently released versions of our pump may not incur warranty costs in a manner similar to previously released pumps. If we are unable to increase our production volumes while sustaining or reducing our overall cost of sales, including through arrangements such as volume purchase discounts, negotiation of pricing and cost reductions with our suppliers, more efficient training programs for customers, improved warranty performance or fluctuations in warranty estimates, it will be difficult to reduce our per unit costs and our ability to achieve profitability will be constrained.

In addition, the per unit cost of our products is significantly impacted by our overall production volumes, and any factors that prevent our products from achieving market acceptance, cause our production volumes to decline, or result in our sales growing at a slower rate than we expect, would significantly impact our expected per unit costs, which would adversely impact our gross margins. In addition, we may not achieve anticipated improvements in manufacturing efficiency as we undertake actions to expand our manufacturing capacity. If we are unable to effectively manage our overall costs while increasing our production volumes and lowering our per unit costs, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results.

Manufacturing risks may adversely affect our ability to manufacture products, which could negatively impact our sales and operating margins.

Our business strategy depends on our ability to manufacture our current and proposed products in sufficient quantities and on a timely basis so as to meet consumer demand, 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;
- 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;
- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently produce future products or implement changes in current products in response to consumer demand or regulatory requirements;
- our inability to manufacture multiple products simultaneously while utilizing common manufacturing equipment; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facilities.

As demand for our products increases, and as the number of our commercial products expands, we will have to invest additional resources to purchase components, hire and train employees, and enhance 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. In addition, although we expect some of our products under development to share product features and components with our current products, manufacturing of these products may require modification of our production lines, hiring of specialized employees, identification of new suppliers for specific components, qualifying and implementing additional equipment and procedures, obtaining new regulatory approvals, or developing new manufacturing technologies. Ultimately, it may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

If we fail to increase our production capacity to meet consumer demand while also maintaining product quality standards, obtaining and maintaining regulatory approvals, and efficiently managing costs, our sales and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results.

We depend on a limited number of third-party suppliers for certain components and products, and the loss of any of these suppliers, their inability to provide us with an adequate supply of components or products, or our ability to adequately forecast customer demand, could harm our business.

We currently rely, and expect to continue to rely, on third-party suppliers to supply components of our current products and our potential future products, including our disposable cartridges. For example, we rely on plastic injection molding companies to provide plastic molded components, electronic manufacturing suppliers to provide electronic assemblies, and machining companies to provide machined mechanical components. We also purchase all of our infusion sets and pump accessories from third-party suppliers. For our business strategy to be successful, our suppliers must be able to provide us with components and products in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed-upon specifications, at acceptable costs and on a timely basis.

Although we have long-term supply agreements with many of our suppliers, these agreements do not include long-term capacity commitments. Under most of our supply agreements, we make purchases on a purchase order basis and have no obligation to buy any given quantity of components or products until we place written orders, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of components or products until they accept an order. In addition, our suppliers may encounter problems that limit their ability to manufacture components or products for us, including financial difficulties, damage to their manufacturing equipment or facilities or problems with their own suppliers. As a result, our ability to purchase adequate quantities of our components or products may be limited. If we fail to obtain sufficient quantities of high-quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed and our business could suffer.

We generally use a small number of suppliers for our components and products, some of which are located outside the United States including China and Mexico. Depending on a limited number of suppliers exposes us to risks, including limited control over cost such as tariffs, availability, quality and delivery schedules. Moreover, in some cases, we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us. We have in the past been, and we may in the future be, required to make significant "last time" purchases of component inventories that are being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and applicable regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver products at the level our business requires could harm our reputation and limit our ability to meet our sales projections, which could have a material adverse effect on our business, financial condition and operating results.

We place orders with our suppliers using our forecasts of customer demand, which are based on a number of assumptions and estimates, in advance of purchase commitments from our customers. As a result, we incur inventory and manufacturing costs in advance of anticipated sales, which sales ultimately may not materialize or may be lower than expected. If we overestimate customer demand, we may experience higher inventory carrying costs and increased excess or obsolete inventory, which would negatively impact our results of operations.

We may also have difficulty obtaining components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of our suppliers to comply with regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. Such a failure by our suppliers could also require us to cease using the components, seek alternative components or technologies, and modify our products to incorporate alternative components or technologies, which could necessitate additional regulatory approvals. Any disruption of this nature, or any increased expenses associated with any such disruption, could negatively impact our ability to manufacture our products on a timely basis, in sufficient quantities, or at all, which could harm our commercialization efforts and have a material adverse impact on our operating results.

If we cannot reliably manufacture our proprietary infusion set connector, or if it does not achieve market acceptance, we may not achieve our financial projections.

In September 2017, we began commercial sales in the United States of products with our customized t:lock connector, which is used to connect our pump cartridge to our infusion set offerings. Our t:lock connector replaced the standard Luer-lok connector that historically joined an infusion set to our proprietary disposable insulin cartridges. Concurrently, we began selling infusion sets that are compatible with t:lock. Starting in 2018, we initially offered standard Luer-lok cartridges and infusion sets in select international markets, and transitioned to our t:lock connector in international markets during 2019.

We believe the transition to the t:lock connector, for our direct customers and distributors in the United States and international markets, is substantially complete. However, during 2020 there may be limited circumstances where we continue offering both styles of cartridges and infusion sets in international markets to facilitate the transition of customer supplies. Due to the variability in purchasing patterns, standard Luer-lok inventories may not be consumed at the predicted rates and we may be required to offer both styles of insulin cartridges and infusion sets for a longer period than anticipated or we may be left with excess quantities of standard Luer-lok inventories that we cannot sell at standard prices or at all, which would negatively impact our results of operations.

While the t:lock connector was designed based on customer feedback, and all standard Luer-lok infusion sets that we recently offered are now available with the t:lock connector, it is possible that t:lock may not continue to gain market acceptance by current or potential customers, their caregivers, or healthcare providers. Any negative market response to the t:lock connector may impact a current customer's decision to purchase a new pump from us at the time of renewal. In addition, potential customers may decide not to purchase our insulin pumps if they do not prefer the t:lock connector or t:lock compatible infusion sets, which could have a material adverse impact on our business, financial condition and operating results.

Our business operations are primarily located in San Diego, California, and any disruption at one of our facilities could adversely affect our business and operating results.

Substantially all of our current operations are conducted in San Diego, California, including our manufacturing processes, research and development activities and management and administrative functions. In addition, the majority of our inventories of component supplies and finished goods is stored at two facilities in San Diego. We also store finished goods at certain third-party warehouses in California and Texas for the fulfillment of certain customer orders. In the second half of 2019, we commenced limited customer and technical support activities in Boise, Idaho. We expect our operations in Boise to expand substantially during 2020. We take precautions to safeguard our facilities, including by acquiring insurance, employing back-up generators, adopting health and safety protocols and utilizing off-site storage of computer data. However, vandalism, terrorism or a natural disaster, such as an earthquake, fire or flood, or other catastrophic event, could damage or destroy our manufacturing equipment or our inventories of component supplies and finished goods, cause substantial delays in our operations, result in the loss of key information, result in reduced sales, and cause us to incur additional expenses. Our insurance coverage may not be sufficient to provide coverage with respect to the damages incurred in any particular case, and our insurance carrier may deny coverage with respect to all or a portion of our claims. Regardless of the level of insurance coverage or other precautions taken, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

We may not experience the anticipated operating efficiencies from the transition of our manufacturing and warehousing operations.

At the beginning of 2018 we completed the transition of our manufacturing operations to our Barnes Canyon facility and during the fourth quarter of 2019 we commenced operations at a new logistics warehouse in San Diego. We expect that both of these actions will allow for future capacity for product manufacturing and warehousing expansion. However, we may not experience the anticipated operating efficiencies at either facility. In addition, beginning in 2020 we expect to utilize a third party for a portion of our cartridge manufacturing. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which would have a material adverse impact on our operating results. In addition, we or our contract manufacturers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints and environmental factors, any of which could delay or impede our ability to meet customer demand and have a material adverse impact on our business, financial condition and operating results. In addition, because of the custom nature of our cartridge manufacturing process and product components, and the highly regulated nature of our products overall, in the event of any problems with our contract manufacturer, we may not be able to quickly establish additional or alternative arrangements.

We expect that the management and support of our new facilities and the increase of our manufacturing volumes will place significant burdens on our management team, particularly in areas relating to operations, quality, regulatory, facilities and information technology. We may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate, either from our own facilities or from our use of contract manufacturing. Further, additional increases in demand for our products may require that we further expand our business operations, which may require that we obtain additional facilities, make additional investments in capital equipment or increase our utilization of external third parties to perform contracted manufacturing services for us.

If we do not enhance our product portfolio to meet the demands of our market, we may fail to effectively compete, which may impede our ability to become profitable.

In order to increase our sales and market share in the insulin-dependent diabetes market, we must enhance and broaden our product portfolio in response to the evolving demands of people with insulin-dependent diabetes, their caregivers and healthcare providers, as well as competitive pressures and technologies. We may not be successful in developing, obtaining regulatory approval for, or marketing our proposed products when anticipated, or at all. In addition, notwithstanding our market research efforts, our future products may not be accepted by people with insulin-dependent diabetes, their caregivers, healthcare providers or third-party payors. The success of any proposed product offerings will depend on numerous factors, including our ability to:

- identify the product features and functionality that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in an insulin pump, and successfully incorporate those features into our products;
- develop and introduce products in sufficient quantities and in a timely manner;
- offer products at a price that is competitive with other products then available;
- work with third-party payors to obtain reimbursement for our products;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of proposed products; and
- obtain the necessary regulatory approvals for proposed products.

If we fail to generate demand by continuing to develop products that incorporate features and functionality requested by people with insulin-dependent diabetes, their caregivers or healthcare providers, or if we do not obtain regulatory clearance or approval for proposed products in time to meet market demand, we may be unable to compete and may fail to generate sales sufficient to achieve or maintain profitability. We have in the past experienced, and may in the future experience, delays in various phases of product development and commercialization, including during research and development, manufacturing, limited release testing, marketing and customer education efforts. Any delays in our anticipated regulatory submissions or approvals, or subsequent product launches, may significantly impede our ability to successfully compete in our markets. In particular, such delays could cause customers to delay or forego purchases of our products, or to purchase our competitors' products. Even if we are able to successfully develop proposed products when anticipated, these products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by changing consumer preferences or the introduction by our competitors of products embodying new technologies or features, or alternative methods for the treatment of diabetes.

Any concerns regarding the safety and efficacy of our products could limit sales and cause unforeseen negative effects to our business prospects and financial results.

Currently there are only limited published studies to evaluate the safety or effectiveness of our products in a controlled setting. As a result, people with insulin-dependent diabetes and healthcare providers may be slower to adopt or recommend our products, we may not have comparative data that our competitors have or are generating, third-party payors may not be willing to provide coverage or reimbursement for our products and we may be subject to greater regulatory and product liability risks. These and other factors could slow the adoption of our products and result in our sales being lower than anticipated. In addition, future studies or clinical experience may indicate that treatment with our products is not superior to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability.

If the results of clinical studies or other experience, such as our monitoring or investigation of customer complaints, indicate that our products may cause or create an unacceptable risk of unexpected or serious complications or other unforeseen negative effects, we could be required to inform our customers of these risks or complications or, in more serious circumstances, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, which could result in significant legal liability, harm to our reputation, and a decline in our product sales.

Any alleged illness or injury associated with any of our products or product recalls may negatively impact our financial results and business prospects depending on a number of factors, including the scope and seriousness of the problem, degree of publicity, reaction of our customers and healthcare professionals, competitive response, and consumer perceptions generally. Even if such an allegation or product liability claim lacks merit, cannot be substantiated, is unsuccessful or is not fully pursued, the negative publicity surrounding any assertion that our products caused illness, injury or death could adversely affect our reputation with customers, healthcare professionals, third-party payors, and existing and potential collaborators, and could adversely affect our operating results and cause a decline in our stock price. Furthermore, general concerns regarding the perceived safety or reliability of any of our products, or any component thereof, may have a similar adverse effect on us.

We may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products or technologies, pursue new markets, or protect our intellectual property assets. We may also elect to amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process, and may subject us to business risks. For example, other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities, or may be the counterparty in any such arrangements. We may not be able to identify or complete any such collaboration in a timely manner, on a cost-effective basis, on acceptable terms or at all. In addition, we may not realize the anticipated benefits of any such collaborations that we do identify and complete. In particular, these collaborations may not result in the development of products or technologies that achieve commercial success or result in positive financial results, or may otherwise fail to have the intended impact on our business.

Additionally, we may not be in a position to exercise sole decision-making authority regarding a collaboration, licensing or other similar arrangement, which could create the potential risk of creating impasses on decisions. Further, our collaborators and business partners may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators, such as Dexcom and TypeZero, or any future collaborators devote to our arrangement with them or our future products. Disputes between us and our current, future or potential collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

For example, we have entered into multiple development agreements with Dexcom, which provide us non-exclusive licenses to integrate various currently available generations of Dexcom CGM technology with our insulin pump products. Our agreements with Dexcom related to G5 and G6 CGM currently run until June 2020 with automatic one-year renewals unless a party provides prior notice to the contrary. Under certain circumstances, these agreements may be terminated by either party without cause or on short notice. Our current agreements with Dexcom do not grant us rights to integrate future generations of Dexcom CGM technology with any of our current or future products. Termination of any of our agreements with Dexcom would require us to redesign certain current products and products under development, and attempt to integrate an alternative CGM system into our insulin pump systems, which would require significant development and regulatory activities that could result in an interruption or substantial delay in the availability of the product to our customers. The termination of our existing commercial agreements with Dexcom would disrupt our ability to commercialize our existing products and our development of future products, which could have a material adverse impact on our financial condition and results of operations, negatively impact our ability to compete and cause our stock price to decline.

We operate our business in regions subject to natural disasters and other catastrophic events, and any disruption to our business resulting from natural disasters will adversely affect our revenue and results of operations.

We operate our business in regions subject to natural disasters, including earthquakes, hurricanes, floods, fires and other catastrophic events. For example, a portion of our administrative offices located in San Diego are in an area that is prone to flooding, which has occasionally temporarily disrupted our business operations. Any natural disaster could adversely affect our ability to conduct business and provide products and services to our customers, and the insurance we maintain may not be adequate to cover our losses resulting from any business interruption resulting from a natural disaster or other catastrophic events. Any future disruptions to our operations could have a material adverse impact on our financial condition and results of operations in future periods.

A security breach or other significant disruption to our information technology systems, or failures of our pumps' software to perform as we anticipate, could materially disrupt our operations or result in the loss, theft, misuse, unauthorized disclosure, or unauthorized access to sensitive company information relating to our customers, suppliers or employees, which could damage our relationships, expose us to litigation or regulatory proceedings, or harm our reputation, any of which could have an adverse and material effect on our business, financial condition and operating results.

The efficient operation of our business depends on our information technology and communication systems, as well as those of our third-party business partners. We rely on such systems to effectively store, process and transit proprietary sales and marketing data, accounting and financial functions, manufacturing and quality records, inventory management, product development tasks, research and development data, customer service and technical support functions. Our information technology systems, including those that support t:connect, our current and future mobile applications, as well as those involved in the operation of our Tandem Device Updater, are vulnerable to damage or interruption from a number of causes, including earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, malware, ransomware or other destructive software, cyberattacks, power losses, and computer system or data network failures. Should any of those risks occur, it could adversely impact the availability, confidentiality and integrity of information assets contained in those systems.

Our business also involves the storage and transmission of a substantial amount of confidential, personal, or other sensitive information, including health information and other personal information relating to our customers, the personal information of our employees and other individuals, and our proprietary, financial, operational or strategic information. Should any of the foregoing risks occur, it could also result in the loss, theft, misuse, unauthorized disclosure, or unauthorized access of such sensitive information, which could lead to significant reputational or competitive harm, litigation involving us or our business partners, regulatory proceedings, or substantial liabilities, fines, penalties or expenses. As a result, we strive to maintain and regularly update reasonable security measures, and to respond quickly and effectively if and when data security incidents do occur. Like many businesses, we are subject to numerous data privacy and security risks, including threats arising from computer viruses or hackers, cyberattacks and ransom-ware attacks. The continuously evolving nature of those risks may prevent us from protecting all of this information despite our efforts to do so. Many of our service providers are subject to similar risks. Whether or not our security measures and those of our service providers are ultimately successful, our expenditures on those measures could have an adverse impact on our financial condition and results of operations, and divert management's attention from pursuing our strategic objectives. From time to time we have experienced various threats to our information technology systems, and we are currently investigating the extent of unauthorized access to data on our networks following a recent phishing attack. As a result of the ongoing investigation we may determine that substantial confidential, personal or other sensitive information was compromised, and in that case we may be subject to regulatory proceedings and substantial fines, penalties and expenses, as well as significant reputational harm, which may have a material adverse impact on us. We are unable to predict the direct or indirect impact of any such incidents to our business.

In addition to the risks regarding information technology systems and processing of sensitive information, our insulin pumps and other products rely on software that could contain unanticipated vulnerabilities, which could make our products subject to computer viruses, cyber-attacks, or failures. These risks significantly increased after July 2016, when we received FDA clearance of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps and may increase further following the launch of our new mobile application. We may also face new risks relating to our information technology systems as we continue to commercialize our products outside of the United States and are subject to additional regulations relating to the use and protection of personal information and as we launch new mobile applications.

The failure of our or our service providers' information technology systems or our pumps' software or other mobile applications to perform as we anticipate, or our failure to effectively implement new information technology systems and privacy policies and controls, could disrupt our entire operation or adversely affect our software products. For example, we market our Tandem Device Updater as having the unique capability to deploy software updates to our pumps, which may allow customers remote access to new and enhanced features. The failure of our Tandem Device Updater to provide software updates as we anticipate, including as a result of our inability to secure and maintain necessary regulatory approvals, the inability of our pumps to properly receive software updates, errors or viruses embedded within the software being transmitted, or the failure of our customers to properly utilize the system to complete the update, could result in decreased sales, increased warranty costs, and harm to our reputation, any of which could have a material adverse effect on our business, financial condition and operating results.

If we are found to have violated laws concerning the privacy and security of patient health information or other personal information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of domestic and international laws protecting the privacy and security of personal information, including HIPAA and related regulations, PIPEDA, and GDPR, or similar applicable laws. These laws place limits on how we may collect, use, share and store medical information and other personal information, and they impose obligations to protect that information against unauthorized access, use, loss, and disclosure.

If we, or any of our service providers who have access to the personal data for which we are responsible, are found to be in violation of the privacy or security requirements of HIPAA, PIPEDA, or GDPR, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results. Although we utilize a variety of measures to secure the data that we control, even compliant entities can experience security breaches or have inadvertent failures despite employing reasonable practices and safeguards.

We may also face new risks relating to data privacy and security as the United States, individual U.S. states, E.U. member states, and other international jurisdictions adopt or implement new data privacy and security laws and regulations as we continue to commercialize our products worldwide. For example, the California Consumer Privacy Act, which took effect on January 1, 2020, may impose additional requirements on us and increase our regulatory and litigation risk. As we continue to expand, our business will need to adapt to meet these and other similar legal requirements.

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

We depend upon key employees in a competitive market, and if we are unable to provide meaningful equity incentives to retain key personnel, it could adversely affect our ability to execute our business strategy.

We are highly dependent upon the members of our management team, as well as other key employees. In our industry, it is common to attract and retain executive talent and other employees with compensation packages that include a significant equity component. We have issued, and may continue to issue, additional equity incentives that we believe will enhance our ability to retain our current key employees and attract the necessary additional executive talent. It may be more difficult to continue to incentivize employees during a period of rapid growth in our overall headcount while limiting the utilization of the share reserve under our current stock incentive plans. However, even if we issue significant additional equity incentives, there can be no assurance that we will be able to attract and retain key executive talent. A loss of any of our key personnel, or our inability to hire new personnel, may have a material adverse effect on our ability to execute our business strategy.

We began commercialization of our products outside of the United States, which may result in a variety of risks associated with international operations that could materially adversely affect our business.

During 2018, we began commercialization of the t:slim X2 insulin pump in select geographies outside of the United States. We have limited experience commercializing our products outside of the United States and expect that we will be subject to additional risks related to international business markets, including:

- different regulatory requirements for product approvals in foreign countries;
- differing U.S. and foreign medical device import and export rules;
- more restrictive privacy laws relating to personal information of end users and employees, including GDPR;
- reduced protection for our intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad or with U.S. regulations that would apply to activities in such foreign jurisdictions, such as the FCPA;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters, or incidence of disease.

In addition, entry into international markets may require significant financial resources, impose additional demands on our manufacturing, quality, regulatory, customer support and other general and administrative personnel, and could divert management's attention from managing our core business. We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. Accordingly, if we are unable to expand internationally, manage the complexity of our global operations successfully or if we incur unanticipated expenses, we may not achieve the expected benefits of this expansion and our financial condition and results of operations could be materially and adversely impacted.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to successfully manage acquisitions, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and

- increased legal and accounting costs relating to the acquisitions or to compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies into our business. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to our Financial Results and Need for Financing

We may need or otherwise determine to raise additional funds in the future and if we are unable to raise additional funds when necessary or desirable, we may not be able to achieve our strategic objectives.

At December 31, 2019, we had $176.5 million in cash, cash equivalents and short-term investments. Our management expects the continued growth of our business, including the expansion of our customer service infrastructure to support our growing base of customers, our plans to expand commercial sales of our products outside of the United States, the growth of our manufacturing and warehousing operations, increase the size of our facility footprint due to increasing headcount and additional research and development activities, will continue to increase our expenses. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Accordingly, our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our insulin pump products, and the related insulin cartridges and infusion sets, and any other future products that we may develop and commercialize;
- the gross profits and gross margin we realize from the sales we generate;
- the costs associated with maintaining and expanding an appropriate sales, clinical and marketing infrastructure;
- the expenses we incur or other capital expenditures we make to maintain or enhance our manufacturing operations, including leasing additional property, hiring additional personnel, purchasing additional manufacturing equipment and other measures taken to add manufacturing capacity;
- the expenses associated with developing and commercializing our proposed products or technologies;
- the costs associated with maintaining and expanding our customer service infrastructure;
- the cost of obtaining and maintaining regulatory clearance or approval for our products and our manufacturing facilities;
- the cost of ongoing compliance with legal and regulatory requirements;
- the expenses we incur in connection with potential litigation or governmental investigations;
- expenses we may incur or other financial commitments we may make in connection with current and potential new business or commercial collaborations, development agreements or licensing arrangements;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these and other factors we may in the future seek additional capital from public or private offerings of our equity or debt securities, or from other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing or debt service costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

If we are unable to raise additional capital when necessary, we may not be able to maintain our existing sales, marketing, clinical and customer service infrastructure, enhance our current products or develop new products, take advantage of future opportunities, respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results.

Our operating results may fluctuate significantly from quarter to quarter.

There has been and may continue to be meaningful variability in our operating results from quarter to quarter, as well as within each quarter, especially around the time of anticipated new product launches or regulatory approvals by us or our competitors, and as a result of the commercial launch of our products in geographies outside of the United States. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

- our ability to increase sales and gross profit from our insulin pump products, including the related insulin cartridges and infusion sets, and to commercialize and sell our future products;
- the number and mix of our products sold in each quarter;
- acceptance of our products by people with insulin-dependent diabetes, their caregivers, healthcare providers and third-party payors;
- the pricing of our products and competitive products, including the use of discounts, rebates or other financial incentives by us or our competitors;
- the effect of third-party coverage and reimbursement policies;
- our ability to maintain our existing infrastructure;
- the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans;
- interruption in the manufacturing or distribution of our products;
- our ability to simultaneously manufacture multiple products that meet quality, reliability and regulatory requirements;
- seasonality and other factors affecting the timing of purchases of our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- results of clinical research and trials on our existing and future products;
- the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements for product quality and reliability;
- regulatory clearance or approvals affecting our products or those of our competitors; and
- the timing of revenue and expense recognition associated with our product sales pursuant to applicable accounting standards.

In addition, we expect our operating expenses will continue to increase as we expand our business, which may exacerbate the quarterly fluctuations in our operating results. If our quarterly or annual operating results fall below the expectation of investors or securities analysts, the price of our common stock could decline substantially. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially, and these price fluctuations could result in further pressure on our stock price. We believe quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Risks Related to our Intellectual Property and Potential Litigation

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

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of December 31, 2019, our patent portfolio consisted of approximately 86 issued U.S. patents and 68 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2036. We are also seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we have 16 U.S. trademark registrations and 23 foreign trademark registrations.

We have applied for patent protection relating to certain existing and proposed products and processes. If we fail to file a patent application timely in any jurisdiction, we may be precluded from doing so at a later date. Further, we cannot assure you that any of our patent applications will be approved in a timely manner or at all. The rights granted to us under our patents, and the rights we are seeking to have granted in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested or circumvented by our competitors, or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Even if we are successful in receiving patent protection for certain products and processes, our competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside of the United States, effective enforcement in those countries may not be available.

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

We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. We also enter into confidentiality agreements with potential collaborators and other counter-parties, and the terms of our collaboration agreements typically contain provisions governing the ownership and control of intellectual property. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information.

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

The medical device industry is characterized by patent litigation, and from time to time, we may be 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 not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

From time to time, we may receive communications from third parties alleging our infringement of their intellectual property rights or offering a license to intellectual property that is alleged to relate to products that we are currently developing. Any intellectual property-related discussions, disputes or 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;
- prevent or limit our ability to sell a product that we are currently developing;
- 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; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

We do not currently maintain insurance to cover the expense or any liability that may arise from an intellectual property dispute with a third party. Any litigation or claim against us, even those without merit, or even preparing for a potential dispute or litigation before it arises, may cause us to incur substantial costs, and could place a significant strain on our financial resources and divert the attention of management from our core business. Any litigation or claim against us may also harm our reputation. Further, as we launch new products and increase our sales, and the number of participants in the diabetes market increases, we believe the possibility of our involvement in intellectual property disputes will increase.

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

Many of our employees were previously employed at other medical device companies, including those that are our direct competitors or could potentially become our direct competitors. In some cases, those employees joined our company recently. 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 these former employers or competitors. In addition, we have been and may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we successfully defend against these claims, litigation could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. We cannot guarantee that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize proposed products, which could have an adverse effect on our business, financial condition and operating results.

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the design, manufacture, testing and sale of medical devices. We are subject to product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition, injury or death to customers. The risk of one or more product liability claims or lawsuits may be even greater after we launch new products with new features or enter new markets where we have no prior experience selling our products and rely on newly-hired staff or new independent distributors or contractors to provide new customer training and customer support. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, including death, which could result in product liability claims. We may also identify deficiencies in our products that we determine are immaterial and do not pose safety risks, and therefore decide not to initiate a voluntary recall. However, any such deficiency may be more significant than we expect and lead to product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, 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, harm our reputation and adversely affect our ability to attract and retain customers, any of which could have a material adverse effect on our business, financial condition and operating results.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial deductibles for which we are responsible. In addition, we expect the cost of our product liability insurance will increase as our product sales increase and we may also increase the amount of our deductibles over time. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, financial condition and operating results. In addition, any product liability claim brought against us, with or without merit, could result in further increases of our product liability insurance premiums. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all. Our inability to obtain sufficient insurance coverage to protect again potential product liability claims could prevent or limit our commercialization of current products or products currently under development.

Risks Related to our Legal and Regulatory Environment

Our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other U.S. governmental agencies regulate numerous elements of our business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance or approval;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption from pre-market review applies. 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 is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through the 510(k) clearance process may require a new 510(k) submission. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis or at all for our proposed products.

We may pursue 510(k) clearance for additional products or product modifications in the future. If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our forecasts.

The FDA can delay, limit or deny clearance or approval of one of our devices for many reasons, including:

- our inability to demonstrate that our products are safe and effective for their intended users;
- the data from our clinical trials may be insufficient to support clearance or approval; and
- failure of the manufacturing process or facilities we use to meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared or approved products on a timely basis.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue from these products or achieving profitability. Moreover, customers may defer purchasing our existing products in anticipation of a new product launch. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some customers from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, delays by the FDA or other regulators in granting clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. Any of these sanctions could result in higher than anticipated costs, lower than anticipated sales, and diversion of management time and resources, any of which could have a material adverse effect on our reputation, business, financial condition and operating results.

Further, we commenced commercial sales of our products in select international markets during the third quarter of 2018. As we expand our operations outside of the United States and launch new products, we will become subject to various additional regulatory and legal requirements under the applicable laws and regulations of the international markets we enter. These additional regulatory requirements may involve significant costs and expenditures and, if we are not able to comply with any such requirements, our international expansion and business could be significantly harmed.

Modifications to our products may require new 510(k) clearances or PMAs, or may require us to cease marketing or recall the modified products until clearances are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary for changes that we have made to our products. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared or approved products, for which we concluded that new clearances or approvals were not necessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Further, the FDA's ongoing review of and potential changes to the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or by applying more onerous review criteria to such submissions.

If we or our third-party suppliers, contract manufacturers and service providers fail to comply with the FDA's good manufacturing practice regulations, this could impair our ability to market our products in a cost-effective and timely manner.

We and our third-party suppliers, contract manufacturers and service providers are required to comply with the FDA's Quality System Regulation (QSR), which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may impose inspections or audits at any time. We cannot assure you that our facilities or our contract manufacturer or component suppliers' facilities would pass any future quality system inspection or audit. If we or our suppliers, contract manufacturers and service providers have significant non-compliance issues or if any corrective action plan that we or our suppliers, contract manufacturers or service providers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us and the manufacturing or distribution of our devices could be interrupted and our operations disrupted.

If we, or our suppliers, manufacturers and service providers, fail to adhere to QSR requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

A recall of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us.

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. The FDA has broad discretion to require the recall of a product or to require that manufacturers alert customers of safety risks, and may do so even in circumstances where we do not believe our product poses an unacceptable risk to health. In addition, manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found or alert customers of unanticipated safety risks. A government-mandated or voluntary recall by us, one of our distributors or any of our other third-party suppliers could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls or notices relating to any products that we distribute would divert managerial and financial resources, and have an adverse effect on our reputation, financial condition and operating results.

Further, under the FDA's Medical Device Reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

Any adverse event involving any products that we distribute could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our failure to comply with U.S. federal and state fraud and abuse laws, including anti-kickback laws and other U.S. federal and state anti-referral laws, could have a material, adverse impact on our business.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws, physician self-referral laws, and false claims laws. Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

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

- the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, paying or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and state Medicaid programs;

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

- federal and state physician referral laws, such as the Stark Law, that prohibit a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, with which the physician has a financial relationship unless that financial relationship meets an exception;

- federal and state laws, such as the Civil Monetary Penalties Law, that prohibit an individual or entity from offering or transferring remuneration to any person eligible for benefits under a federal or state health care program which such individual or entity knows or should know are likely to influence such eligible individual's choice of provider, practitioner or supplier of any item or service for which payment may be made under federal health care programs such as Medicare and state Medicaid programs;

- federal criminal laws enacted as part of HIPAA that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- federal disclosure laws, such as the Physician Payments Sunshine Act, which require certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians;

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

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

- federal and state laws governing the use, disclosure and security of personal information, including protected health information, such as HIPAA and the Health Information Technology for Economic and Clinical Health.

Possible sanctions for violation of these laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other federal healthcare programs, and forfeiture of amounts collected in violation of those prohibitions and in some circumstances, treble damages. Any violation of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results. Recently, federal government agencies have published proposed rules for public comment which would make material modifications to several of these laws, including but not limited to the Anti-Kickback Statute, the Stark Law and HIPAA. It is unknown if or when these proposed rules may be adopted and what final form the proposed rules may take and how they may impact our business operations.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, in conjunction with other federal agencies, has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from our core business. Additionally, if a healthcare company settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any of these challenges could have a material adverse effect on our reputation, business, financial condition and operating results. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

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

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

Legislative or regulatory healthcare reforms may result in downward pressure on the price of and decrease reimbursement for our products, and uncertainty regarding the healthcare regulatory environment could have a material adverse effect on our business.

The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to propose and pass new legislation and regulations designed to, among other things, expand healthcare coverage to more individuals, contain or reduce the cost of healthcare, and improve the quality of healthcare outcomes. This legislation and regulation may result in decreased reimbursement for medical devices, which may create additional pressure to reduce the prices charged for medical devices. Reduced reimbursement rates could significantly decrease our revenue, which in turn would place significant downward pressure on our gross margins and impede our ability to become profitable.

The Patient Protection and Affordable Care Act, or PPACA, substantially changed the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the medical device industry. However, a number of legislative changes have been proposed and adopted since the PPACA was enacted, and legislation has also been proposed that could modify or repeal the PPACA. The uncertainties regarding the future of the PPACA, and other healthcare reform initiatives, may have an adverse effect on our customers' purchasing decisions regarding our products.

In the future, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. Cost control initiatives could decrease the price that we receive for our products. At this time, we cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they may have on the existing regulatory environment, or our ability to operate our business. Any of these factors could have a material adverse effect on our operating results and financial condition.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

The PPACA imposes, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, although this tax has been suspended for calendar years 2016, 2017, 2018 and 2019. It is unclear at this time if the moratorium will be further extended. We do not believe that our products are subject to this tax based on the retail exemption under applicable Treasury Regulations. However, the availability of this exemption is subject to interpretation by the Internal Revenue Service, or the IRS, and the IRS may disagree with our analysis. Absent further legislative action, the medical device excise tax applies to sales of taxable medical devices beginning on January 1, 2020, and future products that we manufacture, produce or import may be subject to this tax (unless the retail exemption or other applicable exemption applies). The financial impact this tax may have on our business is unclear and there can be no assurance that our business will not be materially adversely affected by it. Additionally, Congress could terminate the moratorium or further change the law related to the medical device tax in a manner that could adversely affect us.

Risks Related to our Common Stock

The price of our common stock may continue to fluctuate significantly.

The trading price of our common stock has been volatile in recent years. We believe our stock price has been, and will continue to be, subject to wide fluctuations in response to a variety of factors, including the following:

- actual or anticipated fluctuations in our financial and operating results from period to period;
- our actual or perceived need for additional capital to fund our operations;
- market acceptance of our current products and products under development, and the recognition of our brand;
- introduction of proposed products, technologies or treatment techniques by us or our competitors;
- announcements of significant contracts, acquisitions or divestitures by us or our competitors;
- regulatory approval of our products or the products of our competitors, or the failure to obtain such approvals on the projected timeline or at all;
- speculative trading practices of market participants;
- issuance of securities analysts' reports or recommendations;
- threatened or actual litigation and government investigations;
- sales of shares of our common stock by our employees, directors or principal stockholders; and
- general political or economic conditions.

These and other factors might cause the market price of our common stock to fluctuate substantially. Fluctuations in our stock price may negatively affect the liquidity of our common stock, which could further impact our stock price.

In recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. These changes may occur without regard to the financial condition or operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce the market price of our common stock.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could reduce our stock price and prevent our stockholders from replacing or removing our current management.

Our amended and restated certificate of incorporation and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions:

- authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;
- provide for the adoption of a staggered board of directors whereby the board is divided into three classes each of which has a different three-year term;
- provide that the number of directors shall be fixed by the board;
- prohibit our stockholders from filling board vacancies;
- provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;
- prohibit stockholders from calling special stockholder meetings;
- prohibit stockholders from acting by written consent without holding a meeting of stockholders;
- require the vote of at least two-thirds of the outstanding shares to approve amendments to the certificate of incorporation or bylaws; and
- require advance written notice of stockholder proposals and director nominations.

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our board of directors is authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue 5,000,000 shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, and to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our common stock, and the issuance of such shares in the future may reduce the value of our common stock.

U.S. federal income tax reform could adversely affect us and our stockholders.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the 2017 Tax Act, which significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The 2017 Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. We do not expect tax reform to have a material impact on our projection of minimal cash taxes. Our net deferred tax assets and liabilities were revalued at the newly-enacted U.S. corporate rate, and the impact was recognized in our tax expense, offset by a full valuation allowance, in the year of enactment. We continue to examine the impact that this tax reform legislation may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2019, we had federal net operating loss, or NOL, carryforwards of approximately $248.7 million, which includes the reduction recorded in 2019 discussed below. Of the total federal net operating loss carryforwards, $208.5 million will begin to expire in 2026, unless previously utilized. If there is an "ownership change" with respect to our company, as defined under Section 382 of the Code, the utilization of our NOL and research credit carryforwards may be subject to substantial limitations imposed by the Code, and similar state provisions. Limitations imposed on our ability to utilize NOL carryforwards could cause U.S. federal income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause NOL carryforwards to expire unused, in each case reducing or eliminating the benefit of our NOL carryforwards. In general, an ownership change occurs whenever there is a shift in ownership of our company by more than 50% by one or more 5% stockholders over a specified time period.

We have completed an analysis through December 31, 2018 to determine whether our net operating losses and credits are likely to be limited by Section 382. Based on this study, the Company determined that offerings of our securities caused an ownership change, as defined under Section 382, in 2018 and the resulting limitation significantly reduced the Company's ability to utilize its net operating loss and credit carryovers before they expire. As a result, in 2019 the Company significantly reduced its deferred tax assets for the net operating loss and research credit carryforwards that are projected to expire unused. In addition, future ownership changes under Section 382 may further limit the Company's ability to fully utilize any remaining tax benefits.

With respect to our NOLs generated in 2018 and thereafter, the 2017 Tax Act may reduce the tax benefit of our NOLs. Under the 2017 Tax Act, our ability to carry back NOLs incurred after December 31, 2017 to previous tax years is eliminated. Under prior law, we could carry back NOLs for two years and carry forward NOLs for 20 years. Under the 2017 Tax Act, NOL carryforwards may be carried forward indefinitely. However, for NOLs arising after December 31, 2017, NOL carryforwards will be limited to 80% of our taxable income. Our NOLs generated in 2017 and in prior years will not be subject to the limitations under the 2017 Tax Act.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Accordingly, investors may have to sell some or all of their shares of our common stock in order to generate cash flow from their investment.

Regulations related to "conflict minerals" may cause us to incur additional expenses and could limit the supply and increase the cost of certain metals used in manufacturing our products.

The SEC adopted a rule requiring disclosures by public companies of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured. The rule requires companies to perform due diligence, disclose and annually report to the SEC whether or not such minerals originate from the Democratic Republic of Congo or an adjoining country. The rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals used in the manufacture of our products, which could increase our expenses. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. For example, Mr. Sheridan, our principal executive officer, and Ms. Vosseller, our principal financial and accounting officer, are involved in a personal relationship and share a primary residence. While our board of directors is informed of the relationship and appropriate actions have been taken to ensure compliance with Company policies and procedures, the existence of this relationship could create additional risk, or the perception of additional risk, that our controls and procedures may not be effective. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or any testing conducted by our independent registered public accounting firm in connection with Section 404(b) of the Sarbanes-Oxley Act may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are required to disclose changes made to our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

We may be at increased risk of securities class action litigation.

In the past, securities class action litigation has been instituted against companies following periods of volatility in the overall market and in the price of a company's securities. We believe this risk may be particularly relevant to us as we have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business, financial condition and results of operations. Our stock price volatility and the increase in our market capitalization during the past year may also result in higher expenses associated with our directors' and officers' liability insurance program.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecasts of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Substantially all of our operations are currently conducted at leased facilities, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions. As of December 31, 2019, we occupied facilities with an aggregate total of approximately 341,000 square feet, as follows:

- Roselle Street Leases: approximately 88,000 square feet of general office and laboratory space located on Roselle Street in San Diego, California. All of our existing leases for facilities on Roselle Street are scheduled to expire in May 2022. We have a one-time option to terminate our Roselle Street Leases effective as of May 2021 upon delivery of advance notice to the landlord and the payment of an early termination fee.

- Barnes Canyon Lease: approximately 48,880 square feet of general office, manufacturing and warehouse space located on Barnes Canyon Road in San Diego, California, which is scheduled to expire in November 2023. We have a one-time option to extend the term of the Barnes Canyon Lease for a period of not less than three years and not greater than five years, by delivering notice to the landlord at least nine months and not more than 12 months prior to the expiration of the lease.

- Vista Sorrento Parkway Lease: approximately 59,013 square feet of general office space located on Vista Sorrento Parkway in San Diego, California, which is scheduled to expire in January 2023. We have a one-time option to extend the term of the Vista Sorrento Parkway Lease for a period of four years, by delivering written notice to the landlord in accordance with the terms of the lease.

- Marindustry Place Lease: approximately 40,490 square feet of general office and warehouse space located on Marindustry Place, San Diego, California, which is scheduled to expire in April 2026. We have a one-time option to extend the term of the Marindustry Place Lease for a period of no less than three years and no more than five years by delivering written notice to the landlord in accordance with the terms of the lease.

- Shoreline Lease: approximately 94,562 square feet of general office space located on Shoreline Drive, Boise, Idaho. The Shoreline Lease term is scheduled to commence in July 2020, and expire in June 2027. We have a one-time option to extend the term of the Shoreline Lease for a period of three years by delivering written notice to the landlord in accordance with the terms of the lease.

- Boise Short-Term Lease: approximately 9,109 square feet of general office space located on Shoreline Drive, Boise, Idaho. This is a short-term lease that is scheduled to expire in September 2020.

- Markham Lease: approximately 667 square feet of general office space located in Markham, Ontario, Canada. This is a month-to-month lease that can be canceled by delivering written notice to the landlord in accordance with the terms of the lease.

In January of 2020, we entered into a sub-lease agreement for approximately 30,703 square feet of general office space located on High Bluff Drive, in San Diego, California. The High Bluff lease is scheduled to expire in March 2022.

We believe that the facilities that we presently occupy will be sufficient to support our current operations and that suitable additional facilities would be available to us should our operations require it.

Item 3. Legal Proceedings.

From time to time, we are involved in various legal proceedings arising from or related to claims incident to the normal course of our business activities. Although the results of such legal proceedings and claims cannot be predicted with certainty, we believe we are not currently a party to any legal proceeding(s) which, if determined adversely to us, would, individually or taken together, have a material adverse effect on our business, operating results, financial condition or cash flows. However, regardless of the merit of the claims raised or the outcome, legal proceedings may have an adverse impact on us as a result of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock began trading on the NASDAQ Global Market on November 14, 2013 under the symbol "TNDM." Prior to such time, there was no public market for our common stock. The following table sets forth intraday the high and low sales prices per share of our common stock as reported on the NASDAQ Global Market for the period indicated.

	Price Range	
	High	Low
Year Ended December 31, 2019:		
First Quarter	$ 74.81	$ 32.00
Second Quarter	$ 72.19	$ 51.37
Third Quarter	$ 74.30	$ 56.69
Fourth Quarter	$ 71.99	$ 52.31
Year Ended December 31, 2018:		
First Quarter	$ 5.23	$ 2.14
Second Quarter	$ 25.50	$ 4.75
Third Quarter	$ 52.55	$ 20.08
Fourth Quarter	$ 44.10	$ 26.40

Holders of Record

As of February 19, 2020, there were approximately 48 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans, as set forth in this Annual Report under the caption "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in Part III, Item 12, is incorporated herein by reference.

Unregistered Sales of Equity Securities

None.

Repurchases of Equity Securities

We did not repurchase any of our equity securities during 2019 or 2018.

PART II

Item 6. Selected Financial Data.

The selected financial data presented below under the heading "Consolidated Statement of Operations Data" for the years ended December 31, 2019, 2018, and 2017 and the selected financial data presented below under the heading "Consolidated Balance Sheet Data" as of December 31, 2019 and 2018 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report. The selected financial data presented below under the heading "Consolidated Statement of Operations Data" for the years ended December 31, 2016 and 2015 and the selected financial data presented below under the heading "Consolidated Balance Sheet Data" as of December 31, 2017, 2016 and 2015 are derived from our audited consolidated financial statements not included in this Annual Report. The selected financial data presented below should be read in conjunction with the information included under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 and the consolidated financial statements and the related notes in Part II, Item 8. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

Consolidated Statement of Operations Data:

	Year Ended December 31,				
(in thousands, except per share data)	**2019**	**2018**	**2017**	**2016**	**2015**
Sales	$ 362,305	$ 183,866	$ 107,601	$ 84,248	$ 72,850
Cost of sales	168,093	94,044	63,507	60,656	46,270
Gross profit	194,212	89,822	44,094	23,592	26,580
Operating expenses:					
Selling, general and administrative	165,735	105,226	86,377	82,834	78,621
Research and development	45,199	29,227	20,661	18,809	16,963
Total operating expenses	210,934	134,453	107,038	101,643	95,584
Operating loss	(16,722)	(44,631)	(62,944)	(78,051)	(69,004)
Total other income (expense), net	(7,882)	(77,929)	(10,081)	(5,411)	(3,404)
Loss before income taxes	$ (24,604)	$ (122,560)	$ (73,025)	$ (83,462)	$ (72,408)
Income tax expense (benefit)	149	51	8	(15)	10
Net loss	$ (24,753)	$ (122,611)	$ (73,033)	$ (83,447)	$ (72,418)
Net loss per share, basic and diluted	$ (0.42)	$ (2.55)	$ (12.87)	$ (27.30)	$ (25.04)
Weighted average shares used to compute basic and diluted net loss per share	58,507	48,129	5,677	3,057	2,892

Consolidated Balance Sheet Data:

	As of December 31,				
(in thousands)	**2019**	**2018**	**2017**	**2016**	**2015**
Cash and cash equivalents	$ 51,175	$ 41,826	$ 13,700	$ 44,678	$ 43,088
Short-term investments	$ 125,283	$ 87,201	$ 479	$ 8,860	$ 28,018
Working capital	$ 176,745	$ 121,597	$ 28,071	$ 60,616	$ 80,464
Property and equipment, net	$ 32,923	$ 17,151	$ 19,631	$ 18,409	$ 15,526
Total assets	$ 326,110	$ 206,294	$ 95,346	$ 112,392	$ 124,725
Notes payable	$ —	$ —	$ 76,541	$ 78,960	$ 29,275
Total stockholders' equity (deficit)	$ 194,979	$ 131,275	$ (29,148)	$ (5,927)	$ 63,468

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis together with "Selected Financial Data" in Part II, Item 6 and our consolidated financial statements and related notes in Part II, Item 8. The following discussion contains forward-looking statements, which statements are subject to considerable risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Risk Factors" in Part I, Item 1A.

Certain statements contained in this Annual Report are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act, and are subject to the "safe harbor" created by these sections. Future filings with the SEC, future press releases and future oral or written statements made by us or with our approval, which are not statements of historical fact, may also contain forward-looking statements. Because such statements include risks and uncertainties, many of which are beyond our control, actual results may differ materially from those expressed or implied by such forward-looking statements. Some of the factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements can be found under the caption "Risk Factors" in Part I, Item 1A, and elsewhere in this Annual Report. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

Overview

We are a medical device company with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. Our goal is to lead in insulin therapy management by building a robust ecosystem and portfolio of data-driven products and services around our flagship insulin pumps. We believe our competitive advantage is rooted in our consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing, sales and support activities principally focus on our flagship pump platform, the t:slim X2 Insulin Delivery System (t:slim X2), and our complementary product offerings. The simple-to-use t:slim X2 is based on our proprietary technology platform and is the smallest durable insulin pump available. It is the only pump currently available in the United States that is capable of remote feature updates, which positions us well to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. We aim to improve and simplify the lives of people with diabetes and those of their healthcare providers, by delivering innovative hardware and software solutions, as well as best-in-class customer support.

Since our initial commercial launch, we have been able to rapidly innovate and bring more products to market than our competitors. We have commercially launched seven insulin pumps in the United States since 2012 and two pumps outside the United States since 2018. Four of our insulin pumps have featured integration with continuous glucose monitoring (CGM) technology, and two have featured an automated insulin delivery (AID) algorithm. We believe that the three new classifications defined by the United States Food and Drug Administration (FDA) for the interoperability of devices for AID will help support continued rapid innovation by streamlining the regulatory pathway for integrated products. In June 2018, the t:slim X2 was the first insulin pump designated as compatible with integrated continuous glucose monitoring (known as iCGM) devices; in February 2019, the t:slim X2 was the first in a new device category called Alternate Controller Enabled Infusion Pumps (ACE pumps); and in December 2019, Control-IQ technology for the t:slim X2 insulin pump was the first automated insulin dosing software in a new interoperable automated glycemic controller category.

In the four-year period ended December 31, 2019, we shipped approximately 142,000 insulin pumps, which is representative of our estimated global installed customer base on the typical four-year reimbursement cycle. Approximately 118,000 of these pumps were shipped to customers in the United States, and approximately 24,000 were shipped to international markets.

Today, our t:slim X2 hardware platform represents 100% of our new pump shipments. It is the only commercial insulin pump that allows users to update their pumps' software quickly and easily from a personal computer. We have offered in-warranty t:slim customers in the United States four different software updates for no-cost using the Tandem Device Updater, including our two AID algorithms, Basal-IQ technology and Control-IQ technology. Basal-IQ technology launched in August 2018 and is a predictive low glucose suspend feature that is designed to temporarily suspend insulin delivery to help reduce the frequency and duration of hypoglycemic events. Control-IQ technology launched in January 2020 and is an advanced hybrid-closed loop feature, designed to help increase a user's time in targeted glycemic range. It is the first and only system cleared to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. Outside the United States we began selling efforts with t:slim X2 with Dexcom G5 integration in the third quarter of 2018, offering no-cost software updates for Basal-IQ technology in the third quarter of 2019, and intend to begin offering Control-IQ technology updates in select geographies in the second half of 2020.

Our insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, we sell disposable products that are used together with our pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body.

Our insulin pumps are compatible with the Tandem Device Updater, a revolutionary tool that allows pump users to update their pumps' software quickly and easily from a personal computer. This unique offering positions us to bring future innovations, including our next generation AID algorithms, to our in-warranty t:slim X2 customers independent of the typical four-year insurance pump reimbursement cycle, faster than the industry has been able to in the past. The Tandem Device Updater launched in the United States in the first quarter of 2017 and outside of the United States in the third quarter of 2019. Since its launch, we have offered in-warranty t:slim customers in the United States four different software updates for no-cost using the Tandem Device Updater, including Basal-IQ technology and, most recently, Control-IQ technology. Outside the United States we began offering no-cost software updates for Basal-IQ technology in the third quarter of 2019 and intend to begin offering Control-IQ technology updates in the second half of 2020, subject to required regulatory and reimbursement approvals.

For the years ended December 31, 2019, 2018 and 2017, our consolidated sales were $362.3 million, $183.9 million, and $107.6 million, respectively. For the years ended December 31, 2019, 2018 and 2017, our net loss was $24.8 million, $122.6 million, and $73.0 million, respectively. Worldwide pump sales accounted for 68%, 67%, and 66% of our total sales, respectively, for the years ended December 31, 2019, 2018 and 2017, while pump-related supplies and accessories accounted for the remainder in each year. Our accumulated deficit as of December 31, 2019 and 2018 was $624.8 million and $600.1 million, respectively. These amounts included $216.6 million and $147.4 million of non-cash stock-based compensation charges and non-cash changes in the fair value of common stock warrants as of December 31, 2019 and 2018, respectively.

In the United States, we have rapidly increased sales since the commercial launch of our first product by expanding our sales, clinical and marketing organization, by developing, commercializing and marketing multiple differentiated products that utilize our proprietary technology platform and consumer-focused approach, and by providing strong customer support. Our sales have further increased following our scaled product launches in geographies outside of the United States. We believe that by demonstrating our product benefits and the shortcomings of existing insulin therapies, more people will choose our insulin pumps for their therapy needs, allowing us to further penetrate and expand the market worldwide. In addition, we believe publications, such as the results from the study using Control-IQ technology that was published in the *New England Journal of Medicine* in October 2019, will be valuable in demonstrating the clinical outcome benefits derived from our system to healthcare providers and payors. We also believe we are positioned well to address consumers' needs and preferences with our current products and products under development and by offering customers access to our future innovations through the Tandem Device Updater, as they are approved by the local regulating bodies. At the same time, by innovating and offering new product features and benefits using our t:slim X2 platform, we are able to leverage a shared global manufacturing and supply chain infrastructure. In the United States, we are able to leverage a single sales, marketing, and clinical organization, as well as our domestic customer support services. In Canada, we have a separate sales organization and our customer support infrastructure benefits from close collaboration with our United States organization. In other international geographies, we have contracted with experienced distribution partners to commercialize and support our t:slim X2 platform.

Products Under Development

Our products under development support our strategy of focusing on both consumer and clinical needs, and include AID system enhancements, a connected (mobile) health offerings and a next-generation hardware platform which we call the t:sport Insulin Delivery System (t:sport). We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionality that will allow us to meet the needs of people in differentiated segments of the insulin-dependent diabetes market, including the following:

- *t:sport Insulin Delivery System* – Approximately half the size of our t:slim X2 pump, the t:sport pump is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. We anticipate that t:sport will feature a 200-unit cartridge, an on-pump bolus button, a rechargeable battery, an AID algorithm, and a Bluetooth radio. t:sport is being designed for use with leading U-100 insulins, and we are evaluating the use of insulin concentrates to provide to people with greater insulin needs. We anticipate that t:sport will be our first insulin pump to support full pump-control from our mobile application, subject to FDA review and approval. A separate controller may be offered in addition to or in advance of full mobile control availability.

- *Connected (Mobile) Health Offerings* – We are currently preparing for the launch of a mobile application that has been designed to utilize the capability of the Bluetooth radio integrated with the t:slim X2 to wirelessly upload pump data to t:connect, receive notification of pump alerts and alarms, and provide a discrete, secondary display of glucose and insulin data. Future updates of this app will integrate other health-related information from third party sources, and support future pump-control capabilities for our products under development.

    - The launch of the first generation of this mobile application in the United States follows the roll-out of our Control-IQ technology and, by allowing for the wireless upload of data to t:connect, is intended to reduce patient burden and increase healthcare provider office efficiency by reducing the manual steps historically required for data extraction.

    - Over time, we also intend to offer additional features and enhancements to the mobile application, including partial or full control of pump features.

For additional information, see the section of this Annual Report under the caption "Business" in Part I, Item 1.

Pump Shipments

From inception through June 2018, we derived nearly all of our sales from the shipment of insulin pumps and associated supplies to customers in the United States. Starting in the third quarter of 2018, we commenced sales of our t:slim X2 insulin pump in select international geographies. We consider the number of insulin pump units shipped per quarter to be an important metric for managing our business.

In the four-year period ended December 31, 2019, we shipped approximately 142,000 insulin pumps, of which approximately 118,000 were shipped to customers in the United States, and approximately 24,000 were shipped to international markets. In the year ended December 31, 2019, we shipped 73,431 insulin pumps worldwide, compared to 34,493 insulin pumps shipped in 2018.

Pump shipments to customers in the United States by fiscal quarter were as follows:

	Pump Units Shipped for Each of the Three Months Ended in Respective Years - U.S.				
	March 31	June 30	September 30	December 31	Total
2012	—	9	204	844	1,057
2013	852	1,363	1,851	2,406	6,472
2014	1,723	2,235	2,935	3,929	10,822
2015	2,487	3,331	3,431	6,234	15,483
2016	4,042	4,582	3,896	4,418	16,938
2017	2,816	3,427	3,868	6,950	17,061
2018	4,444	5,447	7,379	12,935	30,205
2019	9,669	12,799	13,814	17,453	53,735

Pump shipments to international customers by fiscal quarter were as follows:

	Pump Units Shipped for Each of the Three Months Ended in Respective Years - International				
	March 31	June 30	September 30	December 31	Total
2018	N/A	N/A	1,055	3,233	4,288
2019	5,063	8,459	4,025	2,149	19,696

Technology Upgrade Program

Beginning in the third quarter of 2016 through the third quarter of 2017, we offered a Technology Upgrade Program under a variable pricing structure, as a pathway for certain existing customers to obtain the t:slim X2. The accounting treatment for the program required us to defer up to 100% of sales at the time of pump shipment and recognize them in a subsequent period, either when the upgrade was fulfilled or at the expiration of the program. We recognized the deferred amount of sales and cost of sales at the earlier of when the obligations under the program were satisfied or upon the expiration of the program. If a customer elected to participate in the program, we recognized any upgrade fees that we received and the associated costs at the time of fulfilling the given obligation. For the year ended December 31, 2017, we recorded incremental net sales of $5.0 million with a corresponding increase of $3.1 million in gross profit as a result of the Technology Upgrade Program. The program expired on September 30, 2017 and, therefore, had no impact on our 2018 and 2019 financial results.

Trends Impacting Financial Results

Overall, we have experienced considerable sales growth since the commercial launch of our first product in the third quarter of 2012, while incurring operating losses since our inception. Our operating results have historically fluctuated on a quarterly or annual basis, particularly in periods surrounding anticipated regulatory approvals, the commercial launch of new products by us and our competitors, and the commercial launch of our products in geographies outside of the United States. We expect these periodic fluctuations in our operating results to continue.

We believe that our financial condition and operating results, as well as the decision-making process of our current and potential customers, has been and will continue to be impacted by a number of general trends, including the following:

- market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers;
- the introduction of new products, treatment techniques or technologies for the treatment of diabetes, including the timing of the commercialization of new products by us and our competitors;
- seasonality in the United States associated with annual insurance deductibles and coinsurance requirements associated with the medical insurance plans utilized by our customers and the customers of our distributors;
- timing of holidays and summer vacations, which may vary by geography;
- the buying patterns of our distributors and other customers, both domestically and internationally;
- changes in the competitive landscape, including as a result of companies entering or exiting the diabetes therapy market;
- access to adequate coverage and reimbursement for our current and future products by third-party payors, and reimbursement decisions by third-party payors;
- the magnitude and timing of any changes to our facilities, manufacturing operations and other infrastructure;
- anticipated and actual regulatory approvals of our products and competitive products; and
- product recalls impacting, or the suspension or withdrawal of regulatory clearance or approval relating to, our products or the products of our competitors.

In addition to these general trends, we believe the following specific factors have materially impacted, and could continue to materially impact our business going forward:

- continued increase in demand following the commercial launch of t:slim X2 and the demonstrated success of our Tandem Device Updater;
- anticipated new product launches;
- increased opportunity to achieve customer renewals as customers become eligible for insurance reimbursement to purchase a new insulin pump at the end of the typical four-year reimbursement cycle;
- benefit in 2018 and 2019 following the announcement by Johnson & Johnson that it discontinued the operations of Animas Corporation (Animas) and discontinued availability of Animas pump supplies in September 2019;

- designation by UnitedHealthcare of one of our competitors as its preferred, in-network durable medical equipment provider of insulin pumps for most customers age seven and above;
- ability to enter into and maintain agreements with CGM partners for CGM integration;
- expansion and new product launches in select international geographies;
- accounting variability and complexity associated with certain commercial programs, such as the Technology Upgrade Program offered in 2016 and 2017 that provided a pathway for in-warranty customers to our next-generation hardware platform; and
- ability to effectively scale our operations to support rapid growth, including expanding our facilities, advancing our research and development efforts, increasing manufacturing capacity through third-party manufacturers, and hiring and retaining employees in customer service and support functions.

In addition to working to achieve our sales growth expectations, we intend to continue to leverage our infrastructure investments to realize additional manufacturing, sales, marketing and administration cost efficiencies with the goal of improving our operating margins and ultimately achieving sustained profitability. We achieved profitability for the first time in the fourth quarter of 2018, and again in the fourth quarter of 2019, though we may be unable to achieve profitability consistently from period to period. We believe we can ultimately achieve sustained profitability by driving incremental sales growth in U.S. and international markets, meeting our pump renewal sales objectives, maximizing manufacturing efficiencies on increased production volumes, and leveraging the investments made in our sales, clinical, marketing and customer support organizations.

Recent Developments

In December 2019, the FDA cleared our t:slim X2 insulin pump with Control-IQ technology, an advanced hybrid-closed-loop feature designed to help increase time in range, and the first and only system cleared to deliver automatic correction boluses in addition to adjusting insulin delivery to help prevent high and low blood sugar. The system integrates with Dexcom G6 continuous glucose monitoring (CGM), which requires no fingersticks for calibration or diabetes treatment decisions.

Components of Results of Operations

Sales

We offer products for people with insulin-dependent diabetes. We commenced commercial sales of our original t:slim insulin pump platform in the United States in the third quarter of 2012 and continued to launch various iterations of that platform during the following years. In October 2016, we began shipping our flagship pump platform, the t:slim X2 insulin pump. The t:slim X2 hardware platform, which includes remote software update capabilities, now represents 100% of our new pump shipments. Accordingly, in the third quarter of 2018 we discontinued new sales of all prior platform versions. Our products also include disposable cartridges and infusion sets. In addition, we offer accessories including protective cases, belt clips, and power adapters, although sales of these products are not significant.

We primarily sell our products through national and regional distributors in the United States on a non-exclusive basis. These distributors are generally providers of medical equipment and supplies to individuals with diabetes. Our primary end customers are people with insulin-dependent diabetes. Similar to other durable medical equipment, the primary payor is generally a third-party insurance carrier and the customer is usually responsible for any medical insurance plan copay or coinsurance requirements. We believe our existing sales, clinical, and marketing infrastructure will allow us to continue to increase sales by allowing us to promote our products to a greater number of potential customers, caregivers and healthcare providers.

In the third quarter of 2018, we began the launch of our t:slim X2 with G5 through distribution partners outside the United States, including in select European countries, Australia, New Zealand, and South Africa. During the second quarter of 2019, we began selling our t:slim X2 with Basal-IQ technology in certain of these geographies. Our independent distributor partners perform all sales, customer support and training in their respective markets. In Canada, we market with a direct sales force and, similar to the United States, use a distributor partner for certain billing and fulfillment activities. Historically, we have experienced consistent levels of reimbursement for our products in the United States, but we expect the average sales price will vary in international markets based on a number of factors, such as the geographical mix, nature of the reimbursement environment, government regulations and the extent to which we rely on distributor relationships to provide sales, clinical and marketing support.

In general, in the United States we have experienced, and expect to continue to experience, pump shipments being weighted heavily towards the second half of the year, with the highest percentage of pump shipments expected in the fourth quarter due to the nature of the reimbursement environment. Consistent with our historical seasonality, we also expect domestic pump shipments from the fourth quarter to the following first quarter to decrease significantly. Internationally, we do not expect this same impact from seasonality associated with reimbursement, although the quarterly sales trends may be impacted by summer vacations and launches into new geographies. While the opportunity to transition former Animas customers during 2019 positively impacted our quarterly sales trends worldwide, we do not anticipate future significant benefit.

In addition, our quarterly sales have fluctuated, and may continue to fluctuate, substantially in the periods surrounding anticipated and actual regulatory approvals and commercial launches of new products by us or our competitors. We believe customers may defer purchasing decisions if they believe a new product may be launched in the future. Additionally, upon the announcement of FDA approval or commercial launch of a new product, either by us or one of our competitors, potential new customers may reconsider their purchasing decisions or take additional time to consider the anticipated or new approval or product launch in making their purchasing decisions. For instance, we believe certain customers paused in their decision-making during the second half of 2019 in anticipation of the commercial availability of the t:slim X2 with Control-IQ technology. However, it is difficult to quantify the extent of the impact of these or similar events on future purchasing decisions.

Cost of Sales

Historically, we have manufactured our pumps and disposable cartridges at our manufacturing facility in San Diego, California. In 2020, we anticipate outsourcing a portion of our cartridge manufacturing to an experienced third-party contract manufacturer. Infusion sets and pump accessories are manufactured by third-party suppliers. Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs, freight, reserves for expected warranty costs, scrap and excess and obsolete inventories. Manufacturing overhead expenses include expenses relating to quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management. We anticipate that our cost of sales will continue to increase as our product sales increase.

Over the long term, we expect our overall gross margin percentage, which for any given period is calculated as sales less cost of sales divided by sales, to improve, as our sales increase and our overhead costs are spread over larger production volumes. We expect we will be able to leverage our manufacturing cost structure across our products that utilize the same technology platform and manufacturing infrastructure and will be able to further reduce per unit costs with increased automation, process improvements and raw materials cost reductions. Pumps have, and are expected to continue to have, a higher gross margin than our pump-related supplies. Therefore, the percentage of pump sales relative to total sales will have a significant impact on gross margin. We also expect our warranty cost per unit to decrease as we release additional product features and functionality utilizing the Tandem Device Updater. However, our overall gross margin may fluctuate in future quarterly periods as a result of numerous factors aside from those associated with production volumes and product mix. In addition, as demand for our products increases, we have begun, and may continue, to make additional investments in manufacturing capacity or increase our reliance on third parties for manufacturing-related services, either of which could have a negative impact on gross margin in the near-term. Specifically, in 2020, we plan to invest in additional manufacturing equipment to meet anticipated long-term demand for our cartridges, which may initially place downward pressure on the gross margin on our supplies.

Other factors impacting our overall gross margin may include the changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors in domestic and international markets, the timing and success of new regulatory approvals and product launches, the impact of the valuation and amortization of employee stock option grants on non-cash stock-based compensation expense allocated to cost of sales, changes in warranty estimates, training costs, licensing and royalty costs, cost associated with excess and obsolete inventories, and changes in our manufacturing processes, capacity, costs or output.

Selling, General and Administrative

Our selling, general and administrative (SG&A) expenses primarily consist of salary, cash-based incentive compensation, fringe benefits and non-cash stock-based compensation for our executive, financial, legal, marketing, sales, clinical, customer support, technical services, insurance verification, regulatory affairs and other administrative functions. We began expanding our U.S. field sales and clinical organization during the third quarter of 2019 to support an expected increase in demand. We expect to have approximately 90 territories by early 2020. Our existing territories are maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel. Our operations in Canada are supported by a direct sales force of approximately 17 field representatives. Other significant SG&A expenses include those incurred for product demonstration samples, commercialization activities associated with new product launches, travel, trade shows, outside legal fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs. Overall, we expect our SG&A expenses, including the cost of our customer support infrastructure, to increase as our customer base grows in the United States and international markets. We will continue to evaluate, and may further increase, the number of our field sales and clinical personnel in order to optimize the coverage of our existing territories. Additionally, we realized a notable increase in non-cash stock-based compensation expense allocated to SG&A beginning in the third quarter of 2018, and again in the second quarter of 2019, due to the valuation of certain employee stock option grants and the impact on the valuation of the significant increase in our stock price over the previous year. We expect higher non-cash stock-based compensation expense will be sustained through the first half of 2020 and will begin to decline in future quarters. Our SG&A expenses may also increase due to anticipated costs associated with additional compliance and regulatory reporting requirements.

Research and Development

Our research and development (R&D), activities primarily consist of engineering and research programs associated with our products under development, as well as activities associated with our core technologies and processes. R&D expenses are primarily related to employee compensation, including salary, fringe benefits, non-cash stock-based compensation and temporary employee expenses. We also incur R&D expenses for supplies, development prototypes, outside design and testing services, depreciation, allocated facilities and information services, clinical trial costs, payments under our licensing, development and commercialization agreements and other indirect costs. We expect our R&D expenses to increase as we advance our products under development and develop new products and technologies, partially offset by future expected declines in non-cash stock-based compensation.

Other Income and Expense

Other income and expense primarily consists of changes in the fair value of certain warrants issued in our public offering of common stock in October 2017, and interest earned on our cash equivalents and short-term investments. In 2018 and 2017, it also included interest expense and amortization of debt discount and debt issuance costs associated with our Amended and Restated Term Loan Agreement (Term Loan Agreement) with Capital Royalty Partners II, L.P. and its affiliated funds (CRG), and a $5.3 million loss on extinguishment of debt associated with the full repayment of amounts due under the Term Loan Agreement in August 2018. Prior to the repayment, there was $82.7 million of outstanding principal under the Term Loan Agreement, which accrued interest at a rate of 11.5% per annum. As a result of the full repayment, we did not incur any interest expense or costs associated with the Term Loan Agreement subsequent to the third quarter of 2018. Other income also includes interest earned on our cash equivalents and short-term investments. We expect other income and expense to fluctuate from period to period primarily due to the revaluation of certain outstanding common stock warrants, which expire in the fourth quarter of 2022.

Results of Operations

(in thousands, except percentages)	Year Ended December 31, 2019	2018	2017
Sales:			
Domestic	$ 302,084	$ 174,188	$ 107,601
International	60,221	9,678	—
Total sales	362,305	183,866	107,601
Cost of sales	168,093	94,044	63,507
Gross profit	194,212	89,822	44,094
Gross margin	54%	49%	41%
Operating expenses:			
Selling, general and administrative	165,735	105,226	86,377
Research and development	45,199	29,227	20,661
Total operating expenses	210,934	134,453	107,038
Operating loss	(16,722)	(44,631)	(62,944)
Other income (expense), net:			
Interest and other income	3,271	1,462	239
Interest and other expense	(78)	(7,584)	(11,341)
Loss on extinguishment of debt	—	(5,313)	—
Change in fair value of stock warrants	(11,075)	(66,494)	1,021
Total other expense, net	(7,882)	(77,929)	(10,081)
Loss before income taxes	$ (24,604)	$ (122,560)	$ (73,025)
Income tax expense	149	51	8
Net loss	$ (24,753)	$ (122,611)	$ (73,033)

Comparison of Years Ended December 31, 2019 and 2018

Sales. For the year ended December 31, 2019, sales were $362.3 million, which included $60.2 million of international sales. For the year ended December 31, 2018, sales were $183.9 million, which included $9.7 million of international sales which commenced in the third quarter of 2018.

The increase in total sales of $178.4 million in 2019, as compared to 2018, was primarily driven by a 113% increase in worldwide pump shipments to 73,431 in 2019, compared to 34,493 in 2018. Worldwide pump shipments were positively impacted by strong demand for our products following the August 2018 domestic launch of t:slim X2 with Basal-IQ technology and the commencement of commercial sales of t:slim X2 with G5 integration in select international geographies beginning in the third quarter of 2018, as well as the fulfillment of international pump demand from backlog that existed at the end of 2018 due to supply constraints. In addition, worldwide sales in 2019 and 2018 were positively impacted by the transition of former Animas customers to our products. However, we do not anticipate significant benefit from conversion of Animas customers beyond 2019. Sales from pump-related supplies increased 91% primarily due to an overall increase in our installed base of customers reordering supplies. The ratio of the number of infusion sets shipped to the number of cartridges shipped was over 100% in both of the years ended December 31, 2019 and 2018.

Domestic sales by product were as follows (in thousands):

	Year Ended December 31, 2019	2018
Pump	$ 205,492	$ 115,719
Infusion sets	66,034	40,260
Cartridges	30,022	17,796
Other	536	413
Total Domestic Sales	$ 302,084	$ 174,188

International sales by product were as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Pump	$ 42,094	$ 8,205
Infusion sets	11,221	629
Cartridges	6,656	781
Other	250	63
Total International Sales	$ 60,221	$ 9,678

Sales to distributors accounted for 73% and 78% of our total domestic sales for the years ended December 31, 2019 and 2018, respectively. Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor. Sales to distributors accounted for 92% and 100% of our total international sales for the years ended December 31, 2019 and 2018, respectively.

Cost of Sales and Gross Profit. Our cost of sales in 2019 was $168.1 million, resulting in gross profit of $194.2 million, compared to $94.0 million of cost of sales in 2018 resulting in gross profit of $89.8 million. The gross margin for 2019 was 54%, compared to 49% in 2018.

The improvement in both gross profit and gross margin was primarily the result of the increase in insulin pump sales which have a higher gross margin than pump-related supplies. Gross margin and gross profit also increased as a result of per-unit manufacturing cost improvements from higher production volumes and continued overall manufacturing efficiencies gained from our new manufacturing facility which became fully operational at the beginning of 2018. On an aggregate basis, other non-manufacturing costs, which primarily consist of warranty, freight and training costs, also reflected improvement on a per unit basis. Non-cash stock-based compensation expense allocated to cost of sales increased to $6.4 million in 2019 compared to $2.6 million in 2018, due primarily to the valuation of certain 2018 and 2019 employee stock option grants and the impact on the valuation of the significant increase in our stock price.

Selling, General and Administrative Expenses. SG&A expenses increased 58% to $165.7 million in 2019 from $105.2 million in 2018. Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. These expenses increased $49.6 million during 2019 compared to 2018, which included an increase of $23.6 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our growing installed customer base, and a $26.0 million increase in non-cash stock-based compensation expense. Non-cash stock-based compensation expense allocated to SG&A increased to $42.9 million in 2019, compared to $16.8 million in 2018, due primarily to the valuation of certain 2018 and 2019 employee stock options grants and the impact on the valuation of the significant increase in our stock price. We also experienced increased costs for equipment and supplies, outside consulting and services, and travel of $10.9 million.

Research and Development Expenses. R&D expenses increased 55% to $45.2 million in 2019 from $29.2 million in 2018. The increase in R&D expenses was primarily the result of an increase of $4.8 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts, and a $4.5 million increase in non-cash stock-based compensation expense. Non-cash stock-based compensation expense allocated to R&D increased to $8.8 million in 2019, compared to $4.3 million in 2018, due primarily to the valuation of certain 2018 and 2019 employee stock option grants and the impact on the valuation of the significant increase in our stock price. We also experienced increased costs for outside consulting and services, clinical trials, and supplies of $5.8 million.

Other Income (Expense). Total other expense in 2019 was $7.9 million, compared to $77.9 million in 2018. Other expense in 2019 primarily consisted of a $11.1 million revaluation loss from the change in fair value of certain warrants due to the significant appreciation in our stock price during 2019, offset by interest and other income of $3.3 million. Other expense in 2018 consisted primarily of a $66.5 million revaluation loss from the change in fair value of certain warrants due to the significant appreciation in our stock price during 2018, $7.6 million of interest expense associated with the Term Loan Agreement, as well as a $5.3 million loss on extinguishment of debt associated with the full repayment of our Term Loan Agreement in August 2018. Interest and other income primarily consisted of interest earned on our cash equivalents and short-term investments, for which our average invested balances were significantly higher in 2019 as compared to 2018.

Comparison of Years Ended December 31, 2018 and 2017

Sales. For the year ended December 31, 2018, sales were $183.9 million, which included $9.7 million of international sales which commenced in the third quarter of 2018. For the year ended December 31, 2017, sales were $107.6 million, which included incremental net pump sales of $5.0 million as a result of the Technology Upgrade Program in place at that time.

The increase in total sales of $76.3 million in 2018, as compared to 2017, was primarily driven by a 102% increase in worldwide pump shipments to 34,493 in 2018, compared to 17,061 in 2017. Worldwide pump shipments were positively impacted by strong demand for our products following the August 2018 domestic launch of t:slim X2 with Basal-IQ technology, the August 2017 launch of t:slim X2 with G5 integration, and the commencement of commercial sales in select international geographies beginning in the third quarter of 2018. Additionally, sales from pump-related supplies increased 66% primarily due to the September 2017 launch of infusion set products using the t:lock connector, as well as an overall increase in our installed customer base of customers reordering supplies. The ratio of the number of infusion sets shipped to the number of cartridges shipped increased to over 100% in 2018 from 69% in the year ended 2017.

Domestic sales by product were as follows (in thousands):

	Year Ended December 31,	
	2018	**2017**
Pump	$ 115,719	$ 71,518
Infusion sets	40,260	21,444
Cartridges	17,796	14,173
Other	413	466
Total Domestic Sales	$ 174,188	$ 107,601

International sales by product were as follows (in thousands):

	Year Ended December 31,	
	2018	**2017[(1)]**
Pump	$ 8,205	$ —
Infusion sets	629	—
Cartridges	781	—
Other	63	—
Total International Sales	$ 9,678	$ —

(1) International sales commenced in the third quarter of 2018. We did not have any international sales during the year ended December 31, 2017.

Sales to distributors accounted for 78% and 75% of our total domestic sales for the years ended December 31, 2018 and 2017, respectively. Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor. The percentage was particularly impacted in 2018 by the mid-2017 launch of the t:lock connector, which resulted in greater purchases of infusion sets by our independent distributors during the period as compared to the same period during the prior year. Sales to distributors accounted for 100% of our total international sales for the year ended December 31, 2018.

Cost of Sales and Gross Profit. Our cost of sales in 2018 was $94.0 million, resulting in gross profit of $89.8 million, compared to $63.5 million of cost of sales and gross profit of $44.1 million in 2017, which included incremental gross profit of $3.1 million associated with the Technology Upgrade Program.

The gross margin for 2018 was 49%, compared to 41% in 2017. The incremental gross profit associated with the Technology Upgrade Program benefited our 2017 gross margin by one percentage point.

The improvement in both gross profit and gross margin was primarily the result of the increase in insulin pump sales which have a higher gross margin than pump-related supplies, as well as per-unit cost improvements on all products from increased production volumes and manufacturing efficiencies. On an aggregate basis, other non-manufacturing costs, which primarily consist of warranty, freight and training costs, also reflected improvement on a per unit basis. Non-cash stock-based compensation expense allocated to cost of sales increased to $2.6 million in 2018, compared to $1.4 million in 2017, due primarily to the valuation of certain 2018 employee stock option grants and the impact on the valuation of the significant increase in our stock price during 2018.

Selling, General and Administrative Expenses. SG&A expenses increased 22% to $105.2 million in 2018 from $86.4 million in 2017. Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. These expenses increased $18.4 million during 2018 compared to 2017, which included an increase of $11.6 million in salaries, incentive compensation and other employee benefits due in part to an increase in personnel to support our growing installed customer base, as well as the impact of our strong year-over-year sales growth on incentive-based compensation. Additionally, there was a $6.8 million increase in non-cash stock-based compensation expense. Non-cash stock-based compensation expense allocated to SG&A increased to $16.8 million in 2018, compared to $10.0 million in 2017, due primarily to the valuation of certain 2018 employee stock option grants and the impact on the valuation of the significant increase in our stock price during 2018.

Research and Development Expenses. R&D expenses increased 41% to $29.2 million in 2018 from $20.7 million in 2017. The increase in R&D expenses was primarily the result of an increase of $4.1 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts, and a $3.1 million increase in non-cash stock-based compensation expense due to the significant increase in our stock price in 2018. In addition, our strong year-over-year sales growth drove a substantial year-over-year increase in incentive-based compensation. Non-cash stock-based compensation expense allocated to R&D increased to $4.3 million in 2018, compared to $1.2 million in 2017, due primarily to the valuation of certain 2018 employee stock option grants and the impact on the valuation of the significant increase in our stock price during 2018.

Other Income (Expense). Total other expense in 2018 was $77.9 million, compared to $10.1 million in 2017. Other expense in 2018 primarily consisted of a $66.5 million revaluation loss from the change in fair value of certain warrants due to the significant appreciation in our stock price during 2018, $7.6 million of interest expense associated with the Term Loan Agreement, as well as a $5.3 million loss on extinguishment of debt associated with the full repayment of our Term Loan Agreement in August 2018. Other expense in 2017 consisted primarily of interest expense associated with the Term Loan Agreement. The outstanding principal balance under the Term Loan Agreement was $82.7 million prior to the repayment and as of December 31, 2017. Interest and other income primarily consisted of interest earned on our cash equivalents and short-term investments, for which our average invested balances were significantly higher in 2018 as compared to 2017.

Liquidity and Capital Resources

At December 31, 2019, we had $176.5 million in cash and cash equivalents and short-term investments. We believe that our cash and cash equivalents and short-term investments balance will be sufficient to satisfy our liquidity requirements for at least the next 12 months from the date of this filing.

Historically, our principal sources of cash have included private placements and public offerings of equity securities, debt financing, and cash collected from product sales. Since the beginning of 2018, we completed the following financings:

- In February 2018, we completed a registered public offering of 34,500,000 shares of common stock at a public offering price of $2.00 per share. The gross proceeds from the offering were approximately $69.0 million, before deducting underwriting discounts and commissions and other offering expenses.

- In August 2018, we completed a registered public offering of 4,035,085 shares of common stock at a public offering price of $28.50 per share. The gross proceeds from the offering were $115.0 million, before deducting underwriting discounts and commissions and other offering expenses.

- From January 2018 through December 2019, we received proceeds of $29.9 million from the exercise of 8,829,235 outstanding warrants which were originally issued in a registered public offering of common stock in October 2017. As of December 31, 2019, there were warrants to purchase 417,315 shares outstanding relating to the October 2017 offering.

- From January 2018 through December 2019, we issued 1,554,995 shares of common stock upon the exercise of stock options, and 409,653 shares of common stock were purchased under our 2013 Employee Stock Purchase Plan, which generated aggregate proceeds of $26.3 million.

Our historical cash outflows have primarily been associated with cash used for operating activities such as the development and commercialization of our products, the expansion and support of our sales, marketing, clinical and customer support organizations, the expansion of our R&D activities, the expansion of our commercial activities to select international geographies, the acquisition of intellectual property, expenditures related to increases in our manufacturing capacity and improvements to our manufacturing efficiency, overall expansion of our facilities and operations, and other working capital needs. Additionally, we have used cash to pay the interest expense associated with our Term Loan Agreement. The outstanding balance associated with the Term Loan Agreement was fully repaid in August 2018, and we have ceased incurring interest expense and other costs associated with the Term Loan Agreement subsequent to the third quarter of 2018.

We expect our sales performance and the resulting operating income or loss, as well as the status of each of our new product development programs, will significantly impact our cash flow from operations, liquidity position and cash management decisions.

The following table shows a summary of our cash flows for the years ended December 31, 2019, 2018 and 2017:

	Year Ended December 31,		
(in thousands)	**2019**	**2018**	**2017**
Net cash provided by (used in):			
Operating activities	$ 41,906	$ (8,319)	$ (66,136)
Investing activities	(56,955)	(90,739)	2,782
Financing activities	24,207	117,184	40,376
Effect of foreign exchange rate changes on cash	191	—	—
Total	$ 9,349	$ 18,126	$ (22,978)

Operating activities. Net cash provided by operating activities was $41.9 million for the year ended December 31, 2019, compared to net cash used of $8.3 million and $66.1 million for the same periods in 2018 and 2017, respectively.

The improvement to net cash provided by operating activities for 2019 compared to 2018 was primarily driven by higher sales and gross margins in 2019, which resulted in a significant reduction in net loss when adjusted for non-cash expenses, particularly stock-based compensation expense and the change in the fair value of common stock warrants, offset by net changes in working capital. Our operating loss for the year ended December 31, 2018 also included $7.6 million in interest expense, and a $5.3 million loss on extinguishment of debt. Working capital changes in 2019 primarily consisted of increases in accounts receivable and inventories, offset by increases in accounts payable, accrued expenses, employee-related liabilities, deferred revenue, and other long-term liabilities related to warranty reserves for 2019 pump sales. Accounts receivable increased to $46.6 million at December 31, 2019 from $35.2 million at December 31, 2018, as a result of higher sales in the fourth quarter of 2019 as compared to the fourth quarter of 2018. Inventories increased to $49.1 million at December 31, 2019 from $19.9 million at December 31, 2018, primarily to support the growth in our business.

The decrease in net cash used in operating activities for 2018 compared to 2017 was primarily associated with a reduction in the net loss when adjusted for non-cash expenses, particularly the change in the fair value of certain common stock warrants, increased stock-based compensation expense, and a $5.3 million loss on extinguishment of debt in 2018, as well as net changes in working capital. Our operating loss also included $7.6 million and $11.3 million in interest expense during 2018 and 2017, respectively. Working capital changes were due to an increase in accounts receivable as a result of higher sales, offset by a reduction in inventories and increases in employee related liabilities and deferred revenue. Inventories decreased to $19.9 million at December 31, 2018 from $27.0 at December 31, 2017 due to an increase in sales demand during the fourth quarter of 2018, and the timing of pump production and certain inventory receipts.

Investing activities. Net cash used by investing activities was $57.0 million for the year ended December 31, 2019, which was primarily related to purchases of short-term investments of $164.6 million and $19.5 million in purchases of property and equipment, offset by $127.2 million in proceeds from maturities and sales of short-term investments. Net cash used by investing activities was $90.7 million for the year ended December 31, 2018, which was primarily related to purchases of short-term investments of $123.6 million using the net proceeds from our public offering of common stock in August of 2018, and $3.0 million in purchases of property and equipment, offset by $35.8 million in proceeds from maturities of short-term investments. Net cash provided by investing activities was $2.8 million for the year ended December 31, 2017, which was primarily related to proceeds from maturities of short-term investments of $8.5 million offset by $5.7 million in purchases of property and equipment.

Financing activities. Net cash provided by financing activities was $24.2 million for the year ended December 31, 2019, which was primarily the result of proceeds of $23.9 million from the issuance of common stock under our stock plans. Net cash provided by financing activities was $117.2 million for the year ended December 31, 2018, which was primarily the result of net proceeds of approximately $172.9 million from the public offerings of our common stock in February 2018 and August 2018, as well as proceeds of $29.6 million from the exercise of common stock warrants that were issued in the public offering of common stock in October 2017, offset by the $87.7 million repayment of our term loan and associated financing fees. Net cash provided by financing activities was $40.4 million for the year ended December 31, 2017, which was primarily the result of net proceeds from the issuance of common stock.

Our liquidity position and capital requirements are subject to fluctuation based on a number of factors. In particular, our cash inflows and outflows are principally impacted by the following:

- our ability to generate sales, the timing of those sales, the mix of products sold and the collection of receivables from period to period;
- the timing of any additional financings, and the net proceeds raised from such financings;
- the timing and amount of the exercise of outstanding warrants, and proceeds from the issuance of equity awards pursuant to employee stock plans;
- fluctuations in gross margins and operating margins; and
- fluctuations in working capital, including changes in accounts receivable, inventories, accounts payable, employee related liabilities, and operating lease liabilities.

Our primary short-term capital needs are expected to include expenditures related to:

- support of our commercialization efforts related to our current and future products;
- expansion of our customer support resources for our growing installed customer base;
- research and product development efforts, including clinical trial costs;
- acquisitions of equipment, technology, intellectual property and other assets;
- additional facilities leases and related tenant improvements, and manufacturing equipment to support business growth and increase manufacturing capacity; and
- payments under licensing, development and commercialization agreements.

Although we believe the foregoing items reflect our most likely uses of cash in the short-term, we cannot predict with certainty all of our particular cash uses or the timing or amount of cash used. In addition, from time to time we may consider opportunities to acquire or license other products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Any such transaction may require short-term expenditures that may impact our capital needs. If for any reason our cash and cash equivalents balances, or cash generated from operations is insufficient to satisfy our working capital requirements, we may in the future be required to seek additional capital from public or private offerings of our equity or debt securities, or we may elect to borrow capital under new credit arrangements or from other sources. We may also seek to raise additional capital from such offerings or borrowings on an opportunistic basis when we believe there are suitable opportunities for doing so. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing or debt service costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. There can be no assurance that financing will be available on acceptable terms, or at all. Our ability to raise additional financing may be negatively impacted by a number of factors, including our recent and projected financial results, recent changes in and volatility of our stock price, perceptions about the dilutive impact of financing transactions, the competitive environment in our industry, and uncertainties regarding the regulatory environment in which we operate.

Indebtedness

Repayment of Term Loan Agreement

In August 2018, we fully repaid our term loan with CRG pursuant to the Term Loan Agreement. The balance of the outstanding debt at the time of repayment was $82.7 million. The total repayment amount of $88.8 million included approximately $1.1 million in accrued interest, and approximately $5.0 million in associated financing fees that became due. Therefore, we did not have any borrowings outstanding under the Term Loan Agreement as of December 31, 2019 and December 31, 2018. At the time of repayment, the remaining $5.3 million debt discount balance associated with the financing fees and certain debt issuance costs was accelerated and recognized as a loss on extinguishment of debt during the third quarter of 2018.

Contractual Obligations & Commitments

The following table summarizes the payments due by fiscal period for our outstanding contractual obligations at December 31, 2019:

	Payments Due by Period				
(in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations [1][2]	$ 31,464	$ 7,010	$ 15,209	$ 5,269	$ 3,975
Firm purchase commitments [3]	128,215	112,173	16,042	—	—
Total contractual obligations	$ 159,679	$ 119,183	$ 31,251	$ 5,269	$ 3,975

(1) Operating lease obligations of $23.1 million were included in operating lease liabilities current and long-term in the consolidated balance sheet at December 31, 2019 (see Note 5, "Leases"). The additional $8.3 million included in the above table consists of $8.2 million due under the lease of additional general office space located on Shoreline Drive, Boise, Idaho (Shoreline Lease), which we entered into in November of 2019, and $0.1 million related to short-term leases. Minimum annual lease payments under the Shoreline Lease will be approximately $0.5 million in 2020, $1.1 million in 2021 and 2022, $1.2 million in 2023 and 2024, and $3.1 million thereafter. The Company currently estimates that it will recognize the Shoreline Lease operating lease liabilities on the consolidated balance sheet upon the lease commencement in the first quarter of 2020.

(2) Does not include $2.5 million due under the lease of additional general office space located on High Bluff Drive, San Diego, California, which we entered into in January of 2020. Minimum annual lease payments under the lease will be approximately $1.0 million in 2020, $1.2 million in 2021, and $0.3 million in 2022.

(3) Includes purchase orders that are cancellable under the standard terms of our purchase order agreements. In certain cases, cancellation of outstanding purchase commitments may require payment of costs incurred through the date of cancellation.

Critical Accounting Policies Involving Management Estimates and Assumptions

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about our financial condition and results of operations that are not readily apparent from other sources. Actual results may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this Annual Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Our revenue is generated primarily from sales of our insulin pumps, disposable cartridges and infusion sets to individual customers and third-party distributors that resell the product to insulin-dependent diabetes customers. We are paid directly by customers who use the products, distributors and third-party insurance payors. We recognize revenue when control of our products is transferred to our customers in an amount that reflects the consideration we expect to receive from our customers in exchange for those products. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. Revenue recognition for contracts with multiple deliverables is based on the separate satisfaction of each distinct performance obligation within the contract. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. We consider a performance obligation satisfied once we have transferred control of a product to the customer, meaning the customer has the ability to use and obtain the benefit of the product. Complementary products, such as the t:connect cloud-based data management application and the Tandem Device Updater, are considered performance obligations satisfied over time, as access and support for these products is provided throughout the typical four-year warranty period of the insulin pumps. Accordingly, revenue related to the complementary products is deferred and recognized ratably over a four-year period. There is no standalone value for these complementary products. Therefore, we determine their value by applying the expected cost plus a margin approach and then allocate the residual to the insulin pumps.

Warranty Reserve

We generally provide a four-year warranty on our insulin pumps to end user customers and may replace any pumps that do not function in accordance with the product specifications. Insulin pumps returned to us may be refurbished and redeployed. Additionally, we offer a six-month warranty on disposable cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. We evaluate the reserve quarterly. Warranty costs are primarily estimated based on the current expected product replacement cost and expected replacement rates utilizing historical experience. Recently released versions of our pump may not incur warranty costs in a manner similar to previously released pumps, on which we initially base our warranty estimate of newer pumps. We may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to length of time the pump version has been in the field and future expectations of performance based on new features and capabilities that may become available through Tandem Device Updater. Changes to the actual replacement rates or the expected product replacement cost could have a material impact on our estimated warranty reserve.

Income Taxes

Significant judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

Utilization of our net operating loss and research credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitations may result in the expiration of net operating loss carryforwards before utilization. We have completed an analysis through December 31, 2018 to determine whether our net operating losses and credits are likely to be limited by Section 382. Based on this study, we determined that an ownership change, as defined under Section 382, occurred in 2018 and the resulting limitation significantly reduced our ability to utilize our net operating loss and credit carryovers before they expire. As a result, in 2019 we reduced our deferred tax assets for the net operating loss and research credit carryforwards that are projected to expire unused with a corresponding offset to the valuation allowance recorded against such assets. Additionally, future ownership changes under Section 382 may also limit our ability to fully utilize any remaining tax benefits.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We continually assess the likelihood and amount of potential revisions and adjust the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

Off-Balance Sheet Arrangements

As of December 31, 2019, we did not have any off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

We invest our excess cash primarily in commercial paper, corporate debt securities, U.S. Government-sponsored enterprise securities and U.S. Treasury securities. Some of the financial instruments in which we invest subject us to market risk, in that a change in prevailing interest rates may cause the principal amount of the instrument to fluctuate. Other financial instruments in which we invest subject us to credit risk, in that the value of the instrument may fluctuate based on the issuer's ability to pay.

The primary objectives of our investment activities are to maintain liquidity and preserve principal while maximizing the income we receive from our financial instruments without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are primarily designed to maintain liquidity and preserve principal.

Because of the short-term maturities of our financial instruments, we do not believe that an increase or decrease in market interest rates would have any significant impact on the realized value of our investment portfolio. If a 10% change in interest rates were to have occurred on December 31, 2019, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Our operations are primarily located in the United States, and nearly all of our sales since inception have been made in U.S. dollars. With the exception of a portion of our sales in Canada, our sales outside of the United States are currently made to independent distributors under agreements denominated in U.S. dollars. Accordingly, we believe we do not currently have any material exposure to foreign currency rate fluctuations. As our business in markets outside of the United States increases, we may be exposed to foreign currency exchange risk. We believe this is currently limited to our operations in Canada, where fluctuations in the rate of exchange between the U.S. dollar and the Canadian dollar could adversely affect our financial results. In addition, from time to time, we may have foreign currency exchange risk related to existing assets and liabilities, committed transactions and forecasted future cash flows. In certain circumstances, we may seek to manage such foreign currency exchange risk by using derivative instruments such as foreign currency exchange forward contracts to hedge our risk. In general, we may hedge foreign currency exchange exposures up to 12 months in advance. However, we may choose not to hedge some exposures for a variety of reasons, including prohibitive economic costs.

Item 8. Consolidated Financial Statements and Supplementary Data

Our consolidated financial statements as of December 31, 2019 and 2018 and for each of the three years in the period ended December 31, 2019, and the Report of the Independent Registered Public Accounting Firm are included in this report as listed in the index.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Tandem Diabetes Care, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Tandem Diabetes Care, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2019 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 24, 2020 expressed an unqualified opinion thereon.

Adoption of ASU No. 2016-02

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update (ASU) No. 2016-02, *Leases* (*Topic 842*), and the related amendments.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the account or disclosure to which it relates.

Warranty reserve - Estimation of Product Replacement Reserve

Description of the Matter

As discussed in Note 2 to the consolidated financial statements, the Company has a warranty reserve of $16.7 million. The Company provides insulin pump end customers with a four-year warranty and may replace any pumps that do not function in accordance with the product specifications. Warranty costs are estimated at the time of shipment. Management applies significant judgment to determine relevant assumptions to calculate the reserve, including the assessment of historical warranty experience and replacement cost.

Auditing management's warranty reserve on pumps was complex and judgmental due to the significant estimation required by management in determining the value of the warranty reserve. In particular, the warranty reserve estimate is sensitive due to significant assumptions including replacement rates and replacement product costs, especially as it relates to recently released pump versions for which replacement rates specific to that version are not yet known. As such, replacement rates of recently released pumps are based primarily upon historical rates of prior versions which ultimately may not be predictive of the experience of new pumps, due to new features and capabilities of the more recent releases. These assumptions are affected by actual customer experience and changes in these assumptions could have a material impact on the Company's estimated reserve. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence related to management's significant assumptions in determining the warranty reserve.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's controls over the warranty reserve estimation process. For example, we tested controls over management's review and calculation of significant assumptions underlying the warranty reserve, such as replacement rates and actual replacement product costs, and tested controls over the accuracy and completeness of data used.

To test the Company's warranty reserve, we performed audit procedures that included, among others, testing the completeness and accuracy of the underlying data used in the estimation calculation and evaluated the appropriateness of management's methodology to calculate the warranty reserve. We also evaluated the reasonableness of management's significant assumptions related to replacement rates and replacement cost, including review for contrary evidence. Evaluating management's significant assumptions involved evaluating the historical claims data utilized by management in estimating both the replacement rates and costs of known and anticipated claims. We assessed the historical accuracy of management's estimates by performing a lookback analysis and performing sensitivity analyses of the significant assumptions to evaluate the impact of changes in the warranty reserve that would result from changes in the assumptions. We tested the mathematical accuracy of the warranty reserve calculation and obtained documentation and performed inquiries of Company management to evaluate the completeness of the Company's estimate. In addition, for revisions made to the estimated reserve, we evaluated the reasonableness of the subsequent changes by comparing the revised assumptions to the original estimated assumptions and evaluated the reasons for the subsequent change.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2009

San Diego, CA

February 24, 2020

TANDEM DIABETES CARE, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands except par values)

	December 31,	
	2019	2018
Assets		
Current assets:		
Cash and cash equivalents	$ 51,175	$ 41,826
Short-term investments	125,283	87,201
Accounts receivable, net	46,585	35,193
Inventories, net	49,073	19,896
Prepaid and other current assets	4,025	3,769
Total current assets	276,141	187,885
Property and equipment, net	32,923	17,151
Operating lease right-of-use assets	15,561	—
Other long-term assets	1,485	1,258
Total assets	$ 326,110	$ 206,294
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 17,745	$ 6,824
Accrued expenses	8,014	3,930
Employee-related liabilities	28,320	24,030
Deferred revenue	3,869	4,600
Common stock warrants	23,509	17,926
Operating lease liabilities	6,320	—
Other current liabilities	11,619	8,978
Total current liabilities	99,396	66,288
Operating lease liabilities - long-term	14,063	—
Other long-term liabilities	17,672	8,731
Total liabilities	131,131	75,019
Commitments and contingencies (Note 10)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 59,396 and 57,554 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively.	59	57
Additional paid-in capital	819,626	731,306
Accumulated other comprehensive income (loss)	122	(13)
Accumulated deficit	(624,828)	(600,075)
Total stockholders' equity	194,979	131,275
Total liabilities and stockholders' equity	$ 326,110	$ 206,294

The accompanying notes are an integral part of the consolidated financial statements.

TANDEM DIABETES CARE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except per share data)

	Year Ended December 31,		
	2019	2018	2017
Sales	$ 362,305	$ 183,866	$ 107,601
Cost of sales	168,093	94,044	63,507
Gross profit	194,212	89,822	44,094
Operating expenses:			
Selling, general and administrative	165,735	105,226	86,377
Research and development	45,199	29,227	20,661
Total operating expenses	210,934	134,453	107,038
Operating loss	(16,722)	(44,631)	(62,944)
Other income (expense), net:			
Interest and other income	3,271	1,462	239
Interest and other expense	(78)	(7,584)	(11,341)
Loss on extinguishment of debt	—	(5,313)	—
Change in fair value of common stock warrants	(11,075)	(66,494)	1,021
Total other expense, net	(7,882)	(77,929)	(10,081)
Loss before income taxes	(24,604)	(122,560)	(73,025)
Income tax expense	149	51	8
Net loss	$ (24,753)	$ (122,611)	$ (73,033)
Other comprehensive loss:			
Unrealized gain (loss) on short-term investments	$ 77	$ (13)	$ 1
Foreign currency translation gain	58	—	—
Comprehensive loss	$ (24,618)	$ (122,624)	$ (73,032)
Net loss per share - basic and diluted	$ (0.42)	$ (2.55)	$ (12.87)
Weighted average shares used to compute basic and diluted net loss per share	58,507	48,129	5,677

The accompanying notes are an integral part of the consolidated financial statements.

TANDEM DIABETES CARE, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2016	3,110	$ 3	$ 398,651	$ (1)	$ (404,580)	$ (5,927)
Exercise of stock options	24	—	270	—	—	270
Issuance of common stock in public offering, net of underwriter's discount and offering costs	6,946	7	33,346	—	—	33,353
Issuance of common stock warrants in connection with term loan	—	—	3,331	—	—	3,331
Issuance of common stock for Employee Stock Purchase Plan	39	—	300	—	—	300
Stock-based compensation	—	—	12,557	—	—	12,557
Unrealized gain on short-term investments	—	—	—	1	—	1
Net loss	—	—	—	—	(73,033)	(73,033)
Balance at December 31, 2017	10,119	$ 10	$ 448,455	$ —	$ (477,613)	$ (29,148)
Exercise of stock options	136	—	1,027	—	—	1,027
Exercise of common stock warrants	8,603	9	29,566	—	—	29,575
Issuance of common stock in public offering, net of underwriter's discount and offering costs	38,535	38	172,891	—	—	172,929
Fair value of common stock warrants at time of exercise	—	—	54,000	—	—	54,000
Issuance of common stock for Employee Stock Purchase Plan	81	—	1,364	—	—	1,364
Stock-based compensation	80	—	24,003	—	—	24,003
Unrealized loss on short-term investments	—	—	—	(13)	—	(13)
Adjustment to retained earnings from adoption of ASC 606	—	—	—	—	149	149
Net loss	—	—	—	—	(122,611)	(122,611)
Balance at December 31, 2018	57,554	$ 57	$ 731,306	$ (13)	$ (600,075)	$ 131,275
Exercise of stock options	1,422	1	17,674	—	—	17,675
Exercise of common stock warrants	93	—	327	—	—	327
Fair value of common stock warrants at time of exercise	—	—	5,492	—	—	5,492
Issuance of common stock for Employee Stock Purchase Plan	327	1	6,205	—	—	6,206
Stock-based compensation	—	—	58,622	—	—	58,622
Unrealized gain on short-term investments, net of deferred tax	—	—	—	77	—	77
Foreign currency translation adjustments	—	—	—	58	—	58
Net loss	—	—	—	—	(24,753)	(24,753)
Balance at December 31, 2019	59,396	$ 59	$ 819,626	$ 122	$ (624,828)	$ 194,979

The accompanying notes are an integral part of the consolidated financial statements.

TANDEM DIABETES CARE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2019	2018	2017
Operating Activities			
Net loss	$ (24,753)	$ (122,611)	$ (73,033)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization expense	6,072	5,821	6,866
Interest expense related to amortization of debt discount and debt issuance costs	—	1,721	1,883
Payment in kind interest accrual of notes payable	—	—	1,657
Provision for allowance for doubtful accounts	2,322	1,448	824
Provision for inventories reserve	2,353	607	26
Change in fair value of common stock warrants	11,075	66,494	(1,021)
Amortization of premium (discount) on short-term investments	(565)	539	(16)
Stock-based compensation expense	58,071	23,736	12,628
Loss on extinguishment of debt		5,313	—
Other	(321)	152	159
Changes in operating assets and liabilities:			
Accounts receivable, net	(13,698)	(15,848)	(10,445)
Inventories, net	(30,975)	6,756	(5,894)
Prepaid and other current assets	(584)	(1,576)	1,831
Other long-term assets	(580)	(26)	4
Accounts payable	8,910	1,641	(1,953)
Accrued expenses	4,076	1,097	1,203
Employee-related liabilities	4,285	9,542	3,873
Deferred revenue	4,589	2,074	(3,906)
Other current liabilities	4,216	2,434	(432)
Other long-term liabilities	7,412	2,367	(390)
Net cash provided by (used in) operating activities	41,905	(8,319)	(66,136)
Investing Activities			
Purchases of short-term investments	(164,572)	(123,553)	—
Proceeds from maturities of short-term investments	114,908	35,800	8,500
Proceeds from sales of short-term investments	12,250	—	—
Purchases of property and equipment	(19,541)	(2,986)	(5,718)
Net cash provided by (used in) investing activities	(56,955)	(90,739)	2,782
Financing Activities			
Principal payments on notes payable	—	(87,711)	—
Proceeds from public offerings, net of offering costs	—	172,929	39,806
Proceeds from issuance of common stock under Company stock plans	23,880	2,391	570
Proceeds from exercise of common stock warrants	327	29,575	—
Net cash provided by financing activities	24,207	117,184	40,376
Effect of foreign exchange rate changes on cash	191	—	—
Net increase (decrease) in cash and cash equivalents and restricted cash	9,348	18,126	(22,978)
Cash and cash equivalents and restricted cash at beginning of period	41,826	23,700	46,678
Cash and cash equivalents and restricted cash at end of period	$ 51,174	$ 41,826	$ 23,700
Supplemental disclosures of cash flow information			
Interest paid	$ —	$ 10,805	$ 7,876
Income taxes paid	$ 67	$ 16	$ 22
Supplemental schedule of non-cash investing and financing activities			
Right-of-use assets obtained in exchange for operating lease obligations	$ 11,635	$ —	$ —
Lease incentive - lessor-paid tenant improvements	$ —	$ 13	$ 3,292
Property and equipment included in accounts payable	$ 2,134	$ 125	$ 92
Debt discount included in other long-term liabilities	$ —	$ —	$ 4,137
Common stock warrants issued in connection with term loan	$ —	$ —	$ 3,331
Unsettled purchase of investments classified as cash equivalents in other current liabilities	$ —	$ 1,708	$ —

The accompanying notes are an integral part of the consolidated financial statements

1. Organization and Basis of Presentation

The Company

Tandem Diabetes Care, Inc. is a medical device company with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. The Company is incorporated in the state of Delaware. Unless the context requires otherwise, the terms the "Company" or "Tandem" refer to Tandem Diabetes Care, Inc., together with its wholly-owned subsidiary in Canada.

The Company manufactures, sells and supports insulin pump products that are designed to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. The Company's manufacturing, sales and support activities principally focus on the t:slim X2 Insulin Delivery System (t:slim X2), the Company's flagship pump platform which is capable of remote feature updates and is designed to display continuous glucose monitoring (CGM) sensor information directly on the pump home screen. The Company's insulin pump products are compatible with the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of the Company's insulin pump software. The Company's insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, the Company sells disposable products that are used together with the pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body.

The Company has commercially launched seven insulin pumps in the United States since 2012 and two pumps outside the United States since 2018. Four of the insulin pumps have featured CGM technology, and two have featured an automated insulin delivery (AID) algorithm. In June 2018, the t:slim X2 was the first insulin pump designated as compatible with integrated CGM (known as iCGM) devices; in February 2019, the t:slim X2 was the first in a new device category called Alternate Controller Enabled Infusion Pumps (ACE pumps); and in December 2019, Control-IQ technology for the t:slim X2 insulin pump was the first automated insulin dosing software in a new interoperable automated glycemic controller category. The Company believes that the three new classifications by the United States Food and Drug Administration (FDA) for the interoperability of devices for AID will help support continued rapid innovation by streamlining the regulatory pathway for integrated products.

The consolidated financial statements included in this Annual Report have been prepared on a basis that assumes that the Company will continue as a going concern, and do not include any adjustments that may result from the outcome of this uncertainty. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of the Company's liabilities and commitments in the normal course of business and does not include any adjustments to reflect the possible future effects of the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

As of December 31, 2019, the Company had $176.5 million in cash and cash equivalents and short-term investments. The Company has incurred operating losses since its inception and had an accumulated deficit $624.8 million as of December 31, 2019, which included a net loss of $24.8 million for the year ended December 31, 2019. Management believes that cash and cash equivalents and short-term investments on hand will be sufficient to satisfy the Company's liquidity requirements for at least the next 12 months from the date of this filing.

The Company's ability to execute on its business strategy, meet its future liquidity requirements, and achieve and maintain profitable operations, is dependent on a number of factors, including its ability to continue to gain market acceptance of its products and achieve a level of revenues adequate to support its cost structure, achieve renewal pump sales objectives, develop and launch new products, expand the commercialization of products into new international markets, maximize manufacturing efficiencies, satisfy increasing production requirements, leverage the investments made in its sales, clinical, marketing and customer support organizations, and operate its business and manufacture and sell products without infringing on third party intellectual property rights.

The Company has funded its operations primarily through private and public offerings of equity securities, and through debt financing which has since been fully repaid. The Company may in the future seek additional capital from public or private offerings of equity or debt securities, or it may elect to borrow capital under new credit arrangements or from other sources. If the Company issues equity or debt securities to raise additional funds, its existing stockholders may experience dilution, it may incur significant financing or debt service costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of its existing stockholders. There can be no assurance that equity or debt financing will be available on acceptable terms, or at all.

Basis of Presentation and Principles of Consolidation

The Company has prepared the accompanying consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The statements include the accounts of Tandem Diabetes Care, Inc. and its wholly-owned subsidiary in Canada. All significant intercompany balances and transactions have been eliminated in consolidation.

The functional currency of our foreign subsidiary is the local currency. We translate the financial statements of our foreign subsidiary into U.S. dollars using period-end exchange rates for assets and liabilities and average exchange rates for each period for revenue, costs and expenses. Translation related adjustments are included in comprehensive loss and in accumulated other comprehensive income (loss) in the equity section of our consolidated balance sheets. Foreign exchange gains or losses resulting from balances denominated in a currency other than the functional currency are recognized in interest and other income or interest and other expense in our consolidated statements of operations.

Reclassifications

Certain reclassifications of prior year amounts related to the presentation of patents and long-term deferred rent on the consolidated balance sheet, and deferred rent on the consolidated statements of cash flows, have been made to conform to the current year presentation.

2. Summary of Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the year ended December 31, 2019, as compared to those disclosed in this Annual Report other than adoption of the new lease accounting standard effective January 1, 2019 (see Note 5, "Leases").

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company’s consolidated financial statements and accompanying notes as of the date of the consolidated financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

Segment Reporting

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker (CODM) in making decisions regarding resource allocation and assessing performance. The Company is organized based on its current product portfolio, which consists primarily of insulin pumps, disposable cartridges and infusion sets for the storage and delivery of insulin. The Company views its operations and manages its business as one segment as key operating decisions and resource allocations are made by the CODM using consolidated financial data.

Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less from the date of purchase and that can be liquidated without prior notice or penalty to be cash equivalents.

Short-Term Investments

The Company's short-term investments are classified as available-for-sale securities. Such securities are carried at fair value as determined by prices for identical or similar securities at the balance sheet date. The Company's short-term investments consist of Level 1 and Level 2 financial instruments in the fair value hierarchy. The net unrealized gains or losses on available-for-sale securities are reported as a component of other comprehensive loss within the statements of operations and accumulated other comprehensive gain (loss) as a separate component of stockholders' equity on the consolidated balance sheets. The Company determines the realized gains or losses of available-for-sale securities using the specific identification method and includes net realized gains and losses as a component of other income or expense within the consolidated statements of operations. The Company periodically reviews available-for-sale securities for other than temporary declines in fair value below the cost basis whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. To date, the Company has not identified any other than temporary declines in fair value of its short-term investments.

Accounts Receivable

The Company grants credit to various customers in the ordinary course of business and is paid directly by customers who use the products, distributors and third-party insurance payors. The Company maintains an allowance for doubtful accounts for potential credit losses. Provisions are made based on historical experience, assessment of specific risk, review of outstanding invoices, and various assumptions and estimates that are believed to be reasonable under the circumstances. Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company maintains deposit accounts in federally insured financial institutions in excess of federally insured limits. The Company also maintains investments in money market funds that are not federally insured. Additionally, the Company has established guidelines regarding investment instruments and their maturities, which are designed to maintain preservation of principal and liquidity.

The following table summarizes customers who accounted for 10% or more of accounts receivable, net:

	December 31,	
	2019	2018
Byram Healthcare	20.4%	15.5%
CCS Medical, Inc.	10.1%	10.1%

The following table summarizes customers who accounted for 10% or more of sales for the periods presented:

	Year Ended December 31,		
	2019	2018	2017
Byram Healthcare	15.4%	15.6%	14.0%
RGH Enterprises, Inc.	14.8%	19.4%	21.5%
CCS Medical	N/A	N/A	10.3%

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and employee-related liabilities are reasonable estimates of their fair values because of the short-term nature of these assets and liabilities. Short-term investments are carried at fair value. The Company believes the fair value of its operating lease liabilities at December 31, 2019 approximated their carrying value, based on the borrowing rates that were available for loans with similar terms as of that date. The estimated fair value of certain of the Company's common stock warrants was determined using the Black-Scholes pricing model as of December 31, 2019 and 2018 (see Note 4, "Fair Value Measurements").

Valuation of Inventories

Inventories are valued at the lower of cost or net realizable value, determined by the first-in, first-out method. Inventory is recorded using standard cost, including material, labor and overhead costs. The Company periodically reviews inventories for potential impairment and adjusts inventory for potentially excess or obsolete goods to state inventories at their net realizable value. Factors influencing these adjustments include quantities on hand and firm purchase commitments, expectations of future use, judgments based on quality control testing data and assessments of the likelihood of scrapping or obsoleting certain inventories based on future demand for its products and market conditions.

Long-Lived Assets

Property and Equipment

Property and equipment, which primarily consist of office furniture and equipment, manufacturing equipment, scientific equipment, computer equipment, and leasehold improvements, are stated at cost, less accumulated depreciation. Property and equipment are depreciated over the estimated useful lives of the assets, generally three to seven years, using the straight-line method. Leasehold improvements are amortized over the lesser of the estimated useful lives of the assets or the remaining lease term. Maintenance and repair costs are expensed as incurred.

Operating Lease Right-of-Use Assets and Liabilities

Lease right-of-use assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized when the Company takes possession of the leased property (the Commencement Date) based on the present value of lease payments over the lease term. Rent expense on noncancelable leases containing known future scheduled rent increases is recorded on a straight-line basis over the term of the respective leases beginning on the Commencement Date. The difference between rent expense and rent paid is accounted for as a component of operating lease right-of-use assets on the Company's consolidated balance sheet. Landlord improvement allowances and other such lease incentives are recorded as property and equipment and as reduction of the right-of-use leased assets, and are amortized on a straight-line basis as a reduction to operating lease costs. Leases with an initial term of 12 months or less are expensed as incurred and are not recorded as right-of-use assets on the consolidated balance sheets (see Note 5, "Leases").

Patents

Costs associated with the purchase or licensing of patents associated with the Company's commercialized products are capitalized. The Company reviews its capitalized patent costs periodically to determine that they have future value and an alternative future use. Costs related to patents that the Company is not actively pursuing for commercial purposes are expensed. The Company amortizes patent costs over the lesser of the duration of the patent term or the estimated useful lives of 10 years, beginning with the date the patents are issued or acquired.

The Company periodically re-evaluates the original assumptions and rationale utilized in the establishment of the carrying value and estimated lives of all of its long-lived assets, including property and equipment and acquired patents. The determinants used for this evaluation include management's estimate of the asset's ability to generate positive income from operations and positive cash flow in future periods as well as the strategic significance of the asset to the Company's business objective. The Company has not recognized any impairment losses through December 31, 2019.

Research and Development Costs

All research and development costs are charged to expense as incurred. Such costs include personnel-related costs, including stock-based compensation, supplies, license fees, development prototypes, outside design and testing services, depreciation, allocated facilities and information services, clinical trial costs, milestone payments under the Company's development and commercialization agreements and other indirect costs.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred income tax assets or liabilities are recognized based on the temporary differences between financial statement and income tax bases of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. Tax law and rate changes are reflected in income in the period such changes are enacted. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized. The Company includes interest and penalties related to income taxes, including unrecognized tax benefits, within income tax expense.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of examinations by tax authorities in determining the adequacy of its provision for income taxes. The Company continually assesses the likelihood and amount of potential revisions and adjusts the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. The Company will continue to assess the need for a valuation allowance on its deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

The Company is required to file federal and state income tax returns in the United States and various other state jurisdictions and, starting with 2018, a corporation income tax return in Canada. The preparation of these income tax returns requires the Company to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid by the Company. An amount is accrued for the estimate of additional tax liability, including interest and penalties, for any uncertain tax positions taken or expected to be taken in an income tax return. The Company reviews and updates the accrual for uncertain tax positions as more definitive information becomes available. For further information, see Note 7, "Income Taxes."

Revenue Recognition

Revenue is generated primarily from sales of insulin pumps, disposable cartridges and infusion sets to individual customers and third-party distributors that resell the products to insulin-dependent diabetes customers.

In January 2018, the Company adopted the Revenue from Contracts with Customers Standard which superseded existing revenue guidance under U.S. GAAP and International Financial Reporting Standards. Pursuant to the Revenue from Contracts with Customers Standard's core principle, subsequent to January 1, 2018, the Company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company elected to implement this new standard utilizing the modified retrospective method. Under this approach, the Company applied the new standard to all new contracts initiated on or after the effective date, and for contracts which had remaining obligations as of the effective date the Company recorded an adjustment to the opening balance of accumulated deficit. The accounting for the significant majority of the Company's revenues was not impacted by the new guidance. On January 1, 2018, the Company recorded a net reduction to accumulated deficit in the amount of $149,000, to reflect the impact of the accounting change. Prior to the implementation of this new standard, revenue was recognized when persuasive evidence of an arrangement existed, delivery had occurred and title passed, the price was fixed or determinable, and collectability was reasonably assured.

Revenue Recognition for Arrangements with Multiple Deliverables

The Company considers the individual deliverables in its product offering as separate performance obligations. The transaction price is determined based on the consideration expected to be received, based either on the stated value in contractual arrangements or the estimated cash to be collected in non-contracted arrangements. The Company allocates the consideration to the individual performance obligations and recognizes the consideration based on when the performance obligation is satisfied, considering whether or not this occurs at a point in time or over time. Generally, insulin pumps, cartridges, infusion sets and accessories are deemed performance obligations that are satisfied at a point in time when the customer obtains control of the promised good, which is upon delivery. Complementary products, such as the t:connect cloud-based data management application and the Tandem Device Updater, are considered performance obligations that are satisfied over time, as access and support for these products is provided throughout the typical four-year warranty period of the insulin pumps. Accordingly, revenue related to the complementary products is deferred and recognized ratably over a four-year period. There is no standalone value for these complementary products. Therefore, the Company determines their value by applying the expected cost plus a margin approach and then allocates the residual to the insulin pumps. At December 31, 2019 and 2018, deferred revenue for these performance obligations that are satisfied over time was $3.5 million and $4.3 million, respectively, classified as current deferred revenue. At December 31, 2019, $5.7 million was classified as non-current deferred revenue which is included in other long-term liabilities on the consolidated balance sheets.

Sales Returns

The Company offers a 30-day right of return to its customers from the date of shipment of any of its insulin pumps, provided a physician's confirmation of the medical reason for the return is received. Estimated allowances for sales returns are based on historical returned quantities as compared to pump shipments in those same periods of return. The return rate is then applied to the sales of the current period to establish a reserve at the end of the period. The return rates used in the reserve are adjusted for known or expected changes in the marketplace when appropriate. The allowance for sales returns is recorded as a reduction of revenue and an increase in deferred revenue in the period in which the related sale is recorded. The amount recorded in deferred revenue on the Company's consolidated balance sheets for allowances for sales returns was $0.4 million and $0.3 million at December 31, 2019 and 2018, respectively. Actual product returns have not differed materially from estimated amounts reserved in the accompanying consolidated financial statements.

Warranty Reserve

The Company generally provides a four-year warranty on its insulin pumps to end user customers and may replace any pumps that do not function in accordance with the product specifications. Insulin pumps returned to the Company may be refurbished and redeployed. Additionally, the Company offers a six-month warranty on disposable cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. We evaluate the reserve quarterly. Warranty costs are primarily estimated based on the current expected product replacement cost and expected replacement rates utilizing historical experience. Recently released versions of the pump may not incur warranty costs in a manner similar to previously released pumps, on which the Company initially bases its warranty estimate of newer pumps. The Company may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to length of time the pump version has been in the field and future expectations of performance based on new features and capabilities that may become available through Tandem Device Updater.

At December 31, 2019 and December 31, 2018, the warranty reserve was $16.7 million and $9.1 million, respectively. The following table provides a reconciliation of the change in estimated warranty liabilities for the years ended December 31, 2019 and 2018:

	December 31,	
(in thousands)	2019	2018
Balance at beginning of the year	$ 9,138	$ 5,640
Provision for warranties issued during the period	18,335	9,617
Settlements made during the period	(10,167)	(7,797)
Increase (decrease) in warranty estimates	(582)	1,678
Balance at end of the year	$ 16,724	$ 9,138
Current portion	$ 4,707	$ 4,206
Non-current portion	12,017	4,932
Total	$ 16,724	$ 9,138

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the estimated fair value of the award, and the portion that is ultimately expected to vest is recognized as compensation expense over the requisite service period on a straight-line basis. The Company estimates the fair value of stock options issued under the Company's Amended and Restated 2013 Stock Incentive Plan (2013 Plan) and the fair value of the employees' purchase rights under the Company's 2013 Employee Stock Purchase Plan (ESPP) using the Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model requires the use of assumptions about a number of variables, including stock price volatility, expected term, dividend yield and risk-free interest rate. For awards that vest based on the achievement of service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures based on historical experience.

Common Stock Warrant Liabilities

The Company accounts for certain stock warrants as a liability in the consolidated financial statements when they contain a provision within the warrant contracts that could require cash settlement in the event the Company did not have an active registration statement. The fair value of these common stock warrants is remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying statements of operations and comprehensive loss.

Advertising Costs

The Company expenses advertising costs as they are incurred. For the years ended December 31, 2019, 2018 and 2017, advertising costs were $0.9 million, $0.9 million, and $1.1 million, respectively.

Shipping and Handling Expenses

Shipping and handling expenses associated with product delivery are included within cost of sales in the Company's statements of operations. Amounts billed to a customer for shipping and handling are reported as revenues.

Comprehensive Loss

All components of comprehensive loss, including net loss, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities and foreign currency translation adjustments.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares that were outstanding for the period, without consideration for common stock equivalents. Diluted loss per share is calculated in accordance with the treasury stock method and reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted to common stock. Dilutive common share equivalents are comprised of warrants, potential awards granted pursuant to the ESPP, and stock options outstanding under the Company's equity incentive plans. For warrants that are recorded as a liability in the accompanying consolidated balance sheets, the calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of the warrants is dilutive to loss per share for the period, an adjustment is made to net loss used in the calculation to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method. For the annual periods ended December 31, 2019, 2018 and 2017, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position (see Note 11, "Selected Quarterly Financial Data (Unaudited)" for further details).

Potentially dilutive securities not included in the calculation of diluted net loss per share (because inclusion would be anti-dilutive) are as follows (in common stock equivalent shares, in thousands):

	Year Ended December 31,		
	2019	2018	2017
Warrants to purchase common stock	611	705	—
Options to purchase common stock	5,619	3,477	—
Awards granted under the ESPP	5	4	—
	6,235	4,186	—

Accounting Pronouncements Issued and Not Yet Adopted

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* which modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The new standard requires the use of forward-looking expected credit loss models based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount, which may result in earlier recognition of credit losses under the new standard. The new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income (loss) rather than reducing the carrying amount under the current, other-than-temporary-impairment model. The standard is effective for public business entities for annual periods beginning after December 15, 2019, and interim periods within those years. The Company will implement the new standard in the first quarter of 2020, and does not expect the adoption to have a material financial impact on its consolidated financial statements based on current economic conditions, its outstanding accounts receivable, and the composition and credit quality of its short-term investments.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. The updated guidance is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, with early adoption permitted. The Company will implement the updated guidance in the first quarter of 2020, which will modify certain fair value measurement disclosures primarily related to our Level 3 liabilities.

3. Financial Statement Information

Short-Term Investments

The Company invests in marketable securities, principally debt instruments of the U.S. Government, financial institutions and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at December 31, 2019 and 2018 (in thousands):

At December 31, 2019	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale securities:					
Commercial paper	Less than 1	$ 24,147	$ 10	$ —	$ 24,157
U.S. Government-sponsored enterprise	Less than 2	33,073	26	—	33,099
U.S. Treasury securities	Less than 2	17,963	17	(1)	17,979
Corporate debt securities	Less than 2	50,011	42	(5)	50,048
Total		$ 125,194	$ 95	$ (6)	$ 125,283

At December 31, 2018	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale securities:					
Commercial paper	Less than 1	$ 53,559	$ —	$ (22)	$ 53,537
U.S. Treasury securities	Less than 1	17,937	—	(2)	17,935
Corporate debt securities	Less than 1	15,718	12	(1)	15,729
Total		$ 87,214	$ 12	$ (25)	$ 87,201

The Company has classified all marketable securities, regardless of maturity, as short-term investments based upon the Company's ability and intent to use any and all of those marketable securities to satisfy the Company's current liquidity requirements.

The Company periodically reviews the portfolio of available-for-sale debt securities to determine if any investment is other-than-temporarily impaired due to changes in credit risk or other potential valuation concerns. The Company believes that the short-term investments held at December 31, 2019 were not other-than-temporarily impaired. Unrealized losses on available-for-sale debt securities at that date were not significant and were due to changes in interest rates, including credit spreads, and not due to increased credit risks associated with specific securities. The Company does not intend to sell the available-for-sale debt securities that are in an unrealized loss position, and it is not more likely than not that the Company will be required to sell these debt securities before recovery of their amortized cost bases, which may be at maturity.

Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31,	
	2019	2018
Accounts receivable	$ 49,889	$ 37,030
Less allowance for doubtful accounts	(3,304)	(1,837)
Accounts receivable, net	$ 46,585	$ 35,193

The following table provides a reconciliation of the change in estimated allowance for doubtful accounts for the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Allowance for Doubtful Accounts
Balance at December 31, 2016	$ 735
Provision for doubtful accounts	824
Write-offs and adjustments, net of recoveries	(524)
Balance at December 31, 2017	$ 1,035
Provision for doubtful accounts	1,448
Write-offs and adjustments, net of recoveries	(646)
Balance at December 31, 2018	$ 1,837
Provision for doubtful accounts	2,322
Write-offs and adjustments, net of recoveries	(855)
Balance at December 31, 2019	$ 3,304

Inventories

Inventories consisted of the following at (in thousands):

	December 31,	
	2019	2018
Raw materials	$ 20,699	$ 6,622
Work-in-process	16,532	2,710
Finished goods	11,842	10,564
Inventories, net	$ 49,073	$ 19,896

Property and Equipment

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

	December 31,	
	2019	2018
Leasehold improvements	$ 13,100	$ 11,313
Computer equipment and software	9,899	8,745
Office furniture and equipment	6,367	4,415
Manufacturing and scientific equipment	33,422	18,306
	62,788	42,779
Less accumulated depreciation and amortization	(29,865)	(25,628)
Property and equipment, net	$ 32,923	$ 17,151

Depreciation and amortization expense related to property and equipment was $5.7 million, $5.5 million, and $6.5 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Intangible Assets Subject to Amortization

Intangible assets subject to amortization consist of patents purchased or licensed that are related to the Company's commercialized products. Capitalized patents at December 31, 2019 and 2018, which are included in other long-term assets on the consolidated balance sheets, are as follows (in thousands):

	December 31,	
	2019	2018
Gross amount	$ 3,247	$ 3,247
Accumulated amortization	(2,470)	(2,117)
Patents, net	$ 777	$ 1,130
Weighted average remaining amortization period (in months)	30	42

Amortization expense related to intangible assets subject to amortization amounted to $0.3 million for each of the years ended December 31, 2019, 2018, and 2017. The amortization expense is recorded in cost of sales in the consolidated statement of operations. The estimated annual amortization is $0.3 million for annual periods 2020 and 2021, and $0.2 million in 2022.

4. Fair Value Measurements

Authoritative guidance on fair value measurements defines fair value, establishes a consistent framework for measuring fair value, and expands disclosures for each major asset and liability category measured at fair value on either a recurring or a nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly for substantially the full term of the asset or liability.

Level 3: Unobservable inputs in which there is little or no market data and that are significant to the fair value of the assets or liabilities, which require the reporting entity to develop its own valuation techniques that require input assumptions.

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2019 and 2018, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands):

		Fair Value Measurements at December 31, 2019		
	December 31, 2019	Level 1	Level 2	Level 3
Assets				
Cash equivalents [1]	$ 43,520	$ 43,520	$ —	$ —
Commercial paper	24,157	—	24,157	—
U.S. Government-sponsored enterprise	33,099	—	33,099	—
U.S. Treasury securities	17,979	17,979	—	—
Corporate debt securities	50,048	—	50,048	—
Total assets	$ 168,803	$ 61,499	$ 107,304	$ —
Liabilities				
Common stock warrants	$ 23,509	$ —	$ —	$ 23,509
Total liabilities	$ 23,509	$ —	$ —	$ 23,509

	December 31, 2018	Fair Value Measurements at December 31, 2018		
		Level 1	Level 2	Level 3
Assets				
Cash equivalents [1]	$ 37,373	$ 37,373	$ —	$ —
Commercial paper	53,537	—	53,537	—
U.S. Treasury securities	17,935	17,935	—	—
Corporate debt securities	15,729	—	15,729	—
Total assets	$ 124,574	$ 55,308	$ 69,266	$ —
Liabilities				
Common stock warrants	$ 17,926	$ —	$ —	$ 17,926
Total liabilities	$ 17,926	$ —	$ —	$ 17,926

(1) Generally, cash equivalents include money market funds and investments with a maturity of three months or less from the date of purchase.

The Company's Level 2 financial instruments are valued using market prices on less active markets with observable valuation inputs such as interest rates and yield curves. The Company obtains the fair value of Level 2 financial instruments from quoted market prices, calculated prices or quotes from third-party pricing services. The Company validates these prices through independent valuation testing and review of portfolio valuations provided by the Company's investment managers. There were no transfers between Level 1 and Level 2 securities during the years ended December 31, 2019 and 2018.

The Company's Level 3 liabilities at December 31, 2019 and 2018 included the Series A warrants issued by the Company in connection with the public offering of common stock in October 2017. The Series A warrants have a term of five years and initially provided holders the right to purchase 4,630,000 shares of the Company's common stock at an exercise price of $3.50 per share. The Series A warrants were initially valued in the aggregate amount of $5.2 million on the date of issuance utilizing a Black-Scholes pricing model.

The Company reassesses the fair value of the outstanding Series A warrants at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include estimates of stock price volatility, expected warrant life and risk-free interest rate. The Company develops its estimates based on publicly available historical data. The assumptions used to estimate the fair values of the outstanding Series A warrants at December 31, 2019 and 2018 are presented below:

	Series A Warrants	
	December 31, 2019	December 31, 2018
Risk-free interest rate	1.6%	3.0%
Expected dividend yield	0.0%	0.0%
Expected volatility	77.2%	78.3%
Expected term (in years)	2.8	3.8

The following table presents a summary of changes in fair value of the Company's total Level 3 financial assets for the years ended December 31, 2019 and 2018:

	2019	2018
Balance at beginning of year	$ 17,926	$ 5,432
Increase in fair value included in change in fair value of common stock warrants	11,075	66,494
Decrease in fair value from warrants exercised during the period	(5,492)	(54,000)
Balance at end of year	$ 23,509	$ 17,926

During the year ended December 31, 2019, the Company issued 93,470 shares of common stock upon the exercise of Series A warrants. During the year ended December 31, 2018, the Company issued 8,603,321 shares of common stock upon the exercise of certain warrants issued in October 2017, and 13,450 warrants expired unexercised. As of December 31, 2019, there were Series A warrants outstanding to purchase 417,315 shares of the Company's common stock (see Note 6, "Stockholders' Equity").

5. Leases

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard and its related amendments (collectively referred to as ASC 842) requires lessees to recognize right-of-use assets and corresponding lease liabilities for all leases with lease terms of greater than 12 months. It also changed the definition of a lease and expanded the disclosure requirements of lease arrangements. In July 2018, the FASB added a transition option for implementation of the standard that allowed companies to continue to use the legacy guidance in ASC 840, *Leases*, including its disclosure requirements, in the comparative periods presented in the year of adoption. The new standard must be adopted using the modified retrospective approach and was effective for the Company starting in the first quarter of fiscal 2019. The Company elected the transition option and certain practical expedients, resulting in the recognition of right-of-use leased assets and corresponding operating lease liabilities of $12.4 million on the consolidated balance sheet upon adoption of the standard as of January 1, 2019. The Company did not restate prior periods. Deferred rent of $1.0 million and $3.8 million as of January 1, 2019 was reclassified from other current liabilities and deferred rent long-term, respectively, to a reduction of the right-of-use leased assets in connection with the adoption of the standard.

The Company's leases consist primarily of operating leases for general office space, laboratory, manufacturing and warehouse facilities, and equipment. Leases with an initial term of 12 months or less are not recorded on the balance sheets. The Company recognizes lease expense for these leases on a straight-line basis over the lease term. Because the Company's leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of future lease payments. The Company used the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date. For lease agreements entered into or reassessed after the adoption of ASC 842, the Company combines lease and non-lease components.

Certain leases include an option to renew, with renewal terms that can extend the lease term for additional periods. The exercise of lease renewal options is at the Company's sole discretion. The depreciable life of assets and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option that is reasonably certain to be exercised.

In January 2019, the Company entered into a lease agreement for approximately 25,332 square feet of additional general administrative office space (Initial Premises) located at 10935 Vista Sorrento Parkway, San Diego, California (Vista Sorrento Parkway Lease). The lease term for the Initial Premises commenced in March 2019 and expires in September 2022. In May 2019, the Company entered into a First Amendment to the Vista Sorrento Parkway Lease (First Amendment) to expand the leased premises by adding approximately 33,681 square feet of additional general administrative office space (Expansion Space), and to extend the lease term for the Initial Premises through January 2023. The lease term for the Expansion Space commenced in May 2019 and expires in January 2023. The Company has a one-time option to extend the term of the Vista Sorrento Parkway Lease, covering both the Initial Premises and the Expansion Space, for a period of four years. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of $3.1 million on the consolidated balance sheet related to the Initial Premises, and $4.7 million related to the First Amendment to the Vista Sorrento Parkway Lease.

In March 2019, the Company entered into a lease agreement for approximately 40,490 square feet of space located at 6495 Marindustry Place, San Diego, California to house additional operations functions, including warehousing and shipping (Marindustry Place Lease). The lease term commenced in May 2019 and expires in April 2026. The Company has a one-time option to extend the term of the Marindustry Place Lease for a period of no less than three years and no more than five years. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of $3.4 million on the consolidated balance sheet related to the Marindustry Place Lease.

The Company's total lease cost recorded in the consolidated statements of operations was $5.7 million for the year ended December 31, 2019, which included $5.5 million of operating lease cost and $0.2 million of short-term lease cost. Rent expense for the years ended December 31, 2018 and 2017 was $2.6 million and $3.5 million, respectively. Cash paid for amounts included in the measurement of lease liabilities, representing operating cash flows from operating leases, was $4.3 million for the year ended December 31, 2019.

Maturities of operating lease liabilities at December 31, 2019 were as follows (in thousands):

Year Ending December 31,		
2020	$	6,320
2021		7,100
2022		5,880
2023		2,232
2024		695
Thereafter		883
Total undiscounted lease payments		23,110
Less: amount representing interest		(2,727)
Present value of operating lease liabilities		20,383
Less: current portion of operating lease liabilities		(6,320)
Operating lease liabilities - long-term	$	14,063

As of December 31, 2019, the weighted average remaining lease term for operating leases was 3.6 years and the weighted-average discount rate used to determine the operating lease liabilities was 6.6%.

In November 2019, the Company entered into a lease agreement for approximately 94,562 square feet of additional general office space located in Boise, Idaho (Shoreline Lease). Subject to limited exceptions, the initial lease term is expected to commence on the earlier of (i) the date on which the Company substantially completes certain specified work related to tenant improvements, (ii) the date on which the Company commences use of the premises, or (iii) July 1, 2020 (the Commencement Date), and will expire 84 months from the first day of the first full month following the Commencement Date. The Company has a one-time option to extend the term of the Shoreline Lease for a period of three years. The Company currently estimates that it will recognize right-of-use leased assets and corresponding operating lease liabilities of approximately $6.6 million on the consolidated balance sheet upon the lease commencement in the first quarter of 2020. Future minimum payments due under the Shoreline Lease are approximately $8.2 million.

6. Stockholders' Equity (Deficit)

Public Offerings

In the first quarter of 2017, the Company completed a registered public offering of 1,850,000 shares of common stock at a public offering price of $12.50 per share. The gross proceeds from the offering were approximately $23.1 million, before deducting underwriting discounts and commissions and other offering expenses.

From July 2017 through September 2017, the Company sold 464,108 shares of common stock under our "at-the-market" offering program at prices ranging from $5.64 to $10.54. The gross proceeds from the offering were $4.3 million, before deducting underwriting discounts and commissions and other offering expenses.

In the fourth quarter of 2017, the Company completed the October Financing, pursuant to which it sold 4,630,000 shares of common stock, Series A warrants to purchase up to 4,630,000 shares of our common stock and Series B warrants to purchase up to 4,630,000 shares of common stock at a public offering price of $3.50 per share and accompanying warrants (October Financing). The gross proceeds from the October Financing were approximately $16.2 million, before deducting underwriting discounts and commissions and other offering expenses.

In the first quarter of 2018, the Company completed a registered public offering of 34,500,000 shares of common stock at a public offering price of $2.00 per share. The gross proceeds from the offering were approximately $69.0 million, before deducting underwriting discounts and commissions and other offering expenses.

In the third quarter of 2018, the Company completed a public offering of 4,035,085 shares of common stock at a public offering price of $28.50 per share. The gross proceeds to the Company from the offering were $115.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Shares Reserved for Future Issuance

The following shares of the Company's common stock were reserved for future issuance at December 31, 2019 (in thousands):

Shares underlying outstanding warrants	710
Shares underlying outstanding stock options	7,175
Shares authorized for future equity award grants	3,143
Shares authorized for issuance pursuant to awards granted under the ESPP	1,692
	12,720

Common Stock Warrants

As of December 31, 2019, there were Series A warrants outstanding to purchase 417,315 shares of the Company's common stock at an exercise price of $3.50 per share, which were issued in connection with the October 2017 Financing, and which expire in October 2022. Also outstanding as of December 31, 2019, were warrants to purchase 193,788 shares of the Company's common stock at an exercise price of $23.50 per share, which were issued in March 2017, and which expire in March 2027 (see Note 8, "Term Loan Agreement"), and warrants to purchase 98,965 shares of the Company's common stock at an exercise price of $73.73 per share, which were issued between August 2011 and August 2012, and which expire between August 2021 and August 2022.

The Company issued 93,470 and 8,603,321 shares of its common stock upon the exercise of warrants during the years ended December 31, 2019 and 2018, respectively.

Stock Plans

In September 2006, the Company adopted the Company’s 2006 Stock Incentive Plan (2006 Plan), under which, as amended, 268,561 shares of common stock were reserved for issuance to employees, non-employee directors and consultants of the Company. The 2006 Plan was closed in 2013 with the approval of the 2013 Plan and no further options will be granted under the 2006 Plan.

In October 2013, the Company’s board of directors approved the 2013 Plan. The 2013 Plan became effective immediately prior to the completion of the Company's initial public offering. An initial 480,900 shares of common stock were reserved for issuance under the 2013 Plan. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock and restricted stock units to individuals who are then employees, officers, directors or consultants of the Company. The 2013 Plan also included an “evergreen” provision, which automatically increased the shares available for issuance January 1 of each year by 4% of common shares outstanding. Accordingly, the shares available for issuance under the 2013 Plan were increased by 404,776 shares and 124,382 shares on January 1, 2018 and 2017, respectively. In June 2018, the Company received approval from its stockholders to increase the number of shares of common stock reserved under the 2013 Plan by 5,500,000 shares, and to remove the evergreen provision. In June 2019, the Company received approval from its stockholders to increase the number of shares of its common stock reserved for issuance under the 2013 Plan by an additional 5,000,000 shares.

The Company issued 1,418,953 and 136,042 shares of its common stock, respectively, upon the exercise of stock options during the years ended December 31, 2019 and 2018.

As of December 31, 2019, there were 3,142,690 shares were available for future issuance under the 2013 Plan, and options to purchase 7,174,927 shares have been granted and are outstanding under the 2006 Plan and 2013 Plan.

Common Stock Options

The maximum term of stock options granted under the 2006 Plan and 2013 Plan is ten years. The options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years.

The following table summarizes stock option activities for the 2006 Plan and 2013 Plan:

	Total Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2017	1,331,269	$ 47.11	8.08	$ —
Granted	4,730,956	$ 20.34		
Exercised	(136,042)	$ 7.55		$ 3,953
Canceled/forfeited/expired	(162,991)	$ 45.46		$ 1,466
Outstanding at December 31, 2018	5,763,192	$ 23.61	8.94	$ 116,988
Granted	3,026,511	$ 54.62		
Exercised	(1,418,953)	$ 12.46		$ 71,808
Canceled/forfeited/expired	(195,823)	$ 42.93		$ 4,190
Outstanding at December 31, 2019	7,174,927	$ 38.40	8.45	$ 181,408
Vested and expected to vest at December 31, 2019	7,074,615	$ 38.30	8.44	$ 179,865
Exercisable at December 31, 2019	3,162,475	$ 29.58	7.75	$ 119,653

Employee Stock Purchase Plan

In October 2013, the Company adopted the ESPP, which enables eligible employees to purchase shares of the Company's common stock using their after-tax payroll deductions, subject to certain conditions. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Eligible employees may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of common stock under the ESPP. The purchase price of common stock under the ESPP is the lesser of: (a) 85% of the fair market value of a share of the Company's common stock on the first date of an offering or (b) 85% of the fair market value of a share of the Company's common stock on the date of purchase. Generally, the ESPP consists of a two-year offering period with four six-month purchase periods.

The ESPP initially authorized the issuance of 55,600 shares of common stock pursuant to purchase rights granted to employees. The number of shares of common stock reserved for issuance increased on January 1 of each calendar year, from January 1, 2014 through January 1, 2018, by the lesser of (a) one percent of the number of shares issued and outstanding on the immediately preceding December 31, or (b) such lesser number of shares as determined by the Administrator. On January 1, 2018 and 2017, the number of shares of common stock reserved for issuance under the ESPP was automatically increased by 31,096 and 101,194 shares, respectively. In June 2018, the Company received approval from its stockholders to increase the number of shares reserved for issuance under the ESPP by 2,000,000 shares and to remove the evergreen provision.

During the years ended December 31, 2019 and 2018, 329,072 shares and 80,581 shares of our common stock, respectively, were purchased under the ESPP for proceeds of $6.2 million and $1.4 million, respectively.

The ESPP was previously suspended in May 2017 due to a lack of available shares. The suspension was accounted for as a cancellation of an award with no consideration. The previously unrecognized compensation cost of $2.4 million was expensed in 2017 as of the suspension date.

Stock-Based Compensation

In June 2019, the Company granted options to purchase 1,644,715 shares of common stock under the 2013 Plan, which were originally awarded between February 2019 and June 2019, subject to and conditioned upon the approval by its stockholders of an increase in the number of shares of common stock reserved for issuance under the 2013 Plan. In total, the Company granted options to purchase 3,026,511 shares of common stock under the 2013 Plan during the year ended December 31, 2019. These options have an exercise price equal to the closing price of the Company's common stock on the applicable award date, and generally vest as to 25% of the underlying shares on the first anniversary of the award, with the balance of the options vesting monthly over the following three years.

In June 2018, the Company granted options to purchase 811,800 shares of common stock under the 2013 Plan, which were originally awarded in December 2017, subject to and conditioned upon the approval by its stockholders of an increase in the number of shares of common stock authorized under the 2013 Plan. These options have an exercise price equal to the closing price of the Company's common stock on the applicable award date, and generally vest as to 50% of the underlying shares on the first anniversary of the award, with the balance of the options vesting monthly over the following year.

The Company also granted options to purchase 3,919,956 shares of common stock under the 2013 Plan during the year ended December 31, 2018. These options have an exercise price equal to the closing price of the Company's common stock on the applicable award date, and generally vest as to 25% of the underlying shares on the first anniversary of the award, with the balance of the options vesting monthly over the following three years, except with respect to options to purchase 3,389,300 shares of common stock granted in June 2018, which vest as to 50% of the underlying shares on the first anniversary of the award, with the balance of the options vesting monthly over the following year.

The following table summarizes the allocation of stock-based compensation expense included in the consolidated statements of operations for all stock-based compensation arrangements (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Cost of sales	$ 6,415	$ 2,581	$ 1,360
Selling, general & administrative	42,857	16,824	10,020
Research and development	8,799	4,331	1,248
Total	$ 58,071	$ 23,736	$ 12,628

The total stock-based compensation capitalized as part of the cost of the Company’s inventories was $1.3 million and $0.8 million at December 31, 2019 and 2018, respectively.

At December 31, 2019, the total unamortized stock-based compensation expense of approximately $104.0 million will be recognized over the remaining weighted average vesting term of approximately three years.

The assumptions used in the Black-Scholes option-pricing model are as follows:

	Stock Options		
	Year Ended December 31,		
	2019	2018	2017
Weighted average grant date fair value (per share)	$ 39.06	$ 12.94	$ 2.65
Risk-free interest rate	2.1%	2.8%	2.1%
Expected dividend yield	0.0%	0.0%	0.0%
Expected volatility	71.8%	71.4%	60.8%
Expected term (in years)	6.0	5.7	5.8

	ESPP		
	Year Ended December 31,		
	2019	2018	2017[1]
Weighted average grant date fair value (per share)	$ 30.32	$ 13.48	N/A
Risk-free interest rate	1.9%	2.5%	N/A
Expected dividend yield	0.0%	0.0%	N/A
Expected volatility	69.9%	81.2%	N/A
Expected term (in years)	1.3	1.3	N/A

(1) There were no grants made pursuant to the ESPP during the year ended December 31, 2017.

Risk-free Interest Rate. The risk-free interest rate assumption was based on the United States Treasury’s rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

Expected Dividend Yield. The expected dividend yield is zero because the Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future.

Expected Volatility. The expected volatility is estimated based on a weighted-average volatility of the Company's actual historical volatility since its initial public offering in November 2013, and the historical stock volatilities of a peer group of similar companies whose share prices are publicly available. The Company continued to use the historical volatility of peer entities during 2019 due to the lack of sufficient historical data of its stock price. The peer group consisted of other publicly traded companies in the same industry and in a similar stage of development.

Expected Term. The Company utilized the simplified method for estimating the expected term of stock option grants. Under this approach, the weighted-average expected term is presumed to be the average of the vesting term and the contractual term of the option. The Company estimates the expected term of the ESPP using expected life for each tranche during the two-year offering period.

The Company also estimates forfeitures at the time of grant, and revises those estimates in subsequent periods if actual forfeitures differ from its estimates. Historical data was used to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

7. Income Taxes

The components of income tax expense (benefit) were as follows (in thousands):

	Year Ended December 31,		
	2019	**2018**	**2017**
Current:			
Federal	$ —	$ —	$ —
State	86	51	8
Foreign	88	—	—
Total current tax expense	174	51	8
Deferred:			
Federal	(21)	—	—
State	(4)	—	—
Foreign	—	—	—
Total deferred income tax benefit	(25)	—	—
Income tax expense	$ 149	$ 51	$ 8

The expense (benefit) for income taxes reconciles to the amount computed by applying the federal statutory rate to loss before taxes as follows (in thousands):

	Year Ended December 31,(1)		
	2019	**2018**	**2017**
Income tax benefit at federal statutory rate	$ (5,167)	$ (25,738)	$ (24,829)
State income tax, net of federal benefit	(1,174)	(1,649)	(2,034)
Warrants revaluation	2,326	13,964	(347)
Research and development credits	(2,091)	(1,425)	(480)
Section 382 limitation	25,043	—	—
Stock-based compensation	(8,974)	1,362	3,214
Officers' compensation	3,133	—	—
Tax Cuts and Jobs Act of 2017	—	—	51,577
Other	972	681	138
Change in valuation allowance	(13,919)	12,856	(27,231)
Income tax expense	$ 149	$ 51	$ 8

(1) For the years ended December 31, 2019 and 2018, as a result of the 2017 Tax Act, the federal statutory rate was 21%. For the year ended and 2017, the federal statutory rate was 34%.

Significant components of the Company's net deferred income tax assets at December 31, 2019 and 2018 are shown below (in thousands). The Company assesses all available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative book loss incurred over the three-year period ended December 31, 2019. Such objective evidence limits the ability to consider other subjective evidence, such as projections for future growth. On the basis of this analysis, a valuation allowance of $109.6 million and $123.5 million at December 31, 2019 and 2018, respectively, has been recorded to offset the net deferred tax asset as realization of such asset is uncertain. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are increased, or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as the Company's projections for future growth.

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss (NOL) carryforwards	$ 66,642	$ 85,761
Research and development tax credits carryforwards	5,931	4,942
Capitalized research and development expenses	8,745	10,759
Accrued compensation	19,794	13,816
Lease liabilities	5,733	196
Other	9,350	8,042
Total deferred tax assets	116,195	123,516
Deferred tax liabilities:		
Lease assets	(4,570)	—
Other	(2,026)	—
Total deferred tax liabilities	(6,596)	—
Less valuation allowance	(109,599)	(123,516)
Net deferred tax assets	$ —	$ —

As of December 31, 2019, the Company had accumulated federal and state NOL carryforwards of approximately $248.7 million, and $250.8 million, respectively, Of the total federal net operating loss carryforwards, approximately $40.2 million were generated after January 1, 2018, and therefore do not expire. NOL generated after January 1, 2018, is subject to 80% limitation in accordance with the Tax Cuts and Jobs Act of 2017. The remaining federal net operating loss carryforwards of $208.5 million will begin to expire in 2026, and state tax loss carryforwards begin to expire in 2020, unless previously utilized. The remaining California NOL carryforwards of $154.4 million will begin expiring in 2028. The Company has no foreign tax loss carryforwards as of December 31, 2019.

The Company also has federal and California research credit carryforwards of approximately $2.8 million and $7.9 million, respectively, as of December 31, 2019. The federal research credit carryforwards will begin expiring in 2028, unless previously utilized. The California research credit will carry forward indefinitely.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Shared-Based Payment Accounting* (ASU 2016-09), which simplified how several aspects of share-based payments are accounted for and presented in the consolidated financial statements. ASU 2016-09 was effective for public companies, and was adopted by the Company, in 2017. Upon adoption of ASU 2016-09, the balance of unrecognized excess tax benefits of approximately $1.8 million, for which a benefit could not be previously recognized, was reversed with the impact recorded to retained earnings which was fully offset by a change to the valuation allowance.

Utilization of the Company's net operating loss and research credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitations may result in the expiration of net operating loss carryforwards before utilization. The Company has completed an analysis through December 31, 2018 to determine whether its net operating losses and credits are likely to be limited by Section 382. Based on this study, the Company determined that an ownership change, as defined under Section 382, occurred in 2018 and the resulting limitation significantly reduced the Company's ability to utilize its net operating loss and credit carryovers before they expire. As a result, in 2019 the Company reduced its deferred tax assets for the net operating loss and research credit carryforwards that are projected to expire unused with a corresponding offset to the valuation allowance recorded against such assets. Additionally, future ownership changes under Section 382 may also limit the Company's ability to fully utilize any remaining tax benefits.

The evaluation of uncertainty in a tax position is a two-step process. The first step involves recognition. The Company determines whether it is more likely than not that a tax position will be sustained upon tax examination, including resolution of any related appeals or litigation, based on only the technical merits of the position. The technical merits of a tax position are derived from both statutory and judicial authority (legislation and statutes, legislative intent, regulations, rulings, and case law) and their applicability to the facts and circumstances of the tax position. If a tax position does not meet the more-likely-than-not recognition threshold, the benefit of that position is not recognized in the financial statements. The second step is measurement. A tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate resolution with a taxing authority.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits at the beginning and end of the years ended December 31, 2019, 2018 and 2017 (in thousands):

	Year Ended December 31,		
	2019	2018	2017
Gross unrecognized tax benefits at the beginning of the year	$ 8,824	$ 8,121	$ 8,167
Increases related to current year positions	1,076	644	411
Increases (decreases) related to prior year positions	(3,320)	59	(457)
Gross unrecognized tax benefits at the end of the year	$ 6,580	$ 8,824	$ 8,121

As of December 31, 2019, the Company had $5.5 million of unrecognized tax benefits that, if recognized and realized would impact the effective tax rate, subject to the valuation allowance.

The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on the Company's consolidated balance sheets and has not recognized interest and penalties in the consolidated statements of operations for the years ended December 31, 2019 and 2018. The Company does not expect any significant increases or decreases, other than the potential reduction as a result of the Section 382 limitation, to its unrecognized tax benefits within the next 12 months.

The Company is subject to taxation in the United States and various other state jurisdictions and, starting with 2018, Canada. For the years ended December 31, 2019, the domestic and foreign components of loss before income taxes were $24.9 million and income before tax of $0.3 million, respectively. Prior to 2019, the losses were all domestic. The Company's tax years from 2006 (inception) are subject to examination by the United States and state authorities due to the carry forward of unutilized NOLs and research and development credits.

In 2017, the Tax Cuts and Jobs Act (2017 Tax Act) was enacted. The 2017 Tax Act included a number of changes to existing U.S. tax laws that impacted the Company, most notably a reduction of the U.S. corporate income tax rate from 35% to 21% for tax years beginning after December 31, 2017. The 2017 Tax Act also provided for the acceleration of depreciation for certain assets placed in service after September 27, 2017 as well as prospective changes beginning in 2018, including additional limitations on executive compensation, limitations on the deductibility of interest and capitalization of research and development expenditures.

Reduction of the U.S. Corporate Income Tax Rate: The Company measures deferred tax assets and liabilities using enacted tax rates that will apply in the years in which the temporary differences are expected to be recovered or paid. Accordingly, the Company's deferred tax assets and liabilities were remeasured in 2017 upon enactment of the 2017 Tax Act to reflect the reduction in the U.S. corporate income tax rate from the highest graduated tax 35% to a 21% flat tax. As a result of the tax rate change, in 2017 we recorded a decrease to our deferred tax assets of $51.6 million and the valuation allowance was decreased by the same amount, resulting in no net tax expense.

The 2017 Tax Act no longer allows deductions for compensation in excess of $1.0 million for certain employees, even if paid as commissions or performance-based compensation. It also subjects the principal executive officer, principal financial officer and three other highest paid officers to the limitation and once the individual becomes a covered person, the individual will remain a covered person for all future years.

8. Term Loan Agreement

In August 2018, the Company fully repaid the term loan made by Capital Royalty Partners II, L.P. and its affiliated funds (CRG) pursuant to the Amended and Restated Term Loan Agreement (Term Loan Agreement). The balance of the outstanding debt during 2018 up until the time of repayment was $82.7 million, and was included in notes payable long-term in the consolidated balance sheet, offset by the debt discount associated with financing fees and certain debt issuance costs. Such discounts were amortized to interest expense over the term of the loan using the effective interest method. At the time of repayment, the remaining unamortized debt discount of $5.3 million was accelerated and recognized as a loss on extinguishment of debt in the consolidated statement of operations for the year ended December 31, 2018. The total repayment amount of $88.8 million included approximately $1.1 million in accrued interest, and approximately $5.0 million in associated financing fees that became due. As a result of the repayment, the Company did not have any borrowings outstanding under the Term Loan Agreement as of December 31, 2019 or December 31, 2018.

Under the Term Loan Agreement, interest was payable at the Company's option, (i) in cash at a rate of 11.5% per annum, or (ii) at a rate of 9.5% of the 11.5% per annum in cash and 2.0% of the 11.5% per annum (PIK Loan) to be added to the principal of the loan and subject to accruing interest.

The Company entered into a series of amendments to the Term Loan Agreement between 2016 and 2018, which included the addition of a financing fee payable at the maturity of the Company's loans, the issuance of 193,788 ten-year warrants to CRG to purchase shares of the Company's common stock at an exercise price of $23.50 per share, and certain other minimum financing covenants. The financing fee was applicable to the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued. As of December 31, 2019, the warrants to purchase 193,788 shares of the Company's common stock at an exercise price of $23.50 per share remained outstanding.

9. Employee Benefits

Employee 401(k) Plan

The Company has a defined contribution 401(k) plan for employees in the United States who are at least 18 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar month following their date of hire. Unless they affirmatively elect otherwise, employees are automatically enrolled in the plan following 30 days from date of rehire or entry date. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. The Company does not provide a matching contribution program.

10. Commitments and Contingencies

Legal and Regulatory Matters

From time to time, the Company may be subject to legal proceedings or regulatory matters arising in the ordinary course of business, including actions with respect to intellectual property, employment, regulatory, product liability and contractual matters. In connection with these proceedings or matters, the Company regularly assesses the probability and amount (or range) of possible issues based on the developments in these proceedings or matters. A liability is recorded in the consolidated financial statements if it is determined that it is probable that a loss has been incurred, and that the amount (or range) of the loss can be reasonably estimated. Because of the uncertainties related to any pending proceedings or matters, the Company is currently unable to predict their ultimate outcome and, with respect to any legal proceeding or regulatory matter where no liability has been accrued, to make a reasonable estimate of the possible loss (or range of loss) that could result from an adverse outcome. At December 31, 2019 and 2018, there were no legal proceedings, regulatory matters, or other disputes or claims for which a material loss was considered probable or for which the amount (or range) of loss was reasonably estimable. However, regardless of the outcome, legal proceedings, regulatory matters, and other disputes and claims can have an adverse impact on the Company because of legal costs, diversion of management time and resources, and other factors.

Operating Leases

The Company leases general office space, laboratory, manufacturing and warehouse facilities, and equipment under noncancelable operating leases. These noncancelable operating leases have initial lease terms from one year to seven years, and the majority of the Company's leases include an option to extend the term of the lease, generally for a period of three to five years. The Company has the right to terminate the lease on the remaining Roselle Street buildings, which expires in May 2022, effective May 31, 2021 upon (i) delivery of written notice to the landlord no later than June 1, 2020, and (ii) an early termination payment to the landlord of approximately $0.4 million.

In connection with one of the operating leases, the Company has a $0.5 million unsecured standby letter of credit arrangement with a bank under which the landlord of the building is the beneficiary. The expiration of the standby letter of credit is July 15, 2022.

Future minimum payments due under noncancelable operating leases as of December 31, 2019 were as follows (in thousands):

Year Ending December 31,		
2020	$	7,010
2021		8,201
2022		7,008
2023		3,388
2024		1,881
Thereafter		3,975
Total	$	31,463

Future minimum payments due under operating leases of $23.1 million were included in operating lease liabilities current and long-term in the consolidated balance sheet at December 31, 2019 (see Note 5, "Leases"). The additional $8.3 million included in the above table consists of $8.2 million due under the lease of additional general office space located on Shoreline Drive, Boise, Idaho, which we entered into in November of 2019, and $0.1 million related to short-term leases. Minimum annual lease payments under the Shoreline Lease will be approximately $0.5 million in 2020, $1.1 million in 2021 and 2022, $1.2 million in 2023 and 2024, and $3.1 million thereafter. The Company currently estimates that it will recognize the Shoreline Lease operating lease liabilities on the consolidated balance sheet upon the lease commencement in the first quarter of 2020.

Purchase Obligations

The Company has agreements with suppliers and other parties to purchase inventory, other goods and services and long-lived assets. Product inventory obligations primarily consist of purchase commitments for raw materials used in the production of insulin pumps and cartridges, and finished goods infusion sets. Cancellation of outstanding purchase commitments is generally allowed but requires payment of certain costs incurred through the date of cancellation. At December 31, 2019, obligations under our purchase agreements totaled $128.2 million, of which $112.2 million is due within one-year.

11. Selected Quarterly Financial Data (Unaudited)

The following financial information reflects all normal recurring adjustments that are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Quarterly financial information for fiscal 2019 and 2018 is presented in the following table, in thousands, except per share data:

	For the Quarter Ended			
	March 31	June 30	September 30	December 31
2019				
Sales	$ 65,995	$ 93,255	$ 94,657	$ 108,398
Gross profit	$ 33,353	$ 49,904	$ 50,683	$ 60,272
Operating expenses	$ 44,350	$ 51,769	$ 56,687	$ 58,128
Operating income (loss)	$ (10,997)	$ (1,865)	$ (6,004)	$ 2,144
Net income (loss)	$ (22,992)	$ (1,512)	$ (2,901)	$ 2,652
Basic net income (loss) per share [(1)(2)]	$ (0.40)	$ (0.03)	$ (0.05)	$ 0.04
Diluted net income (loss) per share [(1)(2)]	$ (0.40)	$ (0.03)	$ (0.09)	$ 0.04
2018				
Sales	$ 27,277	$ 34,126	$ 46,264	$ 76,199
Gross profit	$ 11,404	$ 15,087	$ 21,796	$ 41,535
Operating expenses	$ 26,889	$ 29,084	$ 37,505	$ 40,975
Operating income (loss)	$ (15,485)	$ (13,997)	$ (15,709)	$ 560
Net income (loss)	$ (32,693)	$ (59,359)	$ (34,245)	$ 3,686
Basic net income (loss) per share [(1)(2)]	$ (1.82)	$ (1.17)	$ (0.62)	$ 0.06
Diluted net income (loss) per share [(1)(2)]	$ (1.82)	$ (1.17)	$ (0.62)	$ 0.02

(1) Net income (loss) per share is computed independently for each quarter and the full year based upon the respective average shares outstanding in each period. Therefore, the sum of the quarterly per-share calculations may not equal the reported annual per share amounts.

(2) With the exception of the third and fourth quarter of 2019, and the fourth quarter of 2018, there is no difference in the weighted average shares used to compute basic and diluted net income (loss) per share. (see Note 2, "Summary of Significant Accounting Policies" for further details).

12. Subsequent Event

In January of 2020, the Company entered into a sub-lease agreement for approximately 30,703 square feet of general office space located on High Bluff Drive, in San Diego, California (High Bluff Lease). Subject to limited exceptions, the initial lease term is expected to commence in March 2020 and expires in March 2022. The Company currently estimates that it will recognize right-of-use leased assets and corresponding operating lease liabilities of approximately $2.4 million on the consolidated balance sheet upon the lease commencement in the first quarter of 2020. Future minimum payments due under the High Bluff Lease of approximately $2.5 million are not included in the disclosure of future minimum payments due under noncancelable operating leases as of December 31, 2019.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2019, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2019.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principle financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2019, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework, or 2013 Framework. Based on this assessment, our management concluded that, as of December 31, 2019, our internal control over financial reporting was effective based on those criteria.

Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2019 as stated in its report, which is included herein.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during our last fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitation on Effectiveness of Controls

In designing and evaluating our controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As discussed above, Mr. Sheridan, our principal executive officer, and Ms. Vosseller, our principal financial and accounting officer, are involved in a personal relationship and share a primary residence. While our board of directors is informed of the relationship and appropriate actions have been taken to ensure compliance with Company policies and procedures, the existence of this relationship may create additional risk, or the perception of additional risk, that our controls and procedures may not be effective.

Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Tandem Diabetes Care, Inc.

Opinion on Internal Control over Financial Reporting

We have audited Tandem Diabetes Care, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Tandem Diabetes Care, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2019, and the related notes and our report dated February 24, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California
February 24, 2020

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Certain information regarding our executive officers and family relationships is set forth in the section of this Annual Report entitled "Business" in Part I, Item 1.

We have adopted a code of business conduct and ethics that applies to our Chief Executive Officer and other senior financial officers (our Chief Financial Officer, Vice President of Finance, Controller and other senior financial officers performing similar functions), which we refer to as the Code of Ethics (Senior Financial Officers). Our Code of Ethics (Senior Financial Officers) is designed to meet the requirements of Section 406 of Regulation S-K and the rules promulgated thereunder. We will promptly disclose on our website (i) the nature of any amendment to this Code of Ethics (Senior Financial Officers) that applies to any covered person, and (ii) the nature of any waiver, including an implicit waiver, from a provision of this Code of Ethics (Senior Financial Officers) that is granted to one of the covered persons. We have also adopted a code of business conduct and ethics that applies to all of our directors and employees, which we refer to as the Code of Ethics (Directors and Employees). The Code of Ethics (Senior Financial Officers) and the Code of Ethics (Directors and Employees) are available on our website at www.tandemdiabetes.com under the Investor Center section of the website. However, the information contained on or accessed through our website does not constitute part of this Annual Report, and references to our website address in this Annual Report are inactive textual references only.

The information required by this item that is not referenced or set forth above, will be set forth in our definitive Proxy Statement for our 2020 Annual Meeting of Stockholders, or our Proxy Statement, or in an amendment to this Annual Report, to be filed with the SEC not later than 120 days after the end of the fiscal year ended December 31, 2019, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement, or in an amendment to this Annual Report, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in our Proxy Statement, or in an amendment to this Annual Report, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in our Proxy Statement, or in an amendment to this Annual Report, and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in our Proxy Statement, or in an amendment to this Annual Report, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report:

1. *Financial Statements.* The following documents are included in Part II, Item 8 of this Annual Report and are incorporated by reference herein:

2. *Financial Statement Schedules.* Financial statement schedules have been omitted because they are not required or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

3. *Exhibits.*

		Incorporated by Reference				
Exhibit Number	**Exhibit Description**	**Form**	**File No.**	**Date of First Filing**	**Exhibit Number**	**Provided Herewith**
3.1	Amended and Restated Certificate of Incorporation (as amended through August 17, 2018 and currently in effect)	10-Q	001-36189	1-Nov-18	3.1	
3.2	Amended and Restated Bylaws as currently in effect.	S-1/A	333-191601	1-Nov-13	3.5	
4.1	Description of Capital Stock					X
4.2	Form of Common Stock Certificate.	S-1/A	333-191601	1-Nov-13	4.1	
4.3	Third Amended and Restated Investors' Rights Agreement, dated August 30, 2012.	S-1	333-191601	7-Oct-13	4.2	
4.4	Form of Warrant to Purchase Stock.	S-1	333-216531	8-Mar-17	4.3	
4.5	Form of Preferred Stock Warrant.	S-1	333-191601	7-Oct-13	4.4	
4.6	Form of Series A Warrant to Purchase Common Stock.	8-K	001-36189	13-Oct-17	4.1	
4.7	Form of Series B Warrant to Purchase Common Stock.	8-K	001-36189	13-Oct-17	4.2	
10.1	Amended and Restated Term Loan Agreement, dated April 4, 2014, by and among Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Capital Royalty Partners II—Parallel Fund "B" (Cayman) L.P.	10-Q	001-36189	6-May-14	10.1	

10.2	Term Loan Agreement, dated April 4, 2014, by and among Tandem Diabetes Care, Inc., Capital Royalty Partners II, L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Parallel Investment Opportunities Partners II L.P. and Capital Royalty Partners II (Cayman) L.P.	10-Q	001-36189	6-May-14	10.2
10.3	Consent and Amendment Agreement, dated June 20, 2014, by and among Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P., Capital Royalty Partners II—Parallel Fund "B" (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.	10-Q	001-36189	31-Jul-14	10.3
10.4	Omnibus Amendment Agreement No. 2, dated February 23, 2015, by and among Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P., Capital Royalty Partners II—Parallel Fund "B" (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.	10-Q	001-36189	30-Apr-15	10.1
10.5	Amendment No. 3 to Term Loan Agreement, dated January 8, 2016, by and among Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P., and Capital Royalty Partners II—Parallel Fund "B" (Cayman) L.P.	10-K	001-36189	24-Feb-16	10.5
10.6	Waiver and Amendment No. 4 to Term Loan Agreement, dated March 7, 2017, by and among Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P., and Capital Royalty Partners II —Parallel Fund "B" (Cayman) L.P.	S-1	333-216531	8-Mar-17	10.6
10.7	Waiver and Amendment No. 5 to Term Loan Agreement, dated February 5, 2018, by and among Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P., and Capital Royalty Partners II—Parallel Fund "B" (Cayman) L.P.	8-K	001-36189	7-Feb-18	10.1
10.8	Tandem Diabetes Care, Inc. 2006 Stock Incentive Plan.	S-1	333-191601	7-Oct-13	10.3
10.9	Form of Stock Option Agreement under 2006 Stock Incentive Plan.	S-1	333-191601	7-Oct-13	10.4
10.10	Form of Restricted Stock Purchase Agreement under 2006 Stock Incentive Plan.	S-1	333-191601	7-Oct-13	10.5

10.11	Tandem Diabetes Care, Inc. Amended and Restated 2013 Stock Incentive Plan.	DEF 14A	001-36189	26-Apr-18	Appendix B
10.12	Form of Stock Option Agreement under 2013 Stock Incentive Plan.	S-1/A	333-191601	1-Nov-13	10.7
10.13	Form of Stock Option Agreement under 2013 Stock Incentive Plan (Non-Employee Directors).	S-1/A	333-191601	1-Nov-13	10.8
10.14	Tandem Diabetes Care, Inc. Amended and Restated 2013 Employee Stock Purchase Plan.	DEF 14A	001-36189	26-Apr-18	Appendix C
10.15	Tandem Diabetes Care, Inc. 2018 Cash Bonus Plan.	10-Q	001-36189	30-Jul-18	10.4
10.16	Employee Offer Letter, dated July 8, 2013, by and between Tandem Diabetes Care, Inc. and David B. Berger.	S-1	333-191601	7-Oct-13	10.12
10.17	Employee Offer Letter, dated February 1, 2013, by and between Tandem Diabetes Care, Inc. and John F. Sheridan.	S-1	333-191601	7-Oct-13	10.13
10.18	Employee Offer Letter, dated January 12, 2016, by and between Tandem Diabetes Care, Inc. and Brian B. Hansen.	8-K	001-36189	2-Feb-16	10.1
10.19	Employment Severance Agreement, dated February 1, 2016, by and between Tandem Diabetes Care, Inc. and Brian B. Hansen.	8-K	001-36189	2-Feb-16	10.2
10.20	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Kim D. Blickenstaff.	S-1/A	333-191601	8-Nov-13	10.14
10.21	2018 Compensation Agreement, effective as of January 5, 2018, by and between Tandem Diabetes Care, Inc. and Kim D. Blickenstaff.	10-Q	001-36189	30-Jul-18	10.3
10.22	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and John F. Sheridan.	S-1/A	333-191601	8-Nov-13	10.17
10.23	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and David B. Berger.	S-1/A	333-191601	8-Nov-13	10.18
10.24	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Susan M. Morrison.	S-1/A	333-191601	8-Nov-13	10.19
10.25	Amended and Restated Employment Severance Agreement dated August 2, 2017, by and between the Company and Leigh A. Vosseller.	S-1	333-222553	16-Jan-18	10.25
10.26	Form of Indemnification Agreement.	S-1	333-191601	7-Oct-13	10.11

10.27	Confidential Intellectual Property Agreement, dated July 10, 2012, by and between Tandem Diabetes Care, Inc. and Smiths Medical ASD, Inc.	S-1/A	333-191601	8-Nov-13	10.20	
10.28	Amended and Restated Development and Commercialization Agreement, dated January 4, 2013, by and between Tandem Diabetes Care, Inc. and DexCom, Inc.	10-Q	001-36189	29-Oct-15	10.1	
10.29	Amendment No. 1 to Amended and Restated Development and Commercialization Agreement, dated September 24, 2015, by and between Tandem Diabetes Care, Inc. and DexCom, Inc.	10-Q	001-36189	29-Oct-15	10.2	
10.30	Development Agreement, dated June 4, 2015 by and between Tandem Diabetes Care, Inc. and Dexcom, Inc.	10-Q/A	001-36189	9-Nov-18	10.5	
10.31	Lease Agreement, dated March 7, 2012, as amended through November 5, 2013, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC.	S-1/A	333-191601	8-Nov-13	10.1	
10.32	Fourth Amendment to Lease, dated December 27, 2017, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC	8-K	001-36189	3-Jan-18	10.2	
10.33	Lease Agreement, dated November 5, 2013, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC.	S-1/A	333-191601	8-Nov-13	10.21	
10.34	First Amendment to Lease, dated December 27, 2017, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC	8-K	001-36189	3-Jan-18	10.1	
10.35	Lease Agreement, dated June 30, 2016, by and between Tandem Diabetes Care, Inc. and ARE-SD REGION NO. 36, LLC.	10-Q	001-36189	28-Jul-16	10.3	
10.36	Lease Agreement, dated November 14, 2019, by and between Tandem Diabetes Care, Inc. and Ameri Shore LLC.					X
23.1	Consent of Independent Registered Public Accounting Firm.					X
24.1	Power of Attorney (included on the signature page).					X
31.1	Certification of John F. Sheridan, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X

32.1***	Certification of John F. Sheridan, Chief Executive Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
32.2***	Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X
101.INS	XBRL Instance Document.	X
101.SCH	XBRL Taxonomy Extension Schema Document.	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	X

* Indicates management contract or compensatory plan.

** Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to an application for confidential treatment sent to the Securities and Exchange Commission. Such portions are omitted from this filing and have been filed separately with the Securities and Exchange Commission.

*** This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Tandem Diabetes Care, Inc.

By: /s/ John F. Sheridan

John F. Sheridan
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: February 24, 2020

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints John F. Sheridan and Leigh A. Vosseller, and each of them individually, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ JOHN F. SHERIDAN John F. Sheridan	President, Chief Executive Officer and Director (Principal Executive Officer)	February 24, 2020
/s/ LEIGH A. VOSSELLER Leigh A. Vosseller	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 24, 2020
/s/ DICK P. ALLEN Dick P. Allen	Lead Independent Director	February 24, 2020
/s/ KIM D. BLICKENSTAFF Kim D. Blickenstaff	Executive Chairman of the Board	February 24, 2020
/s/ EDWARD L. CAHILL Edward L. Cahill	Director	February 24, 2020
/s/ HOWARD E. GREENE, JR. Howard E. Greene, Jr.	Director	February 24, 2020
/s/ REBECCA ROBERTSON Rebecca Robertson	Director	February 24, 2020
/s/ DOUGLAS A. ROEDER Douglas A. Roeder	Director	February 24, 2020
/s/ CHRISTOPHER J. TWOMEY Christopher J. Twomey	Director	February 24, 2020
/s/ RICHARD VALENCIA Richard Valencia	Director	February 24, 2020

EXECUTIVE TEAM

John Sheridan
President and Chief Executive Officer

David Berger
EVP and Chief Legal and Compliance Officer

Elizabeth Gasser
EVP, Strategy and Corporate Development

Brian Hansen
EVP and Chief Commercial Officer

Susan Morrison
EVP and Chief Administrative Officer

Leigh Vosseller
EVP and Chief Financial Officer

BOARD OF DIRECTORS

Kim Blickenstaff
Chairman

Dick Allen
Lead Independent Director

Edward Cahill

Howard (Ted) Greene, Jr.

Rebecca Robertson

Douglas Roeder

John Sheridan

Christopher Twomey

Richard Valencia

COMPANY & INVESTOR INFORMATION

Corporate Headquarters
11075 Roselle Street
San Diego, CA 92121
(858) 366-6900

Annual Meeting
The annual meeting of Tandem Diabetes Care stockholders will be held on Wednesday, May 27, 2020. We intend to hold the meeting in person at 3:00 pm Pacific Time at 10935 Vista Sorrento Parkway, San Diego, California 92130. However, we are actively monitoring the impact of the coronavirus, and if it is not advisable to hold this meeting in person, we will announce alternative arrangements as promptly as practicable, which may include switching to a virtual or hybrid meeting format, or changing its time, date or location. Any changes will be announced via press release and additional proxy materials filed with the Securities and Exchange Commission.

Common Stock Listing
Ticker symbol: TNDM
The NASDAQ Global Market

Transfer Agent
American Stock Transfer
& Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
www.astfinancial.com

Independent Registered Public Accounting Firm
Ernst & Young LLP
4370 La Jolla Village Drive, Suite 500
San Diego, CA 92122

Stockholder Inquiries
Stockholders may obtain copies of our news releases, Securities and Exchange Commission filings, including Forms 10-K, 10-Q, and 8-K, and other Company information by accessing our website at www.tandemdiabetes.com or by contacting Investor Relations at (858) 366-6900 x7005.

Forward-looking Statements
This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements included or incorporated by reference in this Annual Report other than statements of historical fact, are forward-looking statements. You can identify these and other forward-looking statements by the use of words such as “may,” “will,” “could,” “anticipate,” “expect,” “intend,” “believe,” “continue” or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements.

Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made except as required by law.

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DIABETES CARE

11075 Roselle Street
San Diego, CA 92121

tandemdiabetes.com