TANDEM DIABETES CARE INC
Form 10-K
February 26, 2019

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, 2018

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	
San Diego, California	92121
(Address of principal executive offices)	(Zip Code)

(858) 366-6900

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	The NASDAQ Stock Market LLC

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 29, 2018, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $1.1 billion based on the closing price for the common stock of $22.02 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 15, 2019, there were 57,717,618 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2019 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, 2018, 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," "belie "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. We believe our competitive advantage is rooted in our unique consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing, sales and support activities exclusively focus on our flagship pump platform, the t:slim X2 Insulin Delivery System, or 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. By delivering innovative hardware and software solutions, as well as best-in-class customer support, we aim to improve and simplify the lives of people with diabetes and their healthcare providers.

We have commercially launched six insulin pumps in the United States since inception, all of which have been developed using our proprietary technology platform. Three of these pumps have featured continuous glucose monitoring technology, or CGM. In the past four years, we have shipped approximately 84,000 pumps, over 4,000 of which were in international markets, which is representative of our estimated global installed customer base on the typical four-year reimbursement cycle.

Domestically, we began commercial sales of our first insulin pump product, t:slim, in August 2012 and subsequently commercialized t:flex in May 2015, t:slim G4 in September 2015, t:slim X2 in October 2016, t:slim X2 with Dexcom G5 Mobile CGM integration, or t:slim X2 with G5, in September of 2017 and t:slim X2 with Basal-IQ technology in August 2018. The Basal-IQ technology is our first-generation Automated Insulin Delivery, or AID, algorithm. This system uses Dexcom's G6 CGM sensor values to temporarily suspend insulin delivery to help minimize the frequency and/or duration of hypoglycemic events. In the second quarter of 2018, the United States Food and Drug Administration, or the FDA, also created a new interoperability designation for integrated continuous glucose monitoring, or iCGM, devices. The t:slim X2 with Basal-IQ technology was the first insulin pump to receive approval for iCGM compatibility, which we expect will streamline the regulatory pathway for integration with future iCGM products as they are approved by the FDA. More recently, in early 2019 the FDA classified our t:slim X2 as the first insulin pump in a new device category referred to as Alternative Controller Enabled infusion pumps, or ACE pumps. We expect this new classification of the t:slim X2 will provide us with more flexibility as we make improvements to current products, create new products and collaborate with third-parties in the development of future AID systems. Interoperability with iCGM and other compatible devices will still require development effort and business agreements. However, the regulatory process can be lengthy and unpredictable, so we believe the FDA's designation of iCGM products and ACE pumps will, collectively, reduce the overall timeline to commercialize interoperable devices. In the second half of 2018, we began selling the t:slim X2 with G5, in select geographies outside the United States, including Canada. We have discontinued sales of our original t:slim, t:flex and t:slim G4 pumps, and our t:slim X2 hardware platform now represents 100% of new pump shipments. However, we continue to provide ongoing service and support for our earlier products.

All people with type 1 diabetes require daily rapid-acting insulin, but only a subset of people with type 2 diabetes require daily rapid-acting insulin, as a large majority manage their therapy through improvements in diet and exercise, oral medications, or injectable therapies such as long acting insulin. According to the Centers for Disease Control and Prevention, or the CDC, 2017 National Diabetes Statistics Report, approximately 23 million people in the United States had diagnosed diabetes, of which type 1 diabetes accounts for approximately 5% to 10%, or approximately 1.2 to 2.3 million people. Of people with type 2 diabetes in the United States, the CDC reports that approximately 14%, or 3.2 million people, manage their diabetes with insulin only. The International Diabetes Federation, or the IDF, estimates that in 2017 approximately 425 million people had diabetes worldwide, of which approximately 10%, or 42.5 million, had type 1. Our target market consists of people in the United States and select geographies worldwide, who require daily rapid-acting insulin.

Our insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to selling insulin pumps, we sell disposable products that are used together with our pumps and 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 United States, 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. The Tandem Device Updater provides our in-warranty domestic customers potential access to new and enhanced features and functionality faster than the industry has been able to in the past. The first use of our Tandem Device Updater was for our deployment of the latest t:slim software to in-warranty t:slim pumps purchased before April 2015. Since that time, we set a new standard of care in our industry by offering all existing in-warranty t:slim X2 customers in the United States two significant software updates: (i) integration with the Dexcom G5 Mobile CGM system in September 2017; and (ii) an upgrade to our new Basal-IQ technology and integration with Dexcom's G6 CGM in August 2018. Our Tandem Device Updater positions us to bring future innovations and AID algorithms to t:slim X2 customers, independent of the typical four-year insurance pump reimbursement cycle. Though we have not utilized our Tandem Device Updater to perform software updates for devices outside the United States, we are currently developing that capability, and intend to do so in the future.

Our innovative approach to product design and development is consumer-focused and based on our extensive study of behavioral sciences, as we believe the user is the primary decision maker when purchasing an insulin pump, and the healthcare provider is a key influencer. Our behavioral science research consists of interviews, focus groups and online surveys to understand what people with diabetes, their caregivers and healthcare providers are seeking in order to improve diabetes therapy management. We also apply the science of human factors to our design and development process, which seeks to optimize our devices, so that users can successfully operate them in their intended environment.

We developed our products to provide the specific features that people with insulin-dependent diabetes seek in a next-generation insulin pump. Our proprietary technology platform allows us to design the slimmest and smallest durable insulin pumps on the market, without sacrificing insulin capacity. Our t:slim X2 platform features our patented Micro-Delivery technology, a miniaturized pumping mechanism that draws insulin from a flexible bag within the pump's cartridge, rather than relying on a syringe and plunger mechanism. It also features an easy-to-navigate software architecture and a vivid color touchscreen. In addition, it features an advanced Bluetooth radio capable of communicating with multiple compatible devices, such as a CGM sensor, and possibly a blood glucose meter or mobile device application. Our platform has a micro-USB connection that supports a rechargeable battery and, in the United States, software updates through the Tandem Device Updater. In addition, this connectivity allows for uploads to our t:connect Diabetes Management Application, or t:connect, in the United States, and other compatible diabetes management applications. t:connect is our custom cloud-based data management application that provides customers and healthcare providers a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters. In April 2017, we launched the t:connect HCP Portal, which is designed to streamline healthcare providers' use of the original t:connect application and improve office efficiency.

Based on customer surveys, approximately half of our domestic customers are new to insulin pump therapy, and the average age of our existing domestic customers is 32 years old, with relatively equal distribution between men and women. Of our customers who converted from another manufacturers' pump, the greatest percentage converted from Medtronic plc, or Medtronic, followed by Animas Corporation, or Animas. In the fourth quarter of 2017, and throughout 2018, we saw a meaningful increase in our sales to former Animas pump users.

For the years ended December 31, 2018, 2017 and 2016, our consolidated sales were $183.9 million, $107.6 million, and $84.2 million, respectively. For the years ended December 31, 2018, 2017 and 2016, our net loss was $122.6 million, $73.0 million, and $83.4 million, respectively. Worldwide pump sales accounted for 67%, 66%, and 74% of our total sales, respectively, for the years ended December 31, 2018, 2017 and 2016, while pump-related supplies and accessories accounted for the remainder in each year. Our accumulated deficit as of December 31, 2018 and December 31, 2017 was $600.1 million and $477.6 million, respectively. This included $147.4 million and $56.9 million of non-cash stock-based compensation charges and non-cash changes in the fair value of common stock warrants as of December 31, 2018 and 2017, respectively.

In the United States, we have rapidly increased sales since our commercial launch 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. More recently, our sales have also rapidly increased following the scaled launch of t:slim X2 in geographies outside 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 both domestically and outside of the United States. We also believe we are well positioned 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 FDA, and as we develop the capability to offer the Tandem Device Updater outside the United States. At the same time, by rapidly innovating and offering new product features and benefits through the 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 customer support infrastructure, both of which benefit 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.

Our headquarters and our manufacturing facility are located in San Diego, California and we employed 653 full-time employees as of December 31, 2018.

The 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. Insulin is a life-sustaining hormone that allows cells in the body to absorb glucose from blood and convert it to energy. As a result, a person with diabetes cannot utilize the glucose properly and it continues to accumulate in the blood. 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.

The IDF estimates that in 2017, approximately 425 million people had diabetes worldwide and that by 2045, this number will increase to 629 million people worldwide. According to the CDC, approximately 23 million people in the United States have diagnosed diabetes.

There are two primary types of diabetes:

- The IDF estimates that people with type 1 diabetes represent approximately 10% of the diabetes population worldwide, or approximately 42.5 million people. Similarly, the CDC estimates that people with type 1 diabetes represent approximately 5% to 10% of individuals with diagnosed diabetes in the United States, or approximately 1.2 to 2.3 million people.
- The IDF estimates that people with type 2 diabetes represent approximately 90% of the diabetes population worldwide, or approximately 382.5 million people. Similarly, the CDC estimates that people with type 2 diabetes represent approximately 90% to 95% of individuals with diagnosed diabetes in the United States, or approximately 20.7 to 21.8 million people. 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. Approximately 14% of people with type 2 diabetes in the United States, or 3.2 million people, manage their diabetes with insulin only.

Throughout this Annual Report, we refer to people with type 1 diabetes and people with type 2 diabetes who require daily rapid acting insulin as people with insulin-dependent diabetes.

People with insulin-dependent diabetes require intensive insulin therapy to manage their blood glucose levels within a healthy range, which is typically between 70-120 milligrams per deciliter, or mg/dL. Blood glucose levels can be

affected by many factors, such as type or quantity of food eaten, illness, stress and exercise. 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. It can also cause the emergency condition ketoacidosis, which can result in vomiting, shortness of breath, coma or death. According to the CDC, in 2014 there were approximately 245,000 emergency department visits for adults with hypoglycemia, and approximately 207,000 visits for hyperglycemic crisis in the United States.

There are two primary therapies used by people with insulin-dependent diabetes, insulin injections and insulin pumps, each of which is designed to supplement or replace the insulin-producing function of the pancreas.

MDI Therapy: The use of insulin injections is often referred to as Multiple Daily Injection, or MDI, therapy. MDI therapy involves the administration of a rapid-acting insulin before meals, or bolus insulin, to bring blood glucose levels down into the healthy range. MDI therapy may also require a separate injection of a long-acting insulin, or basal insulin, to control glucose levels between meals; this type of insulin is typically taken once or twice per day.

MDI can be administered using a traditional needle and syringe with a vial of insulin, or with an insulin pen. When using a traditional needle and syringe, insulin is drawn from a vial to fill the syringe. It is then injected into the person’s body by manually depressing the syringe’s plunger which pushes against the volume of insulin and dispenses it through the needle and into the person’s subcutaneous tissue.

By comparison, to inject insulin using an insulin pen, the person selects a requested amount of insulin using a dial. Next, the person depresses a button, rather than pushing against a plunger, to inject the insulin. Some insulin pens come prefilled with insulin and are disposable. However, others are reusable for extended periods and insulin is inserted into the pen in the form of a prefilled vial that is then dispensed using the pen. Also, more recently, people have begun using insulin pens with additional features, which are

referred to as smart pens. These devices may feature connectivity with mobile apps, and may automatically import glucose readings, calculate recommended dosages, and keep track of insulin dose history.

Insulin Pump Therapy: Insulin pumps are used to perform what is often referred to as continuous subcutaneous insulin infusion, or insulin pump therapy. Generally, durable insulin pumps use a programmable device and an infusion set to administer insulin into the person's body, while patch insulin pumps are disposable and adhere to the body without an infusion set.

Insulin pump therapy uses only rapid-acting insulin to fulfill both mealtime (bolus) and background (basal) requirements. Insulin pump therapy allows a person to customize their bolus and basal insulin doses to meet their insulin needs throughout the day and is intended to more closely resemble the physiologic function of a healthy pancreas.

Insulin pump therapy can provide a person with insulin-dependent diabetes with benefits when used independently or in conjunction with CGM. A pump featuring CGM is known as a sensor augmented pump, or SAP, which allows the pump to receive CGM data directly from a wearable sensor. In addition, SAPs may feature an AID algorithm that is designed to automatically adjust a person's insulin delivery based on their CGM trends 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, 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.

Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. The following chart illustrates some of the key advantages and disadvantages of using MDI therapy versus insulin pump therapy:

Comparison of MDI Therapy vs. Insulin Pump Therapy

Therapy	Advantages	Disadvantages
MDI	Less training and shorter time to educate	Requires injections up to seven times per day
	Less cost (however, insulin pens and smart pens are more expensive than a traditional needle and syringe)	Delivers insulin less accurately than insulin pumps
	Lower risk of technological malfunction	Results in greater variability in blood glucose levels or less accurate glycemic control
		Requires more planning around and restrictions regarding meals and exercise
Insulin Pump	Eliminates individual insulin injections	Requires intensive education on insulin pump therapy and management
	Delivers insulin more accurately and precisely than injections	Wearing a pump can be bothersome
	Often improves HbA1c, a common measure of blood glucose levels over time	More costly
	Fewer large swings in blood glucose levels	Risk of diabetic ketoacidosis if the catheter comes out and insulin infusion is interrupted
	Provides greater flexibility with meals, exercise and daily schedules	
	Can improve quality of life	

Reduces severe low blood glucose episodes

Eliminates unpredictable effects of intermediate or long-acting insulin

Allows exercise without having to eat large amounts of carbohydrates, as insulin delivery can be adjusted

Provides access to AID features

According to the American Diabetes Association, it is estimated that in 2015, between 750,000 and 1 million people worldwide used an insulin pump. Domestically, we estimate that 550,000 people in the United States use an insulin pump, of which approximately 80% have type 1 diabetes. 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 also believe that the adoption of insulin pump therapy would have been even greater if not for the significant and fundamental perceived shortcomings of durable syringe-and-plunger insulin pumps currently available, which we refer to as traditional pumps. 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.

The Opportunity

The foundation of our consumer-focused approach is behavioral sciences, through which we seek to better understand the opportunity within the insulin-dependent diabetes market through research. This opportunity includes both the introduction of the benefits of pump therapy to people using MDI and the introduction of the features and benefits of our pumps to people who use traditional pumps. We have conducted extensive research obtained from interviews, focus groups and online surveys to understand what people with diabetes, their caregivers and healthcare providers are seeking to improve in diabetes therapy management. Based on our research, we believe that the limited adoption of insulin pump therapy by people with insulin-dependent diabetes has been largely due to the shortcomings of traditional pumps currently available. These shortcomings include:

Antiquated style. While consumer electronic devices have rapidly evolved in form and function over the past decade, traditional pumps have not achieved similar advances. Our market research has shown that consumers believe traditional pumps resemble dated consumer technology, as they generally still feature small display screens, push-button interfaces, plastic cases and disposable batteries. Because an insulin pump must be used multiple times throughout the day, often in social settings, its style and appearance are important to users. Our market research has shown that traditional insulin pump users frequently report being embarrassed by the style of their traditional pump. For current MDI users, the style of traditional pumps is often cited as a reason for not adopting pump therapy.

Not adaptable. Traditional pumps are typically sold as a single-product offering that are then iterated to add features, rather than being designed as a technology platform that is easily updatable to support new features and functionality as they are developed and approved by the FDA. We believe this is due to hardware and user interface limitations that prevent traditional pumps from being easily updatable to provide new feature offerings. As a result, consumers have had limited product choices from pump manufacturers, and healthcare providers are required to learn a greater number of user interfaces. We believe the lack of adaptability of traditional pump platforms has been a restricting factor in offering people with diabetes differentiated product features to best meet their therapy needs.

Bulky size. Our market research has shown that consumers view traditional pumps as large, bulky and inconvenient to carry or wear, especially when compared to modern consumer electronic devices, such as smartphones. The size of the pump further contributes to users being embarrassed by the pump. This complaint, along with concerns relating to how and where the pump can be utilized due to its size and shape, is frequently cited among users of traditional pumps. For current MDI users, the size of traditional pumps is often communicated as a reason for not adopting pump therapy.

Difficult to learn and teach. Traditional pumps often rely on complicated and outdated technology and are not intuitive to operate. Our research has shown that it can take several days to competently learn how to use traditional pumps, and when an AID feature is offered, the training time may take even longer. This may lead to frustration, frequent mistakes and additional training, each of which may discourage adoption. We believe difficult-to-use traditional pumps result in a higher frequency of calls by the user to the pump manufacturer or their healthcare provider for support, adding both frustration and cost to the learning process. We also believe that the complicated functionality of traditional pumps significantly limits the willingness of healthcare providers to recommend insulin pump therapy to

many patients and limits the number of patients they consider as candidates for insulin pump therapy.

Complicated to use. Traditional pumps are designed with linear software menus, which require the user to follow display screens sequentially, limiting their ability to access information within workflows or easily return to the starting point. Most traditional pumps require users to scroll through numerous menus and input multiple commands to make selections. This process, which must be performed multiple times per day, can be frustrating and time-consuming. It may also lead to added complexity when a user is programming and operating an AID feature. Our research has shown that the complicated nature of the process can lead to confusion, frustration and fear of making mistakes with the pump, which in turn can limit the user's willingness to take advantage of a pump's features, or even discourage use entirely.

Pump mechanism limitations. Traditional pumps utilize a mechanism in which a lead screw drives a plunger to deliver insulin. This design limits the ability to reduce the size of the pump due to the length and diameter of the syringe and lead screw.

Traditional Pump Mechanism

We believe that these shortcomings of traditional pumps have limited the adoption of pump therapy. By addressing these issues, there is a meaningful opportunity to not only motivate MDI users to adopt pump therapy, but also to respond to the concerns and unmet needs of traditional insulin pump users thereby encouraging increased demand for our pumps.

Our Solution

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. Our development process then applies the science of human factors, which optimizes a device or system to the intended user through iterative usability and design refinement. 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. All of our insulin pump products were developed using this customer-focused approach, as were our related product offerings, including the Tandem Device Updater, t:connect and our customized t:lock connector, which is used to connect our pump cartridge to our infusion set offerings. We expect to continue to utilize this approach as we develop new product offerings and innovations.

Our flagship pump platform, t:slim X2, which we believe addresses the shortcomings of currently available traditional pumps, features:

Contemporary style. t:slim X2, as well as our products under development, has the look and feel of a modern consumer electronic device, such as a smartphone. Relying on extensive consumer input and feedback received during the development process, we believe the modern and innovative design of our products addresses the embarrassing appearance-related concerns of insulin pump users. Key product features such as a high-resolution, color touchscreen with shatter-resistant glass, aluminum casing and rechargeable battery, make t:slim X2 unique in the insulin pump market.

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

Adaptable platform. Our t:slim X2 platform is highly adaptable as a result of a number of features that are inherent within our proprietary technology, including our easy-to-navigate software architecture and touchscreen user interface. Our t:slim X2 is also compatible with the Tandem Device Updater, which is a tool currently available in the United States that allows pump users to update their pumps' software quickly and easily from a personal computer. This tool uniquely allowed us to bring new features and benefits, such as CGM integration and our Basal-IQ technology to customers within their typical four-year insurance pump replacement cycle. It also positions us to bring future innovations and AID algorithms to t:slim X2 customers both domestically and outside of the United States. Our touchscreen also allows us to efficiently implement new language functionality; t:slim X2 is currently available in seven different languages. We believe the adaptability of our pump platform uniquely positions us to address the needs and preferences of people with insulin-dependent diabetes, and to do so quickly as those needs and preferences change and the functionality of our products evolves.

Compact size. With a narrow profile, similar to many smartphones, our t:slim X2 can easily and discreetly fit into a pocket. t:slim X2 is the slimmest and smallest durable insulin pump on the market, while still offering a cartridge with 300 units of insulin. More specifically, our t:slim X2 is 38% smaller than the newest insulin pump form factor offered by our leading competitor. The size and shape of our t:slim X2 was designed to provide increased flexibility with respect to how and where a pump can be worn. Based on extensive consumer input during development, we believe our products address both the embarrassment and functionality concerns related to the size and inconvenience of carrying a traditional pump.

t:slim X2 Profile (Actual Size)

Easy to learn and teach. Our technology platform allows for the use of a color touchscreen and easy-to-navigate software architecture, providing users intuitive access to the key functions of their pumps directly from the home screen. Insulin pump users can quickly learn how to efficiently navigate their pumps' software, thereby enabling healthcare providers to spend less time teaching a person how to use the pump and more time improving management of their diabetes. We believe these features also allow healthcare providers to more efficiently train people to use our pump and have a higher degree of confidence that users can successfully operate our pump, including its more advanced features, such as our Basal-IQ technology. Our touchscreen technology also allows us to offer our t:simulator App, which permits anyone to experience our easy-to-navigate software for any of our pumps free of charge on a mobile device. We believe the ease with which our pump can be learned and taught, and the accessibility of our t:simulator App that broadly demonstrates our software technology, will help attract consumers who may have been frustrated or intimidated by traditional pumps.

t:simulator App Accessible Through Mobile Device

Intuitive to use. Similar to what is found in modern consumer electronic devices, the embedded software displayed on our color touchscreen features intuitive and commonly interpreted colors, language, icons and feedback. Our software also features numerous shortcuts, including a simple way to return to the home screen and view critical information for therapy management. These features were designed to enable users to operate their pump more efficiently and with greater confidence, and to expand the set of therapy features they regularly utilize. Users can also execute most tasks in fewer steps than traditional pumps, which we believe further encourages people to use more advanced pump features. For example, our Basal-IQ technology feature, adds only one new screen. We believe the intuitive features of our pump also allow users to more efficiently manage their diabetes without fear or frustration.

Easy-to-Navigate Pump Software Architecture

Innovative technology. Our Micro-Delivery technology is unique compared to traditional pumps. Its miniaturized pumping mechanism draws insulin from a flexible bag within the pump’s cartridge rather than relying on a mechanical syringe and lead screw mechanism. Our technology was tested under both typical and extreme operating conditions and is designed to last for at least the anticipated four-year warranty of the pump. Our technology allows us to reduce the size of the device as compared to traditional pumps, making t:slim X2 the slimmest and smallest durable insulin pump on the market. In addition, our technology is capable of delivering the smallest increment of insulin compared to any pump currently available, which allows insulin therapy to be individualized for each user.

Quick Access to Pump History

Our Insulin Pump Mechanism

The t:slim X2 features a micro-USB connection that supports a rapid rechargeable battery and uploads to t:connect, both of which can be performed without disconnecting or interrupting insulin delivery. This connection also supports software updates through the Tandem Device Updater.

We believe the t:slim X2 platform will allow us to further penetrate and expand the insulin pump therapy market by addressing the specific product and technology limitations associated with traditional pumps that have been raised by people with diabetes, their caregivers and healthcare providers. We also believe our technology under development provides us with the opportunity to address unmet needs in the insulin-dependent diabetes market, including further advancements in AID and device miniaturization.

Our Strategy

Our goal is to significantly expand and further penetrate the insulin-dependent diabetes market and become the leading provider of insulin pump therapy by focusing on both consumer and clinical needs. We believe we are uniquely positioned to address differentiated segments of the insulin-dependent diabetes market by continually using behavioral sciences to determine what people with insulin-dependent diabetes and healthcare providers desire from insulin therapy, and by offering an adaptable insulin pump that can provide features and functionality to respond to evolving needs and preferences. At the same time, by rapidly innovating and offering new product features and benefits through the t:slim X2 platform, we are also able to leverage a shared global manufacturing and supply chain infrastructure. In Canada, we have a separate sales organization and customer support infrastructure, both of which benefit from close collaboration with our United States organization. In other international geographies, we contract with experienced distribution partners to commercialize and support our t:slim X2 platform.

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

Drive domestic adoption of our products through our sales, marketing and clinical infrastructure. We have achieved commercial success by investing in the development of our domestic sales, marketing and clinical infrastructure. With this base infrastructure, we believe we are well-positioned to introduce our products to more people with insulin-dependent diabetes, their caregivers and healthcare providers, while continuing to provide the highest level of customer service. For example, we are leveraging our infrastructure by marketing our new products, including t:slim X2 with Basal-IQ, to primarily the same healthcare providers as our previous pump products, thereby increasing our efficiency. We believe our continued investments in this infrastructure, when combined with the launch and marketing of new products, will drive continued adoption of our products, while efficiently increasing our revenues over the long-term.

Drive adoption of our products outside of the United States through our Canadian sales and customer support infrastructure, and through our distribution arrangements. We have invested in a small direct sales and customer support infrastructure for our new commercialization efforts in Canada. In other select international geographies, we have contracted with experienced insulin pump distribution partners who are responsible for sales and customer support services in specific geographies. This strategy allowed us to quickly establish access to international markets and support the needs of more people with diabetes outside the United States without the upfront investment and complexities of creating a local infrastructure in each location. We intend to continue to evaluate opportunities to expand into additional international geographies, either directly or through independent distributors.

Promote awareness of our products to consumers, their caregivers and healthcare providers. Our products were specifically designed to address the shortcomings of currently available technologies that we believe have limited the adoption of insulin pump therapy. We intend to continue our direct-to-consumer marketing to promote the insulin therapy features and functionalities offered by our products through our website, the use of social media and online advertising tools, our t:simulator App and motivational spokespeople at industry forums and events. We also expect to leverage our domestic and Canadian sales and clinical forces, together with our marketing specialists, to cultivate relationships with diabetes clinics, insulin-prescribing healthcare professionals and other key opinion leaders. By promoting awareness of our products, we believe we will be able to attract users of our competitors' insulin pump products, as well other pump therapies and MDI, to our products.

Advance our clinical activities to further demonstrate that use of our pump products may contribute to improved clinical outcomes. Data published in the Diabetes Care medical journal from a pivotal study of our t:slim X2 with Basal-IQ technology demonstrated a significant reduction in hypoglycemia without rebound hyperglycemia, compared to time on a t:slim X2 Pump with integrated CGM and no automated insulin suspension. In addition, data analyzed from t:connect suggests that use of our pump products may provide users with improved clinical outcomes. For example, we published retrospective user data comparing our t:slim G4 SAP and a leading competitor's SAP. Our SAP demonstrated statistically significant clinical advantages, including reduced hypoglycemia, increased time in range, and improved overall glycemic control, despite approximately half of our competitors' SAP users actively using a feature that suspends insulin delivery if blood glucose levels fall below a preset threshold. This study suggests that our simple-to-use touchscreen interface may translate to improved clinical outcomes for people with insulin-dependent diabetes. We also continue to be actively involved in multiple clinical trials supporting the use of our AID products in development, which are designed to demonstrate the clinical benefits associated with these products. We plan to continue to invest in clinical activities intended to demonstrate that the use of our products contributes to improved clinical outcomes.

Continue to innovate to provide products that address the unmet needs of people in the insulin-dependent diabetes market. We believe the t:slim X2 platform allows us to provide the most sophisticated and intuitive insulin pump therapy on the market. In addition, our Tandem Device Updater, which is currently available in the United States, is designed to allow pump users to quickly and easily update their pump's software from a personal computer. We successfully demonstrated the utility of this tool in the third quarter of 2017 when, following FDA approval, we simultaneously offered Dexcom G5 Mobile CGM integration to both existing and new t:slim X2 users. Following FDA approval of our Basal-IQ technology, we were able to leverage the t:slim X2 platform to allow in-warranty customers to update their pumps' software to include our first AID algorithm. This eliminated the need for disruptive and costly trade-in programs to upgrade hardware to newer platforms. Historically, software updates offered through the Tandem Device Updater have been at no cost, however in the future we may opt to apply charges for updates in certain circumstances. We also intend to offer use of the Tandem Device Updater to customers outside the United States, subject to any required regulatory approvals and our compliance with applicable privacy regulations in specific international geographies. In addition, we plan to leverage the t:slim X2 platform to continue to pursue advances in AID, including through strategic agreements and commercial product development efforts. As examples of these efforts, we have entered into development agreements with Dexcom, Inc., or Dexcom, to allow the integration of our insulin pumps with Dexcom's currently-available CGM systems. We also entered into a license agreement with TypeZero Technologies, LLC, or TypeZero, which was acquired by Dexcom in August 2018, to allow the integration of TypeZero's AID algorithms. In addition, we intend to continue to explore additional features, functionality and mobile applications for the t:slim X2 platform, as well as a next-generation pump platform, in order to address differentiated segments of the insulin-dependent diabetes market.

Invest in our consumer-focused approach. We believe our consumer-focused approach to product design, marketing and customer care is a key differentiator. Our extensive behavioral science research involving people with diabetes, their caregivers and healthcare providers has driven the design and development of our products and customer care model. This approach allows us to add the product features most requested by people with insulin-dependent diabetes, thereby affording the consumer the opportunity to more efficiently manage their diabetes. We will continue to apply the study of behavioral sciences throughout the design, development and continuous improvement of our products, as well as in the identification of work flow and process improvements and to aid in our customer retention efforts. We will continue to invest in our consumer-focused approach throughout our business.

Broaden direct access to third-party payor reimbursement for our products in the United States. We believe third-party reimbursement is an important determinant in driving consumer adoption of insulin pump therapy. We also believe customer and healthcare provider interest in our products is an important factor that enhances our prospect of contracting with third-party payors. We intend to intensify our efforts to encourage third-party payors to establish direct reimbursement for our products as we expand our market presence and product offerings. We may also pursue additional reimbursement for product features currently in development, such as advanced AID algorithms. In addition, we also plan to participate in clinical studies to demonstrate the benefits of our products relative to other pump products and therapies as a way to gain support from third-party payors.

Leverage our manufacturing operations to achieve cost and production efficiencies. We manufacture our products at our facilities located in San Diego, California. We utilize a semi-automated manufacturing process for our pump products and disposable cartridges. We have significantly increased our manufacturing output since we began commercialization of our products. During 2017, we relocated our manufacturing operations to our new, 50,000 square foot Barnes Canyon facility, which became fully operational at the beginning of 2018. This facility doubled our previous manufacturing capacity for both insulin pumps and cartridges and expanded warehousing for infusion set supplies. The facility is designed to maximize efficiencies in our manufacturing processes and workflows and allow us to further expand our production capacity by replicating our production lines within the same facility. Continued growth in the demand for our products will likely require that we expand our manufacturing, warehouse and logistics facilities in the future. As demand for our products increases, we intend to drive operational efficiencies by leveraging our manufacturing infrastructure, which we expect will result in improvements in gross margin over the long-term. In addition, because the t:slim X2 platform is highly adaptable and can provide new features and functionality through remote software updates, our current systems will not need to change significantly to support new features as they are approved by the FDA, which we expect will create additional manufacturing efficiencies for our current platform.

Our Technology Platform

We have developed an innovative technology platform that we believe is fundamental to the ease-of-use and functionality of t:slim X2 and will provide the foundation for the development of our future products. The key elements of our current technology platform are:

Advanced core technology. Our patented Micro-Delivery technology is our miniaturized pumping mechanism, which is unique compared to traditional pumps. It allows us to reduce the size of the pump as compared to traditional pumps. It was also designed to provide precise dosing as frequently as every five minutes and in increments as small as 0.001 u/hr, or units per hour, as compared to the smallest increment available in traditional pumps, which is 0.025 u/hr. This technology also helps prevent unintentional insulin delivery by limiting the volume of insulin that can be delivered to a person at any one time.

Easy-to-navigate embedded software architecture. Our technology platform was developed using an iterative human factors design process that results in the intuitive software architecture which features commonly interpreted colors, language, icons and feedback. This allows the user to easily navigate the system and perform necessary functions in fewer steps than traditional pumps, including a one-touch method to return to the home screen. Our intuitive software architecture is designed to facilitate ease of learning, teaching and use for traditional pump functionality as well as more advanced features such as AID. The flexible software architecture also facilitates updates to the software through the Tandem Device Updater, which is currently available in the United States, without requiring any hardware changes.

Vivid color touchscreen. Our full color touchscreen allows users to access a streamlined, easy-to-use interface that promotes user confidence. The high-grade, shatter-resistant glass touchscreen provides the user the ability to enter numbers and access features directly, rather than scrolling through numerous screens and options. The touchscreen facilitates safety features that were designed to prevent unintended pump operations. The touchscreen also supports

enhanced visual and tactile feedback.

Lithium-polymer rechargeable battery technology. Our products are the first and only insulin pumps to use a rechargeable battery, unlike traditional pumps that rely on expensive disposable batteries. By using a built-in rechargeable battery, we eliminate the risk of losing personal settings associated with replacing batteries. Our lithium-polymer rechargeable battery charges rapidly with a standard micro-USB connection, and a full charge lasts for five to seven days depending on CGM use. Users report that they keep their battery powered by charging it for just 10 to 15 minutes each day, often while showering or commuting with the use of the car charger. Our battery allows for accessible monitoring of the current charge level on the device's home screen. Our battery has also been tested to last for the four-year warranty life of the pump.

Compatibility and connectivity. Our PC- and Mac-compatible, cloud-based data management application, t:connect, provides our domestic insulin pump users a fast, easy and visual way to display therapy management data from all of our pump products and supported blood glucose meters. Additionally, our pump platform enables rapid data uploads through a micro-USB connection, without interrupting insulin delivery. Internationally, we offer our customers connectivity to a third-party diabetes management application. Providing connectivity to a data management platform empowers people with diabetes, as well as their caregivers and healthcare providers, to quickly and easily identify meaningful insights and trends, allowing them to fine-tune therapy and lifestyle choices for better control of their diabetes.

Our Products

We have commercially launched six insulin pumps since inception, all of which have been developed using our proprietary technology platform. Domestically, we began commercial sales of our first product, t:slim, in August 2012 and subsequently commercialized t:flex in May 2015, t:slim G4 in September 2015, t:slim X2 in October 2016, t:slim X2 with G5 integration in September of 2017 and t:slim X2 with Basal-IQ technology in August 2018. Internationally, we launched the t:slim X2 with G5 in September 2018. Our t:slim X2 hardware platform now represents 100% of new pump shipments, but we continue to provide ongoing service and support to existing t:slim, t:slim G4 and t:flex customers.

Commercial Products

In the past four years, we have shipped approximately 84,000 pumps, over 4,000 of which were in international markets, which is representative of our estimated global installed customer based on the typical four-year insurance pump reimbursement cycle. Today, our commercial efforts exclusively focus on the manufacturing, sale and support of our flagship pump platform, the t:slim X2 insulin delivery system.

The t:slim X2 Insulin Delivery System

The t:slim X2 insulin delivery system is our proprietary pump platform comprised of a t:slim X2 pump, its 300-unit disposable insulin cartridge and an infusion set. We began commercial sales of t:slim X2 in the United States in the fourth quarter of 2016. Measuring 2.0 x 3.1 x 0.6 inches, t:slim X2 is the slimmest and smallest durable insulin pump on the market. It is also the only commercially available insulin pump featuring optional integration with Dexcom's CGM. CGM is a therapy that provides users with real-time access to their glucose levels as well as trend information. Our agreements with Dexcom provide us non-exclusive licenses to integrate our product platform with the Dexcom G5 Mobile CGM System and Dexcom G6 CGM System.

t:slim X2 also features new hardware advancements, including a two-way Bluetooth wireless technology radio for communicating with more than one external device at a time. Domestically, we sell the t:slim X2 with Basal-IQ technology, and outside the United States, we sell the t:slim X2 with G5.

Consistent with our prior generation insulin pumps, the t:slim X2 pump platform features a vivid, full color touchscreen made of high-grade, shatter-resistant glass that provides users the ability to enter numbers and access features directly, rather than scrolling through a list of numbers and screens. We designed the streamlined, user-friendly interface of our products to facilitate rapid access to the features people use most, such as delivering a bolus, viewing remaining insulin on board, viewing insulin cartridge volume and monitoring current pump status and settings. The interface also includes an Options Menu that provides quick and intuitive navigation to key insulin

management features, pump settings, cartridge loading and use history. With just a simple tap of our logo on the pump touchscreen the user immediately returns to the home screen where important administrative features are displayed, including the current battery charge level, a time and date display, and an LED indicator for alerts, alarms and reminders.

In addition, the t:slim X2 allows for the creation of multiple customizable personal profiles, each supporting up to 16 timed insulin delivery settings. This feature allows users to manage their day-to-day insulin therapy with less effort and interruption. Users can quickly and easily adjust insulin settings based on a number of key factors, including basal rate, correction factor, insulin-to-carbohydrate ratio and target blood glucose levels.

Furthermore, the t:slim X2 features a black aluminum case and chrome trim, giving it the look and feel of a modern consumer electronic device, such as a smartphone. It is also watertight, with an IPX7 rating, eliminating concerns about accidentally getting it wet. The t:slim X2 also features a micro-USB connection that supports charging the lithium-polymer battery, software updates through the Tandem Device Updater in the United States, and rapid data uploads to either t:connect or the third-party Glooko diabetes data management application.

In February 2019, we received FDA approval of our de novo application to down-classify the t:slim X2 to a Class II 510(k) device, under the new insulin pump classification referred to as ACE pumps. This classification is intended to help expedite future FDA review of changes to our pump hardware and integration with future products supporting interoperability initiatives. However, we anticipate that the software component of our products related to AID features, such as our Basal-IQ technology, will continue to be subject to review by the FDA under the class III PMA device standards.

t:slim X2 Insulin Delivery System with Basal-IQ Technology

In the United States, we offer the t:slim X2 with our Basal-IQ technology feature. This is our first commercial AID offering.

The t:slim X2 with Basal-IQ technology utilizes Dexcom G6 sensor values to support our AID algorithm, which is designed to temporarily suspend insulin delivery to help minimize the frequency and/or duration of hypoglycemic events. All new domestic pumps are shipped with Basal-IQ technology, and it is then at the discretion of the user and the user's healthcare provider to determine whether or not to use this feature with CGM integration. It is the first and only CGM integrated insulin pump system that does not require fingersticks for calibration or diabetes treatment decisions. Our Basal-IQ technology was developed internally in consultation with clinical thought leaders in AID research. In our market research, a predictive low glucose suspend algorithm was reported as the most valuable AID feature among people with insulin-dependent diabetes and their healthcare providers.

In January 2018, we completed a pivotal study for our t:slim X2 with Basal IQ technology. Results from this study, which were published in the Diabetes Care medical journal, showed that the system achieved the primary outcome of reducing time spent in hypoglycemia compared to SAP therapy alone. This reduction was accomplished without any increase in the rate of hyperglycemia. Study participants reported that the system was easy to use and also reported a high level of confidence using the system.

The t:slim X2 with Basal-IQ technology received FDA approval in June 2018 and launched domestically in August 2018. Concurrent with approval, the t:slim X2 with Basal-IQ technology was also deemed compatible with approved iCGM devices. Currently, the Dexcom G6 CGM is the only iCGM-designated device in the United States; however, we expect this interoperability designation will streamline the regulatory pathway for integration of the t:slim X2 with future iCGM products as they are approved by the FDA. Interoperability with iCGM devices will still require development effort and business agreements; however, the regulatory process can be lengthy and unpredictable, so we believe this designation, together with the FDA's recent designation of the t:slim X2 as an ACE pump, may reduce the overall timeline to commercialize interoperable devices.

We anticipate offering t:slim X2 with Basal-IQ technology in select international markets during 2019. Our ability to offer the t:slim X2 with Basal-IQ technology will depend on several factors, including the availability of Dexcom G6 CGM in the relevant geography.

300-unit Insulin Cartridge being inserted into a t:slim X2 pump

t:slim X2 with G5 Integration

Outside of the United States, we offer the t:slim X2 with G5 integration. The t:slim X2 with G5 integration incorporates the same pump technology and user interface as t:slim X2, but also provides the added convenience of allowing CGM information to be displayed on the pump, thereby eliminating the need to carry an additional device. Based on this information, users are able to utilize the pump to take direct action with their insulin pump therapy.

We believe that our AID and CGM integration advancements, together with future anticipated applications and the global availability of the Tandem Device Updater, will continue to enable users to add significant new features and functionality to their pumps independent of their typical four-year insurance pump replacement cycle.

Our Complementary Products

Tandem Device Updater

The t:slim X2 is 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. The Tandem Device Updater was cleared by the FDA in the third quarter of 2016 and is PC- and Mac- compatible. It is currently only available in the United States.

The Tandem Device Updater was 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. We are uniquely positioned to offer this capability due to the intuitive software architecture and convenient micro-USB connection included within the t:slim X2.

We have launched three different software updates using the Tandem Device Updater. The first was a deployment of updated t:slim software to in-warranty t:slim pumps purchased before April 2015. Next, in September 2017, we set a new standard of care in our industry by offering all existing in-warranty t:slim X2 customers integration with the Dexcom G5 Mobile CGM system through a software update using the Tandem Device Updater. Most recently, we offered all existing in-warranty t:slim X2 customers access to Basal-IQ technology, following their procurement of a prescription and completion of training. We estimate that approximately 40% of our domestic t:slim X2 customers use integrated Dexcom CGM, and about half of those customers have updated their pump to allow use of our Basal-IQ technology. We anticipate that there will be continued adoption of Basal-IQ technology as more people adopt CGM use and with the increasing availability of Dexcom G6 sensors.

Historically, we have made all software updates through the Tandem Device Updater available for no cost to in-warranty users. In the future, this tool has the potential to enable users to add other new features and functionality to their pumps, such as new AID algorithms, independent of the typical four-year insurance pump replacement cycle. We expect that future software upgrades will be implemented through our Tandem Device Updater. Although our reimbursement strategy may vary by product and geography, in the future we may seek to secure additional reimbursement for software updates and or charge for updates as we obtain regulatory approval for their commercialization. We also plan to complete the required development work and submit for the necessary regulatory approvals to offer the Tandem Device Updater outside of the United States beginning in 2019.

t:connect Diabetes Management Application

We commercially introduced the t:connect Diabetes Management Application, or t:connect, our web-based data management application, in the United States in the first quarter of 2013. It provides users, their caregivers and their healthcare providers 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. We also believe t:connect can serve as a key component of mobile health applications that are currently under development.

We developed t:connect to be intuitive by using the same consumer-focused approach utilized in the development of our insulin pumps. It features built-in logic that manages duplicate blood glucose readings from a user's pump and blood glucose meter to ensure report accuracy. t:connect can also generate color-coded graphs and interactive, multi-dimensional reports that make it easy to identify therapy management trends, problems and successes.

In 2017, we launched t:connect HCP, which is an enhanced version of t:connect that we expect will simplify the ability of pump users to share t:connect data with their healthcare providers. This application allows healthcare providers to establish a separate account that centralizes t:connect data from all of their enrolled patients. t:connect and t:connect HCP are not currently available to users or healthcare providers outside the United States.

t:connect Diabetes Management Application

Infusion Sets

In September 2017, we began replacing the standard Luer-lok connector that previously joined an infusion set to our cartridge with a custom connector, the t:lock connector. Our t:lock is similar in its design to that of a standard Luer connector, but on average, reduces the time required to fill tubing by more than 30 seconds and reduces the amount of insulin used in the process by 4.5 units. It also reduces the possibility of air bubbles being trapped in the connector. The transition to our t:lock connector resulted in a substantial increase in our sales of infusion sets beginning in the third quarter of 2017. By the end of 2017, our infusion sets and cartridges were being sold on a one-to-one basis. This trend continued in 2018 and is expected for the long-term. We intend to continue to identify solutions that will enhance our infusion set products to address the perceived shortcomings of existing products on the market.

Pump Accessories

We offer our customers a broad range of accessories for their pumps, such as cases and belt clips, allowing users to customize their device to their individual lifestyle and sense of style. We believe our accessories increase user flexibility and willingness to use and carry their insulin pump.

Products under Development

Our products under development support our strategy of focusing on both consumer and clinical needs, and include new AID systems, a next-generation hardware platform, and connected (mobile) health offerings. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionalities that will allow us to meet the needs of people in differentiated segments of the insulin-dependent diabetes market.

t:slim X2 with Control IQ Technology

Our second-generation AID system, the t:slim X2 with Control-IQ technology, is expected to integrate the t:slim X2 with technology that we licensed from TypeZero and Dexcom's G6 CGM sensor. The iCGM designation for the system also provides the opportunity for integration development efforts with future iCGM sensors that may become available in the market. With our implementation of TypeZero's inControl AID algorithms, our product is intended to both increase and decrease basal insulin based on a user's predicted blood glucose levels from a compatible iCGM sensor, as well as deliver automated correction boluses. In conjunction with Dexcom and TypeZero, which was acquired by Dexcom in August 2018, we have integrated our technologies into the U.S. portion of the Clinical Acceptance of the Artificial Pancreas, or DCLP3, portion of the International Diabetes Closed Loop, or the IDCL, trial. Enrollment for the 6-month study was completed in October 2018. Our t:slim X2 with Control-IQ technology has also been evaluated in several early pediatric studies and we intend to support a pivotal study among pediatric patients with type 1 diabetes that will commence in the first half of 2019. Our goal is to commence commercial sales of the t:slim X2 with Control-IQ technology in the United States in the second half of 2019, followed by an international launch in 2020.

t:slim X2 with Control IQ Technology

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. This product is expected to be half the size of t:slim 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 to provide people with greater insulin needs. t:sport will utilize a pumping mechanism that differs from our current Micro-Delivery technology.

t:sport Shown with Touchscreen Controller

Since 2016, we have engaged in discussions with the FDA regarding whether the t:sport controller can be implemented as a mobile device application or will need to be a separate device. Based on the FDA’s feedback regarding the use of unrestricted mobile phones, we are designing the product so that it will have the technical capability to be controlled using either a dedicated controller or a mobile device. Because of the nature of our touchscreen user interface, we are well positioned to pursue either option.

We anticipate pursuing FDA authorization for t:sport as an ACE pump, and we are designing t:sport to be compatible with our AID algorithms and any available iCGM. Our goal is to receive FDA authorization for this product for use in the United States in 2020, and to thereafter submit for regulatory approvals outside the United States.

Connected (Mobile) Health Offerings

We are currently developing a mobile application that is being designed to utilize the capability of the Bluetooth radio to wirelessly upload pump data to t:connect, receive notification of pump alerts and alarms, integrate other health-related information from third party sources, and support future pump-control capabilities for our products under development. Subject to FDA approval, we intend to launch the first generation of our mobile application with a subset of these features in the United States in 2019.

Mobile Application

Sales and Marketing

Our sales and marketing objectives are to:

- generate demand and acceptance for our product offerings developed using our technology platform among people with insulin-dependent diabetes; and
- promote advocacy and support for our products and brands with healthcare providers.

As of December 31, 2018, we had approximately 70 territories in our U.S. sales organization, with approximately 200 full-time employees on our sales, clinical and marketing team. The vast majority of territories are supported by a territory manager 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 San Diego-based 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. 2017 was our first full year with customers eligible for renewal. Renewal sales to existing customers nearly doubled between 2017 and 2018. Factors such as the timing of competitive product launches, regulatory approvals, advancements in diabetes therapy alternatives, insurance eligibility and other market dynamics may impact the rate of renewal purchases in the future.

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 2019.

In Canada, in the second half of 2018 we established a small direct sales and clinical infrastructure. We also intend to use a local distributor for select order processing and fulfillment services as needed. In October 2018, we received approval from Health Canada to begin marketing the t:slim X2 with G5 integration and commenced marketing and sales efforts. We also began the process of securing reimbursement in each of the provinces, which we expect to continue in 2019.

In other select geographies outside the United States, our efforts have primarily focused on the identification and contracting of distributors in areas where we believe there is a meaningful opportunity for our t:slim X2 insulin pump. Unlike our domestic operations, our international distributors other than in Canada will have substantially greater responsibility for sales, marketing and customer support efforts. Our existing international distributors cover several geographies, including: Australia, Italy, New Zealand, Scandinavia (Denmark, Norway and Sweden), South Africa, Spain, and the United Kingdom.

We began attending prominent international diabetes tradeshows in early 2018 and obtained the right to affix the CE Mark to the t:slim X2 with G5 integration in April 2018. We began our scaled launch in the third quarter of 2018 following the completion of pre-launch activities, such as translating both our pump software and user manual, and distributor sales and customer service trainings. We anticipate continuing to expand our commercial efforts outside the United States throughout 2019, which may include expanding our sales to additional select geographies and contracting with additional international distributors.

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, 2018, we made sales to approximately 55 independent distributors in the United States, and nine independent distributors internationally. In fiscal 2018, sales to Edgepark Medical Supplies, Inc. and Byram Healthcare accounted for 19.4% and 15.6% of consolidated sales, respectively. In fiscal 2017, Edgepark Medical Supplies, Inc. and Byram Healthcare accounted for 21.5% and 14.0% of our sales, respectively. In fiscal 2016, Edgepark Medical Supplies, Inc. and Byram Healthcare accounted for 18.7% and 14.0% of our 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 both our domestic and international distributors carry minimal inventory at any given time.

Healthcare provider focused initiatives. Healthcare providers are a critical resource in helping patients understand and select their diabetes therapy options. Each of our territories in the United States and many of our territories in Canada

are supported by a clinical diabetes specialist who is a certified diabetes educator and holds either a registered nurse or registered dietician license. Our clinical diabetes specialists support and educate healthcare providers on our products and proprietary technology, certify healthcare providers to train people to use our products and support our customers with initial training following the purchase of our products. We have also established a network of independent, licensed diabetes educators who have been certified to train on our products and will conduct customer training on our behalf.

In addition to calling on healthcare providers in their offices, some of our recent marketing initiatives include:

- presentations and product demonstrations at local, regional, national and international tradeshows, including the American Diabetes Association Scientific Sessions and the American Association of Diabetes Educators Annual Meeting, Diabetes Canada and Advanced Technologies and Treatment for Diabetes;

- our Demonstration Unit Program, through which we provide healthcare professionals with our products, or a mobile device that operates our t:simulator App, for pump demonstrations to their patients; and

- business relationships with third-party diabetes management applications, such as Glooko, for the display of Tandem pump data.

Consumer-focused initiatives. We sell our products directly to consumers through referrals from healthcare providers and through leads generated through our promotional activities. Our direct-to-consumer marketing efforts focus on positioning our products as innovative, consumer-focused insulin pumps with a unique Micro-Delivery technology, slim touchscreen design, and an intuitive user interface designed to meet different needs in the diabetes community. In connection with the domestic launch of t:slim X2 with Basal-IQ technology, our marketing also educates consumers and healthcare providers on the benefit of our AID algorithm, and the Dexcom G6 as a more accurate sensor that does not require fingersticks compared to competitive products. Some of our recent consumer-focused marketing initiatives include:

participation at consumer-focused regional diabetes conferences and events including the Juvenile Diabetes Research Foundation, or JDRF, Type One Nation Summits, the American Diabetes Association Expos, Children With Diabetes Friends for Life and Taking Control Of Your Diabetes, or TCOYD, conferences and local diabetes camps;

website enhancements and utilization of social media, online advertising and consumer-focused newsletters to drive online awareness and expand web presence;

promotion of our t:simulator App, which allows anyone to explore the key features of our pump products for free using their mobile device;

corporate sponsorships of organizations focused on people with diabetes, including JDRF, TCOYD and College Diabetes Network; and

community diabetes fundraising and awareness events.

Branding. We developed our comprehensive branding strategy to engage consumers and communicate our identity as a modern and progressive company that works “in tandem” with the diabetes community, healthcare providers, our employees and business partners. We strive to embody this through our product offerings, marketing efforts and interactions throughout our business. Our product names are consistently branded using a “t:” to create uniformity and help consumers quickly identify our products. In the United States, our “pump that gets updated, not outdated” marketing campaign highlights that we are able to offer customers the ability to remotely update or add features on their in-warranty insulin pump. Our other product packaging, website, advertising and promotional materials are a reflection of our consumer-focused approach and modern style. We value having clear, friendly and helpful communications throughout our business.

Animas Transition

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. Animas supply ordering and support was transitioned to Medtronic as of April 2018. Medtronic is offering a portion of Animas customers the option of acquiring a Medtronic insulin pump at no charge. As a result of this change in the insulin pump market, we now offer the only alternative durable insulin pump to Medtronic in the United States. Nevertheless, a large percentage of our new customers still report being new to pump therapy, with approximately half converting from MDI, followed by customers who reported converting from either a Medtronic or Animas pump. However, throughout 2018 we experienced an increase in our percentage of sales to people who reported converting from using an Animas pump. The longer-term impact on our business of Animas’ exit may be dependent on one or more of the following factors:

The offer to Animas customers for a free Medtronic pump is currently limited to customers with a warranty expiration date later than September 30, 2019. It remains uncertain how many Animas customers will avail themselves of this offer.

While Medtronic will have direct access to all Animas customers during the transition period, as those customers' pumps come up for renewal and they make new pump purchasing decisions, they may consider alternative pump options. Our own customer data and other available market research shows a high number of customers converting to our products from an Animas pump, and we believe our pumps are an attractive alternative to both Animas and Medtronic pumps.

We believe one of the product features that has made Animas pumps attractive to their customers is the integration of the Animas Vibe with Dexcom’s CGM technology. We now provide the only commercially available pump that is integrated with Dexcom’s technology.

The opportunity for our international distributors to convert current Animas customers to a Tandem pump. Unlike in the United States, many of our international distributors have existing relationships with Animas customers and will be motivated to keep those individuals as existing customers by replacing Animas pumps with our t:slim X2 as opportunities arise.

Training and Customer Care

Given the chronic nature of diabetes, and the potentially complicated dynamic of health insurance coverage, training and customer care is important for developing long-term relationships with our customers. Our customer care infrastructure, which services the United States and Canada, consists of individuals focused on training, technical services and insurance verification. We provide training to our distribution partners who fulfill these responsibilities outside the United States. We believe our consumer-focused approach enables us to develop a personal relationship with the customer, or potential customer, beginning with the process of evaluating our products, then navigating insurance coverage and extending to our provision of training and ongoing support. Providing reliable and effective ongoing customer support reduces anxiety, improves our customers' overall experiences with our products and helps reinforce our positive reputation in the diabetes community. In order to provide complete training and customer care solutions, we leverage the expertise of our clinical diabetes specialists in the Unites States and Canada who provide one-on-one training, and we offer ongoing complementary technical services, as well as ongoing support with insurance verification.

Training. Our research has shown that it can take several days for a user to competently learn how to use a traditional pump, leading to frustration, frequent mistakes and additional training, each of which may ultimately discourage adoption. As a result, we believe that healthcare providers may be less likely to recommend pump therapy to potential candidates.

By offering an intuitive user interface, we believe healthcare providers will be able to train people to use our products more efficiently than traditional pumps, and will have a higher degree of confidence in their patients' ability to operate it, including the more advanced features. For example, the addition of Basal-IQ technology to our t:slim X2 only added one new screen to our user interface. In addition, the intuitive nature of our pump products likely will allow healthcare providers to spend less time teaching a person how to use their pump and more time helping to improve the management of their diabetes. This ease of training may also help users feel less intimidated and fearful of pump therapy, leading to increased adoption and market expansion.

We tailor our training efforts for insulin pump users and healthcare providers. In some cases, our clinical training managers may certify clinic-based healthcare providers to train their patients on our products. In other cases, a member of our clinical team will conduct one-on-one training on our products with the customer. We have also established a network of independent, licensed diabetes educators who have been certified to train on our products and will conduct customer training on our behalf.

For our customers who purchased t:slim X2 with Basal-IQ technology, we offer online training on the use of the AID algorithm and CGM components of the system. Customers can access one or more modules of the training system at their own pace and at their preferred location, which offers them a convenient method to access the latest training available. In the fourth quarter of 2017, we presented research demonstrating the ease-of-use and effectiveness of computer-based training from the human factors study of the t:slim X2 with Basal-IQ technology. The study

demonstrated a 99% success rate among study participants who performed a series of critical tasks using the system after initial training. Out of 530 tasks performed, only seven task failures were observed, none of which related to safety. In addition, participants in the t:slim X2 with Basal-IQ technology pivotal study reported that the system is easy to use and also reported a high level of confidence using the system. We believe the ease of training on the t:slim X2 with Basal-IQ technology is a competitive advantage compared to currently-available AID systems.

Technical Services. We believe that a difficult-to-use pump will result in users making more frequent calls to the pump manufacturer or their healthcare provider for support in using the device. This can be frustrating for the customer and costly for the pump manufacturer as well as for the healthcare provider. In general, we expect the intuitive nature of our products to result in fewer calls from users requesting support from our technical services team or their healthcare provider. However, because of the significant percentage of our customers who are new to pump therapy, we also anticipate receiving high call volume from customers who are still becoming familiar with the fundamentals of insulin pump therapy. In addition, we have experienced increases to our call volume as our existing customers begin to utilize CGM integration with their t:slim X2, and begin using our AID algorithm. We anticipate experiencing a similar dynamic in the future as we launch new AID systems and new product offerings.

Our customer-focused technical services team provides support to U.S.- and Canadian-based customers seven days a week, 24 hours a day by answering questions, troubleshooting and addressing issues or concerns about the pump, CGM and algorithm components of our systems. In 2018, we began investing in technology solutions to improve the customer’s experience calling into our call center, and improve efficiencies of our internal support infrastructure. We anticipate continuing to invest in this area in 2019, while further leveraging our infrastructure. Our insulin pump products are typically covered by a four-year warranty. The warranty includes our product replacement program, which allows our technical services team members to provide a customer with a replacement device within as little as 24 hours, to minimize the interruption of his or her therapy. We also coordinate product replacements of CGM components where appropriate.

Internationally, our distribution partners provide technical services support to their t:slim X2 customers.

Insurance Verification. Our insurance verification team provides support to U.S. and Canadian based customers, and potential customers, understand their insurance benefits. We work with the customers and their healthcare providers to collect information required by the insurance provider and to determine their insurance benefit coverage for our products and notify them of their benefit.

Following communication of a person's estimated financial responsibility, final confirmation of their desire to purchase the device and method of fulfillment, the customer's order is typically shipped to their home. The initial order generally contains their insulin pump as well as a 90-day supply of infusion sets and cartridges. For customers that we service on a direct basis, a member of our internal team then contacts the customer prior to the end of their 90-day supply to re-verify their insurance benefits and assist in reordering supplies. For customers who purchase our insulin pump through one of our authorized U.S. or international distributors, ongoing supplies are typically also arranged through the distributor.

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. 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.

Over the last ten years, Medicare reimbursement rates for insulin pumps and disposable cartridges have remained relatively unchanged. However, Medicare periodically reviews its reimbursement practices for diabetes-related products. In 2010, Medicare implemented a competitive bidding process for blood glucose strip reimbursement, which resulted in a significant reduction in the reimbursement rate for those products. More recently, in 2017, Medicare announced, and then shortly thereafter suspended, a competitive bidding process for insulin pumps. As a result, there is some uncertainty as to the future Medicare reimbursement rate for our current and future products.

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, 2018, approximately 20% of our shipments 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, 2018, we had executed distributor agreements with approximately 55 independent distributors. 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. We expect this decision will prevent a majority of UnitedHealthcare members from purchasing our insulin pump for the foreseeable future, 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

We currently manufacture our products at our facility in San Diego, California. In 2017, we transitioned our manufacturing operations to a new facility located on Barnes Canyon Road in San Diego, California, which became fully operational at the beginning of 2018. This facility doubled our manufacturing capacity for insulin pumps and cartridges, expanded warehousing for additional infusion set supplies, and provided additional production capacity for new products under development, without significantly increasing the cost of overhead associated with our manufacturing facilities.

The Barnes Canyon facility is designed to optimize our manufacturing processes and allow for greater operational efficiencies, which we believe positions us well to achieve our long-term gross margin targets. By maintaining close proximity to our other business functions, we believe we will enhance our ability to monitor and manage our manufacturing processes, and to adjust manufacturing operations quickly in response to our business needs. The transition to the new manufacturing facility took place primarily in the second half of 2017, during which time we experienced some temporary duplication of operations to support ongoing product requirements, as well as some incremental manufacturing costs. In 2018, we did not make significant capital expenditures in our manufacturing operations. In 2019, we anticipate making capital expenditures in the purchase of an additional manufacturing equipment and to expand our warehousing capacity.

We currently utilize a semi-automated manufacturing process for our pump products and disposable cartridges. The pump production line requires approximately 20 manufacturing assemblers and limited support staff to run the line, and reaches a maximum output of approximately 30,000 pumps per year on a single shift. We currently have two pump manufacturing lines that have capacity to produce 110,000 pumps annually. Disposable cartridges are manufactured on a production line that requires 10 manufacturing operators and limited support staff, and reaches a maximum output of approximately one million cartridges per year on a single shift. We currently have four cartridge manufacturing lines that provide capacity to build 12 million units annually, which we believe can support an installed customer base of approximately 100,000 customers. We also have capacity to add two additional lines in our current facility which will provide approximately six million cartridges annually, to supporting an additional 50,000 customers. We continue to improve the efficiency of our disposable cartridge manufacturing process.

The cartridge automation equipment is designed to operate at capacity. As such, the line is constructed in several modular sections that perform different aspects of the assembly. This is important because at any given time, maintenance, service or inspection can be performed on any one section independent of the rest of the line. The manufacturing process may then continue uninterrupted while the assembly step is performed manually until the automation section is back on-line.

Outside suppliers are the source for most of the components and some sub-assemblies in the production of our insulin pumps. Typically, our outside vendors produce components to our specifications and in many instances to our designs. Any sole and single source supplier is managed through our supplier management program that is focused on reducing supply chain risk. Key aspects of this program include managing component inventory in house and at the supplier, contractual requirements for last time buy opportunities and second sourcing approaches for specific suppliers. Due to the rapid increase in demand for our products over the past 12 months, we have not maintained our desired inventory levels for certain key pump components, which has limited our production capacity. Accordingly, during 2019 we intend to substantially increase our ongoing purchases of key components and sub-assemblies to produce our insulin pump products and make corresponding increases for our warehousing capacity of both raw materials and finished goods.

Our suppliers are evaluated, approved and monitored periodically by our quality department to ensure conformity with the specifications, policies and procedures for 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. This ISO 13485 certification now extends to our new manufacturing facility on Barnes Canyon Road. 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 contemplates that our insulin pump products will be used alongside TypeZero's AID technology in the IDCL Trial. 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.

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, 2018, our patent portfolio consisted of approximately 68 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 23 trademark registrations, including 10 U.S. trademark registrations and 13 foreign trademark registrations.

In July 2012, we entered into an agreement with Smiths Medical, Inc., or Smiths Medical, 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, 2018, 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. However, the market for insulin pumps recently underwent significant changes. For instance, in late 2016, Roche Diabetes Care, a division of F. Hoffman-La Roche, discontinued sales of new insulin pumps in the United States. Roche continues to sell and market its insulin pump products in international markets. In October 2017, Johnson & Johnson announced that it was discontinuing the operations of Animas and exiting the insulin pump business entirely, and designated Medtronic as a preferred partner to facilitate the transition of Animas insulin pump customers. Also, in late 2017, Eli Lilly & Co. announced that it was developing an insulin pump with AID technology and Becton Dickinson recently confirmed that it intends to launch an insulin pump designed for people with type 2 diabetes in 2019. However, it is difficult to predict the potential

impact of these changes on our competitive landscape. There are also several other companies that are currently marketing insulin pump products in international markets.

Our current primary competitors are either publicly traded companies or divisions or subsidiaries of publicly traded companies. These companies have several competitive advantages over us, including greater financial resources for sales and marketing and product development, established relationships with healthcare providers and third-party payors, and larger and more established distribution networks. In some instances, our competitors also 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, and Medtronic offers a traditional insulin pump that is integrated with a CGM system featuring a hybrid closed-loop AID algorithm.

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 entitled “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, or the 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 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 Dexcom's G5 sensor integration, and t:slim X2 with Basal-IQ technology received FDA approval as a Class III device.

Our t:slim X2 with Basal-IQ technology was the first insulin pump to receive approval for iCGM compatibility, a new interoperability designation for integrated iCGM devices. Similarly, as part of the FDA's interoperability initiative, in February 2019, we received FDA approval of our De Novo application to down-classify the t:slim X2 to a Class II device, under the new insulin pump classification referred to as ACE pumps. This classification, as well as the iCGM classification, are intended to help streamline the regulatory pathway for integrated products approved by the FDA. However, we anticipate that the software component of our products related to AID features, such as our Basal-IQ technology and our Control-IQ technology currently in development, will continue to be subject to review by the FDA under the class III PMA device standards.

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 between one and three years 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. 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, 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 recently passed California's 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 EU General Data Protection Regulation, commonly known as GDPR, and similar 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.

In April 2018, we obtained the right to affix the CE Mark to the t:slim X2 with G5 integration. The CE Mark gives us authorization to distribute the t:slim X2 throughout the European Union and in other countries that recognize the CE Mark. In October 2018, we received Health Canada approval to distribute the t:slim X2 with G5 integration throughout Canada. In the third quarter of 2018, we began selling the t:slim X2 with G5 integration in select geographies outside the United States through distributors, and our direct sales efforts in Canada began in the fourth quarter of 2018.

Employees

As of December 31, 2018, we had 653 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 66) has served as our President and Chief Executive Officer and as one of our directors since September 2007. We recently announced that Mr. Blickenstaff will transition to the role of Executive Chairman of our board of directors effective as of March 1, 2019. Prior to joining our company, Mr. Blickenstaff 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 continuous glucose monitoring 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 63) has served as our Executive Vice President and Chief Operating Officer since April 2013. We recently announced that Mr. Sheridan will be appointed as our President and Chief Executive Officer effective as of March 1, 2019, and will serve as our principal executive officer commencing on that date. 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 49) has served as our General Counsel since August 2013, as our Corporate Secretary since January 2015, and as our Executive Vice President since January 2016. Prior to joining our company, from January 2008 until August 2013, he served as Vice President and General Counsel of Senomyx, Inc., a taste science company, and was promoted to Senior Vice President in January 2012. 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 51) 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 an M.B.A. from the School of Business at San Diego State University and a B.S. in Business Administration from the University of Missouri-Columbia.

Susan M. Morrison (age 39) 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 46) has served as our Senior Vice President, Chief Financial Officer and Treasurer since January 2018 and as Executive Vice President since June 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, who is expected to be appointed as our President and Chief Executive Officer as of March 1, 2019, and Ms. Vosseller, who is currently our Executive Vice President, Chief Financial Officer and Treasurer, are involved in a personal relationship. Ms. Vosseller will report directly to Mr. Sheridan in his new position as our President and Chief Executive Officer. 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 intends to consider whether additional internal disclosure controls and procedures are appropriate in light of the circumstances.

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 “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 profitability.

Since our inception in January 2006, we have incurred a significant net loss. As of December 31, 2018, we had an accumulated deficit of $600.1 million. To date, we have financed our operations primarily through public and private sales of our equity securities, debt financing, and cash collected from sales of our products. We have devoted substantially all of our resources to the 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 commercial product, the t:slim Insulin Delivery System, or t:slim, in the third quarter of 2012. In October 2016, we launched t:slim X2, our flagship pump platform, and in August 2017, we commenced commercial sales of t:slim X2 with Dexcom G5 Mobile CGM integration. The t:slim X2 hardware platform now represents nearly 100% of new pump shipments. In June 2018, we received FDA approval to sell our new t:slim X2 with Basal-IQ technology, which is integrated with Dexcom G6 CGM, and commenced sales and shipments of the t:slim X2 with Basal-IQ technology in the United States during the third quarter of 2018. In addition, we commenced sales and shipments of our t:slim X2 with G5 integration in select markets outside the United States during the third quarter of 2018.

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, 2018 and 2017, our gross profit was $89.8 million and $44.1 million, respectively. Although we have achieved a positive overall gross margin, we still operate at a significant net loss and expect that we will continue to do so for the foreseeable future.

To implement our business strategy and achieve 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, and obtain regulatory clearance or approval to commercialize our products currently under development both domestically and internationally. Our expenses may 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 ever be able to achieve or 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;
- 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 insulin pump products or similar products or technologies;
- 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; and
- claims that any of our insulin pump products, or any component thereof or related supplies or systems, 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, which under some circumstances are subject to termination by Dexcom, with or without cause, on relatively short notice. Sales of our products may also be negatively impacted in the event of any regulatory or legal actions relating to Dexcom's CGM products, 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.

Furthermore, sales of our products may be adversely impacted by negative perceptions regarding our financial stability relative to that of our competitors, and our ability to sustain our business operations on a long-term basis. These perceptions may cause people with insulin-dependent diabetes, their caregivers and healthcare providers, as well as independent distributors and third-party payors, to question our ability to continue to sell our products, provide customer service, support our commercial organization, and fulfill our strategic objectives. These concerns may arise from a number of factors, including our recent and projected financial results, changes in and volatility of our stock price, the competitive environment in our industry, and uncertainties regarding the regulatory environment. Any such concerns, whether actual or perceived, could cause consumers to delay the purchase of our products or purchase competitive products.

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 24/7 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 the products of our competitors, the failure to secure regulatory clearance or approvals 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. For instance, Medtronic MiniMed, a division of Medtronic plc, has been the market leader for many years and has the majority share of the traditional insulin pump market in the United States. However, the market for insulin pumps continues to experience significant changes. For instance, in October 2017, Johnson & Johnson announced its plans to discontinue the operations of Animas and to exit the insulin pump business entirely. Animas designated Medtronic as a preferred partner to facilitate the transition of their respective insulin pump customers. In addition, over the past several years Eli Lilly & Co. announced that it was developing an insulin pump and Becton Dickinson announced that it plans to launch an insulin pump designed for persons with type 2 diabetes. 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;
- products supported by long-term clinical data;
- 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, Medtronic offers a traditional insulin pump with a hybrid closed-loop AID functionality and a new CGM system and Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set. These specific features may make the competitive products more desirable to customers and healthcare providers, which could negatively impact sales of our products.

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 Laboratories launched a new blood glucose monitoring system 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. 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, 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, positive lifestyle impact, 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 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 insulin pump products or similar products or technologies generally;
- 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.

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.

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit cost of our products by increasing production volume and manufacturing efficiency, and by reducing raw material and component costs, labor, product-training, warranty and manufacturing overhead costs per unit.

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, warranty, freight, scrap and inventory excess and obsolescence. It also includes manufacturing overhead costs, including expenses relating to quality assurance, inventory procurement and control, facilities, equipment, information technology and operations management. If we are unable to sustain or reduce 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, and improved warranty performance, 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 productivity following the relocation of our manufacturing operations to our Barnes Canyon facility. Furthermore, while we currently believe our proprietary technology platform will allow us to efficiently design and develop new products, changes in the market that require us to modify or replace our existing platform will reduce the efficiencies gained through our platform and could increase our per unit costs or prevent those costs from declining. 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.

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.

We have derived nearly all of our revenue from sales of insulin pumps, and related insulin cartridges and infusion sets, and expect to continue to do so in the foreseeable future. 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 the Centers for Medicare and Medicaid Services, or CMS, which administers the U.S. Medicare program. Medicare periodically reviews its reimbursement practices for diabetes-related products. Medicare previously implemented a competitive bidding process for blood glucose strip reimbursement, which resulted in a significant reduction in the reimbursement rate for those products. In 2017, Medicare announced, and then shortly thereafter suspended, a competitive bidding process for insulin pumps. As a result, there is uncertainty as to the future Medicare reimbursement rate for our products. 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. We expect this decision will prevent a majority of UnitedHealthcare members from purchasing an insulin pump from us for the foreseeable future. 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 adding 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 do not have 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 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.

We expect to derive nearly all of our revenue from the sale of our t:slim X2 insulin pump, and the related insulin cartridges and infusion sets, unless and until we receive regulatory clearance or approval for other products currently under development. As a result, 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 increased the number of sales, marketing, clinical and customer service personnel employed by us since the

initial commercial launch of t:slim 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 the United States, where we have limited experience. Unexpected turnover among our sales, marketing, clinical and customer service 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, 2018, sales to approximately 64 independent distributors represented approximately 79% of our sales. While our goal in the United States is to reduce the percentage of our sales to independent distributors over time as we enter into contracts with additional third-party payors, 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 even increase in the near term, particularly in light of our plans to primarily rely 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 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, 2018, our two largest independent distributors in the United States collectively comprised approximately 35% of our sales, and our nine independent international distributors collectively comprised approximately 5% of our 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, or other arrangements pursuant to which independent distributors may purchase product from us, the terms of the arrangements could result in our product margins to be 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, or 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. In particular, we currently expect to rely on data from the U.S. portion of the Clinical Acceptance of the Artificial Pancreas (DCLP3) portion of the IDCL Trial, to support our development of t:slim X2 with Control IQ technology. We may also rely on data from other portions of the larger IDCL Trial to support additional regulatory submissions. The IDCL Trial is being conducted entirely by third parties over which we have little or no control or influence. In the event that the IDCL Trial is not performed on a timely basis, or if the quality or accuracy of the data obtained from the IDCL Trial is compromised due to the failure to adhere to clinical protocols or

regulatory requirements or for other reasons, our development activities for t:slim X2 with Control IQ technology may be negatively impacted.

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, especially with respect to the IDCL Trial that we intend to rely upon for the development of t:slim X2 with Control IQ technology. 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 and the announcement by Johnson & Johnson that it is discontinuing the operations of Animas and exiting the insulin pump business, as well changes specific to our business, such as the approval of t:slim X2 with Basal-IQ technology and our commencement of commercial sales in international markets during the third quarter of 2018, 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 facing emerging growth 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 and 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 will continue to make comparisons of our historical and future financial results more difficult. In particular, during the term of the Technology Upgrade Program, U.S. GAAP 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.

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.

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 facility.

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. 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, 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, or their inability to provide us with an adequate supply of components or products, 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 or damage to their manufacturing equipment or

facilities. 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. Furthermore, negative perceptions among our suppliers regarding our financial stability, and our ability to sustain our business operations on a long-term basis, may cause one or more of our suppliers to terminate their relationship with us, or claim that our financial condition causes them to demand different payment terms.

We generally use a small number of suppliers for our components and products. Depending on a limited number of suppliers exposes us to risks, including limited control over cost, 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 inventory that is 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.

We may also have difficulty obtaining similar 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 new 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 t:lock, which 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.

We believe the transition period for our direct customers and distributors in the United States to utilize their inventory on hand before transitioning to t:lock is substantially complete. In addition, we are initially offering standard Luer-lok cartridges and infusion sets in select international markets, and expect to transition to our t:lock connector in international markets during 2019. Accordingly, we may continue offering both styles of cartridges and infusion sets to facilitate the transition of customer supplies through 2019, although there may be circumstances that require additional time for some direct customers and distributors to complete the transition. Our supplier of infusion sets must manufacture a variety of lengths and styles of infusion sets with t:lock that match our cartridges. Failure to do so, or to do so at the necessary production volumes, may result in our inability to convert customers to t:lock when anticipated, which would negatively impact our ability to achieve our financial projections. Due to the variability in purchasing patterns, standard Luer-lok inventory 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 inventory that we cannot sell at standard prices or at all, which would negatively impact our results of operations.

While t:lock was designed based on customer feedback, and all standard Luer-lok infusion sets that we currently offer are also available with t:lock, 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 t:lock 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 t:lock or t:lock compatible infusion sets, which could have a material adverse impact on our business, financial condition and operating results.

We currently operate primarily at two locations in San Diego, California, and any disruption at these locations could adversely affect our business and operating results.

Substantially all of our operations are conducted at two locations in San Diego, California, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions. In addition, the majority of our inventory of component supplies and finished goods is stored at one of these locations. We also store finished goods at third-party warehouses in Carson, California and Austin, Texas for the fulfillment of certain customer orders. 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 inventory 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 operations to our new facility.

At the beginning of 2018, we completed the transition of our manufacturing operations to our Barnes Canyon facility that we expect will allow for future product manufacturing expansion. However, we may not experience the anticipated operating efficiencies at the new facility, or we may experience efficiencies to a lesser extent than projected. 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 September 2017, following a site inspection of our Barnes Canyon facility, the FDA issued a Form 483, List of Inspectional Observations, containing two observations. Following our receipt of the Form 483, we began implementing corrective and preventive actions to fully address the FDA observations, and in October 2017, we provided a written response to the FDA. In December 2017, we received a letter from the FDA stating that our initial written response did not fully address the FDA observations, and that the FDA would address the observations during its next regularly scheduled inspection of our facilities. If the FDA is not satisfied, it may issue a warning letter to us or may take other actions, any of which could have a material adverse effect on our business. On August 15, 2018, we closed the voluntary recall initiated on April 12, 2018 for 55 t:slim G4 pumps.

We expect that the management and support of our new manufacturing facility 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 from the new facility. 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 or make additional investments in capital equipment.

If we do not enhance our product offerings through our research and development efforts, 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 offerings 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.

The safety and efficacy of our products is not supported by long-term clinical data, which could limit sales, and our products could cause unforeseen negative effects.

Our t:slim X2 insulin pump received pre-market clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA. The 510(k) clearance process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes and does not always require long-term clinical studies. t:slim X2 with G5 integration and t:slim X2 with Basal-IQ technology received FDA approval under a PMA application. However, currently there are only limited published studies to evaluate the safety or effectiveness of our PMA-approved products in a controlled setting. As a result, we currently lack the breadth of published long-term clinical data supporting the safety and efficacy of our products and the benefits they offer. For these reasons, 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.

We may enter into collaborations, in-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, in-licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products and to pursue new markets, or we may amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities. We may not identify or complete any such transactions or arrangements 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 transaction or arrangement that we do identify and complete. In particular, these collaborations may not result in the development of products that achieve commercial success or result in positive financial results and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators 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, 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 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 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 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, 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.

Any significant disruptions to our information technology systems, or failures of our pumps' software to perform as we anticipate, could have an adverse effect on our business, financial condition and operating results.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage 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 earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures. In addition, our currently-marketed insulin pumps and our products currently under development contain software which could be subject to computer virus, hacker attacks or other 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. We may also face new risks relating to our information technology systems as we begin to commercialize our products outside 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, all of which could have a material adverse effect on our business, financial condition and operating results.

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. Many of these individuals have been employed by us for many years, have played integral roles in the growth of our business, and will continue to provide value to us. In our industry, it is common to attract and retain executive talent and other employees with compensation packages that include a significant equity component. At this time, a substantial number of our outstanding equity awards issued prior to 2017, which generally were issued in the form of stock options, are significantly out of the money and unlikely to be exercised in the future. 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. 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.

If we are found to have violated laws protecting the confidentiality 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 confidentiality and security of personal information, including laws and regulations under HIPAA, PIPEDA, and GDPR. These requirements seek to protect medical records and other personal information from unauthorized access and to ensure that individuals know how we collect, use, store, and transfer their personal information.

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 and 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. We believe we are in substantial compliance with the privacy and security requirements of these laws, however, even compliant entities can experience security breaches or have inadvertent failures that may result in potential claims and liability under such laws.

We may also face new risks relating to security laws and privacy rights as individual U.S states, E.U. member states, and other international jurisdictions adopt new data privacy laws and regulations as we begin to commercialize our products worldwide. As we continue to expand internationally, our business will need to be adapted to meet these and other similar legal requirements.

We are seeking approval to commercialize 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 the 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, or natural disasters.

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

At December 31, 2018, we had $129.0 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 the United States, the growth of our manufacturing and warehousing operations 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 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 the hiring of additional personnel, purchasing manufacturing equipment and other measures 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 capital stock, 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 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. 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;

- 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, 2018, our patent portfolio consisted of approximately 68 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 also have and are seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we have 10 U.S. trademark registrations and 13 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. 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. We received approval of our PMA for t:slim G4 in September 2015 and of our PMA supplement for the t:slim X2 with G5 integration in August 2017. More recently, in June 2018, we received approval of our PMA for the t:slim X2 with Basal-IQ technology. 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. We anticipate that certain of our products currently under development will require the more costly, lengthy and uncertain PMA approval process.

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. For example, based on feedback from the FDA, we recently received approval of a de novo 510(k) application to down-classify the t:slim X2 to a Class II device, under the new insulin pump classification referred to as ACE pumps, and we intend to separately file a PMA for our implementation of the Control-IQ technology. Ultimately, the FDA may not support our new regulatory filing strategy.

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. 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, 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 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 are required to comply with the FDA's Quality System Regulation, or the 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. If we or our suppliers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us. Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results.

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 MDR 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 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 or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

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

- 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;

- 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 protected health information, such as HIPAA and the Health Information Technology for Economic and Clinical Health, or HITECH.

Further, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, or, collectively, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. An individual or entity can now be found guilty under the PPACA without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that claims submitted in violation of the Anti-Kickback Statute automatically constitute false claims for purposes of the False Claims Act. 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. 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.

To enforce compliance with the federal laws, the U.S. Department of Justice, or the DOJ, 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 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 recently 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 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;
- perceptions about our financial stability generally, and relative to our competitors, including our ability to sustain our business operations and achieve profitability;
- 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 TCJA, which significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, 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, 2018, we had federal net operating loss, or NOL, carryforwards of approximately $352.7 million, not considering the limitation discussed below. The federal tax loss carryforwards begin to expire in 2026, unless previously utilized. In addition, if there is an “ownership change” with respect to our company, as defined under Section 382 of the Code the utilization of our NOL carryforwards may be subject to substantial limitations imposed by the Code, and similar state provisions. 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.

Although we have not yet completed an update of our Section 382 analysis subsequent to December 31, 2017, offerings of our securities following that date may have caused an ownership change or could increase the likelihood that we undergo an ownership change for purposes of Section 382 of the Code in the future. Based on preliminary results of the Section 382 analysis, the Company anticipates that an ownership change may have occurred in 2018 and that the resulting limitation would significantly reduce the Company’s ability to utilize its net operating loss and credit carryovers before they expire. 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 such NOL carryforwards to expire unused, in each case reducing or eliminating the benefit of such NOL carryforwards.

With respect to our NOLs generated in 2018 and thereafter, the TCJA may reduce the tax benefit of our NOLs. Under the TCJA, 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 TCJA, 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 TCJA.

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.

The requirements of being a public company have increased our costs and will continue to strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of the NASDAQ Global Market and other applicable securities rules and regulations. Compliance with these rules and regulations has increased our legal and financial compliance costs, made some activities more difficult, time-consuming or costly, and increased demand on our systems and resources.

The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to meet these additional requirements, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to help us comply with these requirements, in the future we may need to hire more employees or utilize external consultants in order to further support our efforts, which will increase our expenses.

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. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm conducted 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.

As of December 31, 2018, we leased an aggregate of 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.

As of December 31, 2018, we also leased approximately 48,880 square feet of general office, manufacturing and warehouse space located on Barnes Canyon Road in San Diego, California, or the Barnes Canyon Lease, 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 36 months and not greater than 60 months, by delivering notice to the landlord at least nine months and not more than 12 months prior to the expiration of the lease.

On January 22, 2019, we entered into a lease agreement for approximately 25,332 square feet of general office space located on 10935 Vista Sorrento Parkway in San Diego, California, or the Pacific Plaza Lease. The Pacific Plaza Lease is scheduled to expire in 2022. We have a one-time option to extend the term of the lease for a period of five years, by delivering prior written notice to the landlord in accordance with the terms of the lease. We intend to transition certain of our administrative operations from our Roselle Street facilities into the Pacific Plaza building during the second quarter of 2019.

Substantially all of our operations are currently conducted at these facilities, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions.

We believe that the facilities that we presently occupy together with the additional facilities that we expect to occupy under the Pacific Plaza Lease 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.

PART II

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, 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
Year Ended December 31, 2017:		
First Quarter	$30.00	$11.00
Second Quarter	$13.00	$7.63
Third Quarter	$12.20	$3.90
Fourth Quarter	$8.88	$2.15

Holders of Record

As of February 19, 2019, there were approximately 53 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 2018 or 2017.

Item 6. Selected Financial Data.

The selected financial data presented below under the heading “Statements of Operations Data” for the years ended December 31, 2018, 2017, and 2016 and the selected financial data presented below under the heading “Balance Sheet Data” as of December 31, 2018 and 2017 have been derived from our audited consolidated financial statements included elsewhere in this Annual Report. The selected financial data presented below under the heading “Statements of Operations Data” for the years ended December 31, 2015 and 2014 and the selected financial data presented below under the heading “Balance Sheet Data” as of December 31, 2016, 2015 and 2014 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 Statements of Operations Data:

	Year Ended December 31,				
(in thousands, except per share data)	2018	2017	2016	2015	2014
Sales	$183,866	$107,601	$84,248	$72,850	$49,722
Cost of sales	94,044	63,507	60,656	46,270	34,474
Gross profit (loss)	89,822	44,094	23,592	26,580	15,248
Operating expenses:					
Selling, general and administrative	105,226	86,377	82,834	78,621	75,121
Research and development	29,227	20,661	18,809	16,963	15,791
Total operating expenses	134,453	107,038	101,643	95,584	90,912
Operating loss	(44,631)	(62,944)	(78,051)	(69,004)	(75,664)
Total other income (expense), net:	(77,929)	(10,081)	(5,411)	(3,404)	(3,789)
Net loss before taxes	$(122,560)	$(73,025)	$(83,462)	$(72,408)	$(79,453)
Provision for income tax (benefit) expense	51	8	(15)	10	71
Net loss	$(122,611)	$(73,033)	$(83,447)	$(72,418)	$(79,524)
Net loss per share, basic and diluted[1]:	$(2.55)	$(12.87)	$(27.30)	$(25.04)	$(34.17)
Weighted average shares used to compute basic and diluted net loss per share[1]:	48,129	5,677	3,057	2,892	2,327

Consolidated Balance Sheet Data:

	As of December 31,				
(in thousands)	2018	2017	2016	2015	2014
Cash and cash equivalents	$41,826	$13,700	$44,678	$43,088	$31,176
Short-term investments	$87,201	$479	$8,860	$28,018	$36,106
Working capital	$121,597	$28,071	$60,616	$80,464	$72,657
Property and equipment, net	$17,151	$19,631	$18,409	$15,526	$12,581
Total assets	$206,294	$95,346	$112,392	$124,725	$106,464

Notes payable	$—	$76,541	$78,960	$29,275	$29,440
Total stockholders' equity (deficit)	$131,275	$(29,148)	$(5,927)	$63,468	$54,572

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. We believe our competitive advantage is rooted in our unique consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing, sales and support activities exclusively focus on our flagship pump platform, the t:slim X2 Insulin Delivery System, or 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. By delivering innovative hardware and software solutions, as well as best-in-class customer support, we aim to improve and simplify the lives of people with diabetes and their healthcare providers.

We have commercially launched six insulin pumps in the United States since inception, all of which have been developed using our proprietary technology platform. Three of these pumps have featured continuous glucose monitoring technology, or CGM. In the past four years, we have shipped approximately 84,000 pumps, over 4,000 of which were in international markets, which is representative of our estimated global installed customer base on the typical four-year reimbursement cycle.

Domestically, we began commercial sales of our first insulin pump product, t:slim, in August 2012 and subsequently commercialized t:flex in May 2015, t:slim G4 in September 2015, t:slim X2 in October 2016, t:slim X2 with Dexcom G5 Mobile CGM integration, or t:slim X2 with G5, in September of 2017 and t:slim X2 with Basal-IQ technology in August 2018. The Basal-IQ technology is our first-generation Automated Insulin Delivery, or AID, algorithm. This

system uses Dexcom's G6 CGM sensor values to temporarily suspend insulin delivery to help minimize the frequency and/or duration of hypoglycemic events. In the second quarter of 2018, the United States Food and Drug Administration, or the FDA, also created a new interoperability designation for integrated continuous glucose monitoring, or iCGM, devices. The t:slim X2 with Basal-IQ technology was the first insulin pump to receive approval for iCGM compatibility, which we expect will streamline the regulatory pathway for integration with future iCGM products as they are approved by the FDA. More recently, in early 2019 the FDA classified our t:slim X2 as the first insulin pump in a new device category referred to as Alternative Controller Enabled infusion pumps, or ACE pumps. We expect this new classification of the t:slim X2 will provide us with more flexibility as we make improvements to current products, create new products and collaborate with third-parties in the development of future AID systems. Interoperability with iCGM and other compatible devices will still require development effort and business agreements; however, the regulatory process can be lengthy and unpredictable, so we believe the FDA's designation of iCGM products and ACE pumps will, collectively, reduce the overall timeline to commercialize interoperable devices.

In the second half of 2018, we began selling the t:slim X2 with G5, in select geographies outside the United States, including Canada. We have discontinued sales of our original t:slim, t:flex and t:slim G4 pumps, and our t:slim X2 hardware platform now represents 100% of new pump shipments. However, we continue to provide ongoing service and support for our earlier products.

Our insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to selling insulin pumps, we sell disposable products that are used together with our pumps and 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 United States, 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. The Tandem Device Updater provides our in-warranty domestic customers potential access to new and enhanced features and functionality faster than the industry has been able to in the past. The first use of our Tandem Device Updater was for our deployment of the latest t:slim software to in-warranty t:slim pumps purchased before April 2015. Since that time, we set a new standard of care in our industry by offering all existing in-warranty t:slim X2 customers in the United States two significant software updates: (i) integration with the Dexcom G5 Mobile CGM system in September 2017; and (ii) an upgrade to our new Basal-IQ technology and integration with Dexcom's G6 CGM in August 2018. Our Tandem Device Updater positions us to bring future innovations and AID algorithms to t:slim X2 customers, independent of the typical four-year insurance pump reimbursement cycle. Though we have not utilized our Tandem Device Updater to perform software updates for devices outside the United States, we are currently developing that capability, and intend to do so in the future.

For the years ended December 31, 2018, 2017 and 2016, our consolidated sales were $183.9 million, $107.6 million, and $84.2 million, respectively. For the years ended December 31, 2018, 2017 and 2016, our net loss was $122.6 million, $73.0 million, and $83.4 million, respectively. Worldwide pump sales accounted for 67%, 66%, and 74% of our total sales, respectively, for the years ended December 31, 2018, 2017 and 2016, while pump-related supplies and accessories accounted for the remainder in each year. Our accumulated deficit as of December 31, 2018 and December 31, 2017 was $600.1 million and $477.6 million, respectively. This included $147.4 million and $56.9 million of non-cash stock-based compensation charges and non-cash changes in the fair value of common stock warrants as of December 31, 2018 and 2017, respectively.

In the United States, we have rapidly increased sales since our commercial launch 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. More recently, our sales have also rapidly increased following the scaled launch of t:slim X2 in geographies outside 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 both domestically and outside of the United States. We also believe we are well positioned 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 FDA, and as we develop the capability to offer the Tandem Device Updater outside the United States. At the same time, by rapidly innovating and offering new product features and benefits through the 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 customer support infrastructure, both of which benefit 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 new AID systems, a next-generation hardware platform, and connected (mobile) health offerings. We intend to

leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionalities that will allow us to meet the needs of people in differentiated segments of the insulin-dependent diabetes market.

Our current products under development include:

- t:slim X2 with Control IQ Technology: Our second-generation AID system is expected to integrate the t:slim X2 with the technology that we licensed from TypeZero and Dexcom's G6 CGM sensor. The iCGM designation for the system also provides the opportunity for integration development efforts with future iCGM sensors that may become available in the market. With our implementation of TypeZero's inControl AID algorithms, our product is intended to both increase and decrease basal insulin based on a user's predicted blood glucose levels from a compatible iCGM sensor, as well as deliver automated correction boluses. In conjunction with Dexcom and TypeZero, which was acquired by Dexcom in August 2018, we have integrated our technologies into the U.S. portion of the Clinical Acceptance of the Artificial Pancreas, or DCLP3, portion of the International Diabetes Closed Loop, or the IDCL, trial. Enrollment for the 6-month study was completed in October 2018. Our t:slim X2 with Control-IQ technology has also been evaluated in several early pediatric studies and we intend to support a pivotal study among pediatric patients with type 1 diabetes that will commence in the first half of 2019. Our goal is to commence commercial sales of the t:slim X2 with Control-IQ technology in the United States in the second half of 2019, followed by an international launch in 2020.

- t:sport Insulin Delivery System: Expected to be 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 people with greater insulin needs. t:sport will utilize a pumping mechanism that differs from our current Micro-Delivery technology.

- Connected (Mobile) Health Offerings: We are currently developing a mobile application that is being designed to utilize the capability of the Bluetooth radio to wirelessly upload pump data to t:connect, receive notification of pump alerts and alarms, integrate other health-related information from third party sources, and support future pump-control capabilities for our products under development. Subject to FDA approval, we intend to launch the first generation of our mobile application with a subset of these features in the United States in 2019.

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

Pump Shipments

Since inception, we have derived nearly all of our sales from the shipment of insulin pumps and associated supplies 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 units shipped per quarter to be an important metric for managing our business.

In 2018, we shipped 34,493 insulin pumps worldwide compared to 17,061 insulin pumps shipped in 2017. In the United States we have shipped more than 79,000 pumps within the four-year period ended December 31, 2018. Pump shipments in the United States by fiscal quarter were as follows:

	Pump Units Shipped for Each of the Three Months Ended in Respective Years [1] - 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[2]	4,042	4,582	3,896	4,418	16,938
2017[2]	2,816	3,427	3,868	6,950	17,061
2018	4,444	5,447	7,379	12,935	30,205

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

	Pump Units Shipped for Each of the Three Months Ended in Respective Years [1] - International				
	March 31	June 30	September 30	December 31	Total
2018	N/A	N/A	1,055	3,233	4,288

(1) The pump units shipped do not reflect returns or exchanges of pump products that occur in the ordinary course of business.

(2) 2016 and 2017 U.S. shipments do not include approximately 3,300 trade-ins fulfilled under the Technology Upgrade Program (discussed below) related to our commercial launch of t:slim X2.

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. Due to the high degree of accounting complexity, the program created unpredictable financial results under U.S. GAAP for the duration of the program. 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. For the year ended December 31, 2016, we recorded a deferral of sales of $4.3 million and a net decrease in gross profit of $4.6 million as a result of the program. The program expired on September 30, 2017 and, therefore, has no impact on our 2018 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, and the commercial launch of products by us and our competitors.

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

- market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers;
- 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 vary by geography;
- the buying patterns of our distributors and other customers;
- the timing of the commercialization of new products by us or our competitors;
- 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; and
- anticipated and actual regulatory approvals of our products and competitive products.

In particular, we believe the following specific trends and factors have impacted, and could continue to materially impact our financial results going forward:

- continued increase in demand following the commercial launch of t:slim X2 and the demonstrated success of our Tandem Device Updater, which we expect will positively impact our sales;
- 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;

- opportunity to attract Animas customers, following the announcement by Johnson & Johnson that it discontinued the operations of Animas and will discontinue availability of pump supplies in late 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, and;

- expansion in select international geographies, which began in the third quarter of 2018.

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 to improve our operating margins, including costs associated with our international launch plans. In the fourth quarter of 2018, we achieved profitability for the first time. However, this may not be sustained in the near term. We believe we can ultimately achieve sustained profitability by driving incremental sales growth, meeting our pump renewal sales objectives, increasing gross profits from additional sales of infusion sets, maximizing manufacturing efficiencies on increased production volumes and leveraging the investments made in our sales, clinical, marketing and customer support organizations.

Subsequent Events

In January 2019, we entered into a lease agreement for 25,332 square feet of additional general administrative office space located at 10935 Vista Sorrento Parkway, San Diego, California. Subject to limited exceptions, the initial lease term is expected to commence on the later of (i) March 1, 2019, or (ii) the date on which the landlord substantially completes certain specified work related to tenant improvements, such date, the Commencement Date, and will expire 42 months from the first day of the first full month following the Commencement Date. We also have a one-time option to extend the term of the lease for a period of five years by delivering prior written notice to the landlord in accordance with the terms of the lease.

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 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 such sales 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 commenced commercial sales of t:slim X2 with G5 in select international geographies. With the exception of Canada where we intend to market with a direct sales force, we expect that most of our commercial sales outside the United States will initially be to independent distributors who will perform all sales, customer support and training in their respective territories. Historically, we have experienced consistent levels of reimbursement for our products in the United States, but the average sales price will vary in international markets based on a number of factors, such as the 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, product shipments being weighted heavily towards the second half of the year, with the highest percentage of product shipments expected in the fourth quarter of the year due to the nature of the reimbursement environment. Consistent with our historical seasonality, we also expect domestic product shipments from the fourth quarter to the following first quarter to decrease significantly. Internationally, we do not expect this same impact from seasonality. However, the opportunity for the transition of former Animas customers in 2019 may also impact our quarterly sales trends worldwide.

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. For instance, customers may defer a purchasing decision if they believe that 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 decision or take additional time to consider the anticipated or new approval or product launch in their purchasing decision. However, we are not able to quantify the extent of the impact of these or similar events on future purchasing decisions.

Cost of Sales

We manufacture our pumps and disposable cartridges at our manufacturing facility in San Diego, California. 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, reserves for expected warranty costs, freight, scrap and inventory excess and obsolescence. 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 products gain broader market acceptance and our product sales increase.

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 over the long-term, 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 proprietary technology platform and manufacturing infrastructure, and will be able to further reduce 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 costs per unit to decrease as we release 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. .

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 and in international markets, the timing and success of new regulatory approvals and product launches, the impact of changes in our stock price on non-cash stock-based compensation, warranty and training costs, inventory obsolescence and changes in our manufacturing processes, capacity, costs or output.

Selling, General and Administrative

Our selling, general and administrative, or 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. In particular, our sales and clinical organization consisted of approximately 70 territories as of December 31, 2018 and our operations in Canada will be supported by a direct sales force of approximately 10 field representatives. Territories in the United States are maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel. We expect to modestly increase our number of sales personnel in the near term in order to optimize the coverage of our existing territories. 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 in international geographies. Additionally, we realized a notable increase in non-cash stock-based compensation expense beginning in the third quarter of 2018 from the increase in our stock price over the past year. We expect higher non-cash stock-based compensation expense will be sustained in future quarters as a result of the valuation of certain employee option grants. 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, or 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, as well as continue to reflect a notable increase in non-cash stock-based compensation due to the impact of the increase in our stock price over the past year.

Other Income and Expense

Other income and expense primarily consists of changes in the fair value of the Series A and Series B warrants issued in our public offering of common stock in October 2017, as well as interest expense and amortization of debt discount and issuance costs associated with our Amended and Restated Term Loan Agreement, or the Term Loan Agreement, with Capital Royalty Partners II, L.P. and its affiliated funds, or CRG. In August 2018, we fully repaid amounts due under the Term Loan Agreement. Prior to that, there was $82.7 million of outstanding principal under the Term Loan Agreement, which accrued interest at a coupon rate of

11.5% per annum. As a result, we recognized a loss on extinguishment of debt in 2018, but there will be no related interest expense or costs associated with the Term Loan Agreement in future years. Our interest and 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 due to revaluations of the outstanding Series A warrants, which expire in the fourth quarter of 2022.

Results of Operations

	Year Ended December 31,		
(in thousands, except percentages)	2018	2017	2016
Sales:			
Pump sales	$115,719	$71,518	$62,507
Pump supplies and other	58,469	36,083	21,741
Total domestic sales	174,188	107,601	84,248
Pump sales	8,205	—	—
Pump supplies and other	1,473	—	—
Total international sales	9,678	—	—
Total sales	183,866	107,601	84,248
Cost of sales	94,044	63,507	60,656
Gross profit	89,822	44,094	23,592
Gross margin	49 %	41 %	28 %
Operating expenses:			
Selling, general and administrative	105,226	86,377	82,834
Research and development	29,227	20,661	18,809
Total operating expenses	134,453	107,038	101,643
Operating loss	(44,631)	(62,944)	(78,051)
Other income (expense), net:			
Interest and other income	1,462	239	296
Interest and other expense	(7,584)	(11,341)	(5,707)
Loss on extinguishment of debt	(5,313)	—	—
Change in fair value of stock warrants	(66,494)	1,021	—
Total other expense, net	(77,929)	(10,081)	(5,411)
Net loss before taxes	$(122,560)	$(73,025)	$(83,462)
Provision for income taxes (benefit)	51	8	(15)
Net loss	$(122,611)	$(73,033)	$(83,447)

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 from international sales that 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.

Total sales increased $76.3 million in 2018 compared to 2017, primarily driven by a 102% increase in worldwide pump shipments to 34,493 in the year ended 2018, compared to 17,061 in the year ended 2017. Worldwide pump shipments were positively impacted by strong demand for our products following the August 2018 launch of t:slim X2 with Basal-IQ technology, the August 2017 launch of t:slim X2 with G5 integration, and the commencement of international sales in the third quarter of 2018. Additionally, sales from pump-related supplies increased 66% 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.

Sales to domestic distributors accounted for 78% and 75% of our total 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 international 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 pump shipments 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. As a whole, other non-manufacturing costs, which primarily consist of warranty, freight and training costs, also reflected improvement.

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, including an increase of $11.6 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our growing installed customer base. In addition, our strong year-over-year sales growth drove a substantial year-over-year increase in incentive-based compensation. Additionally, this included an increase of $6.8 million in non-cash stock-based compensation due to the significant increase in our stock price in 2018.

Research and Development Expenses. R&D expenses increased 41% to $29.2 million in 2018 from $20.7 million in 2017. This increase was primarily the result of an increase of employee-related expenses. This includes a $4.1 million increase in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts. In addition, our strong year-over-year sales growth drove a substantial year-over-year increase in incentive-based compensation. There was also an increase of $3.1 million in non-cash stock-based compensation due to the significant increase in our stock price in 2018.

Other Income (Expense). 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 the Series A and Series B 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. There will be no interest expense or other costs associated with the Term Loan Agreement in future periods. Other income consists primarily 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.

Comparison of Years Ended December 31, 2017 and 2016

Sales. For the year ended December 31, 2017, sales were $107.6 million, which included the recognition of $5.0 million of pump sales originally deferred in prior periods and upgrade fees received as a result of the Technology Upgrade Program. For the year ended December 31, 2016, sales were $84.2 million, reduced by $4.3 million of deferred pump sales as a result of our Technology Upgrade Program.

Sales of insulin pumps were $71.5 million and $62.5 million, respectively, for the years ended December 31, 2017 and 2016. For the year ended December 31, 2017, sales of pump-related supplies were $35.6 million, of which $21.4 million were sales of infusion sets and $14.2 million were sales of cartridges. For the year ended December 31, 2016, sales of pump-related supplies were $21.4 million, of which $9.7 million were sales of infusion sets and $11.7 million were sales of cartridges. The ratio of the number of infusion sets shipped to the number of cartridges shipped increased to 69% for the year ended December 31, 2017, and approached 100% during December, compared to 31% in 2016. Sales of accessories were not significant in either year.

Excluding the impact of the Technology Upgrade Program, the increase in sales was primarily driven by an increase in sales of infusion sets to our distributors, as well as an increase in the sale of pump-related supplies to our growing customer base. Pump shipments only slightly increased in the year ended December 31, 2017 to 17,061 from 16,938 in 2016, which we believe was the result of a number of factors including the highly competitive market, the timing of FDA approval of t:slim X2 with G5, and negative perceptions regarding our financial stability compared to that of our competitors.

Sales to distributors accounted for 75% and 74% of our total sales for the years ended December 31, 2017 and 2016, 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.

Cost of Sales and Gross Profit. Our cost of sales in 2017 was $63.5 million, resulting in gross profit of $44.1 million, which included incremental gross profit of $3.1 million associated with the Technology Upgrade Program. Our cost of sales in 2016 was $60.7 million, resulting in gross profit of $23.6 million in 2016, which included a reduction in gross profit of $4.6 million associated with the Technology Upgrade Program.

The gross margin in 2017 was 41%, compared to 28% in 2016. The incremental gross profit associated with the Technology Upgrade Program benefited our 2017 gross margin by one percentage point. The net reduction of gross profit associated with the Technology Upgrade Program negatively affected our gross margin for 2016 by four percentage points.

Excluding the impact of the Technology Upgrade Program, the improvement in both gross profit and gross margin was primarily the result of per-unit manufacturing cost improvements, including significant raw material cost reductions for pumps and overall manufacturing efficiencies for both pumps and cartridges, as well as contribution from the incremental sales of infusion sets. Other non-manufacturing costs, which primarily consist of warranty, freight and training, also improved.

In addition, in 2016 we recorded a $2.8 million charge for inventory excess and obsolescence as the result of the commercialization of t:slim X2, the launch of the Technology Upgrade Program and the larger than anticipated decrease in t:slim G4 sales in the second half of the year. This inventory excess and obsolescence charge negatively affected our gross margin for 2016 by three percentage points.

Selling, General and Administrative Expenses. SG&A expenses increased 4% to $86.4 million in 2017 from $82.8 million in 2016. Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. These expenses increased $3.7 million during 2017 compared to 2016, including an increase of $0.9 million in salaries and fringe benefits, as well as an increase in cash-based incentive compensation of $2.1 million and stock-based compensation of $0.7 million.

Research and Development Expenses. R&D expenses increased 10% to $20.7 million in 2017 from $18.8 million in 2016. This increase was primarily the result of an increase of employee-related expenses of $1.6 million and $0.9 million in outside consulting expense, including clinical trial costs, which was partially offset by a decrease in expenses associated with supplies and other services.

Other Income (Expense). Other expense in 2017 was $10.1 million, compared to $5.4 million in 2016. Other expense in 2017 and 2016 primarily consisted of interest expense associated with the Term Loan Agreement. The outstanding principal balances under the Term Loan Agreement were $82.7 million and $81.1 million as of December 31, 2017 and December 31, 2016, respectively. In 2017, we also recorded a $1.0 million gain from the change in fair value of the common stock warrants. Other income in 2017 and 2016 was not significant.

Liquidity and Capital Resources

At December 31, 2018, we had $129.0 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 2017, we completed the following financings:

- In August 2018, we completed a registered public offering of 4,035,085 shares of our common stock at a public offering price of $28.50 per share. The gross proceeds from the offering were approximately $115.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.
- In February 2018, we completed a registered public offering of 34,500,000 shares of our 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 payable by us.
- In October 2017, we completed a registered public offering of our common stock, pursuant to which we sold 4,630,000 shares of our 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 our common stock at a public offering price of $3.50 per share and accompanying warrants. The gross proceeds to us from this financing were approximately $16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. During the year ended December 31, 2018, we received proceeds of $29.6 million from the exercise of 8,735,765 outstanding Series A and Series B warrants. As of December 31, 2018, there were Series A warrants to purchase 510,785 shares outstanding and there were no Series B warrants outstanding.

- During the three months ended September 30, 2017, we sold 464,108 shares of our common stock under our "at the market" program, or the ATM Offering, at prices ranging from $5.64 to $10.54 per share. The gross proceeds to us from the offering were $4.3 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. The ATM Offering was terminated in December 2017.
- In March 2017, we completed a registered public offering of 1,850,000 shares of our common stock at a public offering price of $12.50 per share. The gross proceeds to us from the offering were approximately $23.1 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

Our historical cash outflows have primarily been associated with cash used for operating activities such as the development and commercialization of our products and expansion and support of our sales, marketing, clinical and customer support organizations, an increase in our R&D activities, the acquisition of intellectual property, expenditures related to increases in our manufacturing capacity and improvements to our manufacturing efficiency, overall facility expansion, 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, which will result in no interest expense or other costs associated with the Term Loan Agreement in future periods.

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. 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.

The following table shows a summary of our cash flows for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
(in thousands)	2018	2017	2016
Net cash provided by (used in):			
Operating activities	$(8,319)	$(66,136)	$(61,173)
Investing activities	(90,739)	2,782	10,448
Financing activities	117,184	40,376	52,315
Total	$18,126	$(22,978)	$1,590

Operating activities. Net cash used in operating activities was $8.3 million for the year ended December 31, 2018, compared to $66.1 million and $61.2 million for the same periods in 2017 and 2016, respectively.

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 Series A and Series B warrants, increased stock-based compensation expense, and the loss on extinguishment of debt, as well as net changes in working capital. Our operating loss included $10.8 million and $7.9 million in cash paid for interest in 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 inventory and increases in employee related liabilities and deferred revenue.

Inventory decreased to $19.9 million at December 31, 2018 from $27.0 at December 31, 2017 due to an increase in pump production and sales demand during the fourth quarter of 2018, and the timing of certain inventory receipts.

The increase in net cash used in operating activities for 2017 compared to 2016 was primarily due to changes in working capital, offset by an improvement in our operating loss of $10.5 million. Our operating loss included $7.9 million and $4.4 million in cash paid for interest in 2017 and 2016, respectively. Working capital changes were due to lower cash collections from accounts receivable and a reduction in deferred revenue, offset by increases in employee-related and other liabilities and decreases in prepaid and other current assets.

Investing activities. 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 sales and 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 sales and maturities of short-term investments of $8.5 million offset by $5.7 million in purchases of property and equipment. Net cash provided by investing activities was $10.4 million for the year ended December 31, 2016, which was primarily related to proceeds from sales and maturities of short-term investments of $50.0 million offset by the net purchase of $30.6 million in short-term investments and $8.9 million in purchases of property and equipment.

Financing activities. 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 Series A and Series B 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 due to net proceeds from the issuance of common stock. Net cash provided by financing activities was $52.3 million for the year ended December 31, 2016, which was primarily due to net proceeds from issuance of debt under the Term Loan Agreement in the amount of $50.0 million and $2.3 million in proceeds from participation in our employee stock plans.

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 and the collection of receivables generated from those sales from period to period;
- the timing and amount of any additional financings, including the exercise of warrants and proceeds from employee stock incentive plans;
- fluctuations in gross margins and operating margins; and
- fluctuations in working capital.

Our primary short-term capital needs, which are subject to change, include expenditures related to:

- support of our commercialization efforts related to our current and future products;
- research and product development efforts, including clinical trial costs;
- acquisition of equipment and other fixed assets; 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 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 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 capital stock, or we may elect to borrow amounts under new credit lines 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. There can be no assurance that financing will be available on acceptable terms, or at all.

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 repayment included approximately $1.1 million in accrued interest and $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, 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 for the year ended December 31, 2018. We had $82.7 million of aggregate borrowings outstanding at December 31, 2017 and a $4.1 million liability for financing fees.

Under the Term Loan Agreement, interest was payable at our 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, or the PIK Loan, to be added to the principal of the loan and subject to accruing interest. Interest-only payments were due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period, which would have ended on December 31, 2019. The principal balance was due in full at the end of the term of the loan, which was March 31, 2020, or the Maturity Date. We had elected to pay interest in cash at a rate of 11.5% per annum through September 30, 2015. From October 1, 2015 through December 31, 2017, we elected to pay interest in cash at a rate of 9.5% per annum and for a rate of 2.0% per annum to be added to the principal of the loan. As a result, $2.7 million was added to the principal of the loan during that time period, collectively, the PIK Loans.

We entered into a series of amendments to the Term Loan Agreement in 2016, 2017 and 2018, which included the addition of a financing fee payable at the maturity of the term loans, the issuance of warrants to purchase 193,788 shares of our common stock at an exercise price of $23.50 per share, or the CRG Warrant, and certain other minimum financing covenants. The CRG Warrant had a term of 10 years from the date of issuance and would have expired on March 7, 2027. The financing fee was applicable to the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued.

Contractual Obligations & Commitments

The following table summarizes our long-term contractual obligations as of December 31, 2018:

	Payments Due by Period				
(in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations related to facilities [1][2]	$10,831	$2,743	$5,802	$2,286	$ —
Firm purchase commitments [3]	14,541	10,578	3,963	—	—
Total contractual obligations	$25,372	$13,321	$9,765	$2,286	$ —

(1) The Barnes Canyon Lease provided for a tenant improvement allowance, or the TI Allowance, of up to approximately $3.4 million to be applied to non-structural improvements to the Barnes Canyon Building, which we fully utilized. The amounts funded by the landlord are subject to an interest accrual at a rate of 8.0% per annum and must be repaid in full during the base term in monthly installments (TI Rent), paid concurrently with the base rent. TI Rent is not included in the table above. TI Rent is expected to be $0.6 million for each of the years ended December 31, 2019 through 2023.

(2) The above table does not include amounts due under the lease of additional administrative office space located at 10935 Vista Sorrento Parkway, San Diego, California, which we entered into in January 2019. Minimum annual lease payments under the new lease will be approximately $0.4 million in 2019, $1.1 million in 2020, $1.2 million in 2021, and $0.8 million in 2022. The Company will also have a one-time option to extend the term of the lease for a period of five years with prior written notice in accordance with the terms of the lease.

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

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 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.

In January 2018, we adopted the Revenue from Contracts with Customers Standard which supersedes existing revenue guidance under U.S. GAAP and International Financial Reporting Standards. Accordingly, subsequent to January 1, 2018, we recognize revenue when we transfer promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. We elected to implement this new standard utilizing the modified retrospective method. Under this approach, we 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, we recorded an adjustment to the opening balance of accumulated deficit. The accounting for the significant majority of our revenues is not impacted by the new guidance. As a result, on January 1, 2018, we recorded a net reduction to accumulated deficit in the amount of $149,000, reflecting the accounting change.

Prior to the implementation of this new standard, we recognized revenue 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

We consider the deliverables in our product offering to be 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. We allocate the consideration to the individual performance obligations and recognize 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 upon delivery, while access to the complementary products, such as the t:connect cloud-based data management application and the Tandem Device Updater, are considered performance obligations satisfied over the four-year warranty period of the insulin pumps. There is no standalone value for these complementary products. Therefore, the Company determines their value by applying the expected cost-plus margin approach and then allocates the residual to the insulin pumps.

Product Returns

We offer a 30-day right of return to our customers from the date of shipment of any of our insulin pumps, provided a physician’s confirmation of the medical reason for the return is received. Estimated allowances for sales returns recorded as a reduction in revenue 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.

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 to cost of sales. Warranty costs are estimated based on the current expected replacement product cost and expected replacement rates based on historical experience. We evaluate the reserve quarterly and make adjustments when appropriate. Changes to the actual replacement rates could have a material impact on our estimated warranty reserve.

Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet arrangements.

JumpStart Our Business Startups Act of 2012 (JOBS Act)

We completed our initial public offering in November 2013. Accordingly, 2018 was our fifth year as an “emerging growth company” under the JOBS Act. As such, we are required to obtain an audit of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act commencing with the audit of our consolidated financial statements for the fiscal year ending December 31, 2018.

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

We invest our excess cash primarily in commercial paper, corporate debt, government-sponsored enterprise securities and U.S. government treasury securities. Some of the financial instruments in which we invest have market risk associated with them, 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 potentially 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, 2018, 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 Canada, our sales outside the United States are currently made to independent distributors under agreements denominated in U.S. dollars. Accordingly, we have assessed that 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 exchange risk associated with currency exposure related to existing assets and liabilities, committed transactions and forecasted future cash flows. In certain circumstances, we may seek to manage such foreign exchange risk by using derivative instruments such as foreign exchange forward contracts to hedge our risk. In general, we may hedge material foreign 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, 2018 and 2017 and for each of the three years in the period ended December 31, 2018, and the Report of the Independent Registered Public Accounting Firm are included in this report as listed in the index.

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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, 2018 and 2017, 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, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with US 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, 2018, 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 26, 2019 expressed an unqualified opinion thereon.

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.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2009.

San Diego, California

February 26, 2019

TANDEM DIABETES CARE, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands except par values)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$41,826	$13,700
Short-term investments	87,201	479
Accounts receivable, net	35,193	20,793
Inventory, net	19,896	26,993
Prepaid and other current assets	3,769	2,191
Total current assets	187,885	64,156
Property and equipment, net	17,151	19,631
Patents, net	1,130	1,457
Restricted cash - long-term	—	10,000
Other long-term assets	128	102
Total assets	$206,294	$95,346
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$6,824	$5,150
Accrued expense	3,930	2,832
Employee-related liabilities	24,030	14,488
Deferred revenue	4,600	2,526
Common stock warrants	17,926	5,432
Other current liabilities	8,978	5,657
Total current liabilities	66,288	36,085
Notes payable—long-term	—	76,541
Deferred rent—long-term	3,799	4,687
Other long-term liabilities	4,932	7,181
Total liabilities	75,019	124,494
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 200,000 and 100,000 shares authorized as of December 31, 2018 and December 31, 2017, respectively. 57,554 and 10,119 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively.	57	10
Additional paid-in capital	731,306	448,455
Accumulated other comprehensive loss	(13)	—
Accumulated deficit	(600,075)	(477,613)
Total stockholders' equity (deficit)	131,275	(29,148)
Total liabilities and stockholders' equity (deficit)	$206,294	$95,346

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,		
	2018	2017	2016
Sales	$183,866	$107,601	$84,248
Cost of sales	94,044	63,507	60,656
Gross profit	89,822	44,094	23,592
Operating expenses:			
Selling, general and administrative	105,226	86,377	82,834
Research and development	29,227	20,661	18,809
Total operating expenses	134,453	107,038	101,643
Operating loss	(44,631)	(62,944)	(78,051)
Other income (expense), net			
Interest and other income	1,462	239	296
Interest and other expense	(7,584)	(11,341)	(5,707)
Loss on extinguishment of debt	(5,313)	—	—
Change in fair value of stock warrants	(66,494)	1,021	—
Total other expense, net	(77,929)	(10,081)	(5,411)
Loss before taxes	(122,560)	(73,025)	(83,462)
Provision for income tax (benefit) expense	51	8	(15)
Net loss	$(122,611)	$(73,033)	$(83,447)
Other comprehensive loss:			
Unrealized gain (loss) on short-term investments	$(13)	$1	$(21)
Comprehensive loss	$(122,624)	$(73,032)	$(83,468)
Net loss per share - basic and diluted	$(2.55)	$(12.87)	$(27.30)
Weighted average shares used to compute basic and diluted net loss per share	48,129	5,677	3,057

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		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity (Deficit)
Balance at December 31, 2015	3,026	$ 3	$ 384,578	$ 20	$ (321,133)	$ 63,468
Exercise of stock options	15	—	170	—	—	170
Issuance of common stock for Employee Stock Purchase Plan	69	—	2,151	—	—	2,151
Stock-based compensation	—	—	11,752	—	—	11,752
Unrealized loss on short-term investments	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	(83,447)	(83,447)
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	39	172,890	—	—	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

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,		
	2018	2017	2016
Operating activities			
Net loss	$(122,611)	$(73,033)	$(83,447)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	5,821	6,866	5,489
Interest expense related to amortization of debt discount and debt issuance costs	1,721	1,883	274
Payment in kind interest accrual of notes payable	—	1,657	927
Provision for allowance for doubtful accounts	1,448	824	632
Provision for inventory reserve	607	26	3,343
Change in fair value of common stock warrants	66,494	(1,021)	—
Amortization of premium (discount) on short-term investments	539	(16)	(85)
Stock-based compensation expense	23,736	12,628	11,660
Loss on extinguishment of debt	5,313	—	—
Other	152	159	(78)
Changes in operating assets and liabilities:			
Accounts receivable, net	(15,848)	(10,445)	2,251
Inventory, net	6,756	(5,894)	(6,904)
Prepaid and other current assets	(1,576)	1,831	(2,466)
Other long-term assets	(26)	4	(2)
Accounts payable	1,641	(1,953)	3,234
Accrued expense	1,097	1,203	(497)
Employee-related liabilities	9,542	3,873	(1,578)
Deferred revenue	2,074	(3,906)	4,610
Other current liabilities	3,219	260	573
Deferred rent	(785)	(692)	1
Other long-term liabilities	2,367	(390)	890
Net cash used in operating activities	(8,319)	(66,136)	(61,173)
Investing activities			
Purchases of short-term investments	(123,553)	—	(30,622)
Proceeds from sales and maturities of short-term investments	35,800	8,500	50,000
Purchase of property and equipment	(2,986)	(5,718)	(8,930)
Net cash provided by (used in) investing activities	(90,739)	2,782	10,448
Financing activities			
Issuance of notes payable, net of issuance costs	—	—	49,994
Principal payments on notes payable	(87,711)	—	—
Proceeds from public offering, net of offering costs	172,929	39,806	—
Proceeds from issuance of common stock under Company stock plans	2,391	570	2,321
Proceeds from exercise of common stock warrants	29,575	—	—
Net cash provided by financing activities	117,184	40,376	52,315
Net increase (decrease) in cash and cash equivalents and restricted cash	18,126	(22,978)	1,590
Cash and cash equivalents and restricted cash at beginning of period	23,700	46,678	45,088
Cash and cash equivalents and restricted cash at end of period	$41,826	$23,700	$46,678

Supplemental disclosures of cash flow information			
Interest paid	$10,805	$7,876	$4,401
Income taxes paid	$16	$22	$23
Supplemental schedule of noncash investing and financing activities			
Lease incentive - lessor-paid tenant improvements	$13	$3,292	$—
Property and equipment included in accounts payable & other current liabilities	$125	$92	$501
Debt discount included in other long-term liabilities	$—	$4,137	$1,509
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.

TANDEM DIABETES CARE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

Tandem Diabetes Care, Inc. is a medical device company focused on 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.

The Company manufactures and sells insulin pump products that are designed to address large and differentiated needs of the insulin-dependent diabetes market. The Company’s manufacturing and sales activities primarily focus on the t:slim X2 Insulin Delivery System, or t:slim X2, the Company’s flagship pump platform that is capable of remote feature updates and designed to display continuous glucose monitoring, or CGM, sensor information directly on the pump home screen. 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 selling 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’s insulin pump products are compatible with the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of Tandem insulin pump software.

The Company began commercial sales of its first product, t:slim, in August 2012 and subsequently commercialized t:flex in May 2015, t:slim G4 in September 2015 and t:slim X2 in October 2016. The t:slim X2 hardware platform now represents 100% of new pump shipments, but the Company will continue to provide ongoing service and support to existing t:slim, t:slim G4 and t:flex customers. In June 2018, the Company received approval by the United States Food and Drug Administration, or FDA, for t:slim X2 with Basal-IQ technology, the Company’s first-generation Automated Insulin Delivery, or AID, algorithm, and commenced commercial sales of this product in August 2018.

During the third quarter of 2018, the Company commenced sales of the t:slim X2 in select geographies outside the United States, including Australia, Italy, New Zealand, Scandinavia (Denmark, Norway and Sweden), South Africa, Spain, and the United Kingdom.

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.

At December 31, 2018, the Company had $129.0 million in cash and cash equivalents and short-term investments. The Company has incurred operating losses since its inception and, as reflected in the accompanying consolidated financial statements, the Company had an accumulated deficit of $600.1 million as of December 31, 2018. 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, increase gross profits from higher sales of infusion sets, 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 third party intellectual property rights.

The Company has funded its operations primarily through private and public equity and debt financing. The Company may in the future seek additional capital from public or private offerings of its capital stock, or it may elect to borrow additional amounts under new credit lines 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 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 accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP, and 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.

Reverse Stock Split

On October 9, 2017, the Company effected a 1-for-10 reverse stock split of its issued and outstanding shares of common stock. The par value per share and the authorized number of shares of common stock and preferred stock were not adjusted as a result of the reverse stock split. All common stock share and per-share amounts for all periods presented in these consolidated financial statements have been adjusted to reflect the reverse stock split.

Reclassifications

Certain reclassifications of prior year amounts related to the presentation of restricted cash on the statement of cash flows have been made to conform to the current year presentation.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make informed estimates and assumptions 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. Actual results could differ materially from those estimates and assumptions.

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, or the CODM in making decisions regarding resource allocation and assessing performance. The Company's current product offering consists primarily of insulin pumps, disposable cartridges and infusion sets for the storage and delivery of insulin. The Company has viewed its operations and managed 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

Based on the nature of the assets, the Company's short-term investments are classified as either available-for-sale or trading 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 loss as a separate component of stockholders' equity (deficit) on the consolidated balance sheets. Unrealized gains or losses on trading securities are reported as a component of other income or expense within the consolidated statements of operations. 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.

Restricted Cash

The Company recorded $10.0 million of restricted cash as of December 31, 2017, for the minimum cash balance requirement in connection with the Term Loan Agreement (see Note 5, Term Loan Agreement). Due to the full repayment of the term loan in August 2018, no restricted cash balance was required at December 31, 2018.

In January 2018, the Company adopted new guidance from the Financial Accounting Standards Board or the FASB that clarified how entities should classify certain cash receipts and cash payments on the statement of cash flows. As a result, the restricted cash balance that existed in prior periods is included as a component of cash and cash equivalents and restricted cash on the statement of cash flows in the relevant periods presented.

Accounts Receivable

The Company grants credit to various customers in the ordinary course of business. 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 net accounts receivable:

	December 31,	
	2018	2017
Byram Healthcare	15.5%	17.2%
CCS Medical, Inc.	10.1%	16.2%
Edgepark Medical Supplies, Inc.	N/A	17.7%

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

	Year Ended December 31,		
	2018	2017	2016
Edgepark Medical Supplies, Inc.	19.4%	21.5%	18.7%
Byram Healthcare	15.6%	14.0%	14.0%
Solara Medical Supplies, Inc.	N/A	N/A	10.7%
CCS Medical	N/A	10.3%	N/A

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expense, 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 long-term notes payable at December 31, 2017 approximated its carrying value, based on the borrowing rates that were available for loans with similar terms. 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, 2018 and 2017, as discussed in Note 4.

Certain trade-in rights previously offered by the Company pursuant to the Technology Upgrade Program to certain eligible customers were determined to be guarantees under applicable accounting guidance. The Company recorded a liability for the estimated fair value of the guarantees at their inception. The Program expired on September 30, 2017, at which time the remaining guarantee liabilities of $1.1 were recognized as sales.

Valuation of Inventory

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 adjust inventory to its net realizable value, based on 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.

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, 2018.

Deferred Rent

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 when the Company takes possession of the leased property. The difference between rent expense and rent paid is accounted for as deferred rent. The current portion of deferred rent is included in other current liabilities on the Company's consolidated balance sheet. Landlord improvement allowances and other such lease incentives are recorded as property and equipment and as deferred rent and are amortized on a straight-line basis as a reduction to rent expense.

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 product to insulin-dependent diabetes customers. The Company is paid directly by customers who use the products, distributors and third-party insurance payors.

In January 2018, the Company adopted the Revenue from Contracts with Customers Standard which supersedes 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 is not impacted by the new guidance. As a result, on January 1, 2018, the Company recorded a net reduction to accumulated deficit in the amount of $149,000, reflecting 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.

Trade-In Rights

The Company launched a Technology Upgrade Program in 2016, which expired September 30, 2017. The trade-in rights associated with the Program were accounted for as guarantees or rights to return based on specific factors and circumstances, including the period of time the trade-in rights were exercisable, the likelihood that the trade-in rights would be exercised, and the amount of the specified-price trade-in value.

The Company determined that trade-in rights for t:slim G4 Pump customers were generally guarantees. The Company accounted for the guarantees under applicable accounting standards, which require a guarantor to recognize, at the inception of the guarantees, a liability for the estimated fair value of the obligation undertaken in issuing the guarantees. Subsequently, the initial liability recognized for the guarantees was reduced as the Company was released from the risk under the guarantees, which was when the trade-in right was exercised or the right expired. The guarantees were accounted for as an element of a multiple element arrangement. The estimated fair value of the guarantees was based on various economic and customer behavioral assumptions, including the probability that a trade-in right would be exercised, the specified trade-in amount, the expected fair value of the used t:slim G4 Pump at trade-in and the expected sales price of a t:slim X2. Upon expiration of the Program at September 30, 2017, the remaining guarantee liabilities of $1.1 were recognized as sales. There were no guarantee liabilities at December 31, 2018 or December 31, 2017.

The Company determined that t:slim Pump trade-in rights were in-substance rights to return products. Such rights to return were accounted for pursuant to the right of return accounting guidance. As the Company did not have sufficient history to reasonably estimate returns associated with trade-in rights, all eligible t:slim Pump sales between July 2016 and October 2016, which was when the company discontinued new shipments of t:slim, were recorded as deferred revenue until the trade-in right was exercised or the right expired. At December 31, 2018, the Company had no trade-in rights reserve balance. At December 31, 2017, there was $65,000, recorded as a trade-in rights reserve in deferred revenue on the accompanying consolidated balance sheet.

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 upon delivery, while access to the complementary products, such as the t:connect cloud-based data management application and the Tandem Device Updater, are considered performance obligations satisfied over the four-year warranty period of the insulin pumps. There is no standalone value for these complementary products. Therefore, the Company determines their value by applying the expected cost-plus margin approach and then allocates the residual to the insulin pumps. At December 31, 2018 and 2017, $3.8 million and $2.0 million were recorded as deferred revenue for these performance obligations that are satisfied over time.

Product 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 product returns is recorded as a reduction of revenue and accounts receivable in the period in which the related sale is recorded. The amount recorded on the Company's consolidated balance sheets for product return allowance was $0.3 million and $0.2 million at December 31, 2018 and 2017, 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. Warranty costs are estimated based on the current expected replacement product cost and expected replacement rates based on historical experience. The Company evaluates the reserve quarterly and makes adjustments when appropriate. Changes to the actual replacement rates and actual replacement product costs could have a material impact on the Company's estimated liability.

At December 31, 2018 and December 31, 2017, the warranty reserve was $9.1 million and $5.6 million, respectively. The following table provides a reconciliation of the change in estimated warranty liabilities for the years ended December 31, 2018 and 2017:

	December 31,	
(in thousands)	2018	2017
Balance at beginning of the year	$5,640	$5,690
Provision for warranties issued during the period	9,617	5,613
Settlements made during the period	(7,797)	(6,742)
Increases in warranty estimates	1,678	1,079
Balance at end of the year	$9,138	$5,640
Current portion	$4,206	$2,596
Non-current portion	4,932	3,044
Total	$9,138	$5,640

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 2013 Stock Incentive Plan or the 2013 Plan, and shares issued under the Company's 2013 Employee Stock Purchase Plan, or the ESPP, using a Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model requires the use of subjective assumptions including volatility, expected term, and risk-free interest rate. For awards that vest based on service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures based on historical experience.

The Company records the expense for stock option grants to non-employees based on the estimated fair value of the stock options using the Black-Scholes option-pricing model. The fair value of non-employee awards is remeasured at each reporting period as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant.

Warrant Liabilities

The Company accounts for certain 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 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, 2018, 2017 and 2016, advertising costs were $0.9 million, $1.1 million, and $0.9 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.

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.

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 options outstanding under the Company's other equity incentive plans. For warrants that are recorded as a liability in the accompanying consolidated balance sheet, 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 such securities are dilutive to loss per share for the period, an adjustment to net loss used in the calculation is required 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. With the exception of the fourth quarter of 2018, 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. Refer to 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,		
	2018	2017	2016
Warrants for common stock	705	—	—
Common stock options	3,477	—	151
ESPP	4	—	2
	4,186	—	153

Accounting Pronouncements Issued and Not Yet Adopted

In February 2016, the FASB issued ASU 2016-02, Leases or ASU 2016-02. ASU 2016-02 and its related amendments (collectively referred to as ASC 842). The new guidance requires lessees to recognize right-of-use assets and corresponding lease liabilities for all leases with lease terms of greater than twelve months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. In July 2018, the FASB added a transition option for implementation that allows 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 accounting standard must be adopted using the modified retrospective approach and will be effective for the Company starting in the first quarter of fiscal 2019. We have elected the transition option and certain practical expedients, and expect that the adoption of this standard will result in a cumulative-effect transition adjustment for the recognition of right-of-use leased assets and corresponding lease liabilities of approximately $12 million on the consolidated balance sheet as of January 1, 2019 related to lease commitments, which consist primarily of operating leases for facilities, and will not restate prior periods. Deferred rent of $1.0 million and $3.8 million as of January 1, 2019 will be 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 this standard. The Company is finalizing its implementation related to policies, processes and internal controls to comply with the guidance. The January 1, 2019 transition adjustment does not include amounts related to the facility lease entered into in January 2019 (see Note 12, Subsequent Event)

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, or ASU 2016-13, 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 standard is effective for public business entities for annual periods beginning after December 15, 2019, and interim periods within those years. The Company plans to implement the new standard in the first quarter of 2020, and is in the process of reviewing its credit loss models to assess the impact of the adoption of the standard on its consolidated financial statements.

In August 2018, the FASB issued Accounting Standards Update 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. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The Company is in the process of determining the impact the adoption will have on its Consolidated Financial Statements as well as whether to early adopt the new guidance.

In August 2018, the FASB issued ASU 2018-15, Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract, or ASU 2018-15, that changes the accounting for implementation costs incurred in a cloud computing arrangement that is a service contract. The update aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The implementation costs should be presented as a prepaid asset in the balance sheet and expensed over the term of the hosting arrangement. The standard is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2019. Early adoption is permitted. The Company is in the process of assessing the impact of the adoption of the standard on its financial statements.

3. Financial Statement Information

Short-term investments

The Company invests in investment securities, principally debt instruments of the U.S. Government, and 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, 2018 and 2017 (in thousands):

At December 31, 2018	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale investment 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

At December 31, 2017	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Trading securities:					
Mutual funds held for nonqualified deferred compensation plan participants		$ 459	$ 20	$ —	$ 479
Total		$ 459	$ 20	$ —	$ 479

Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31,	
	2018	2017
Accounts receivable	$37,030	$22,071
Less allowance for doubtful accounts, and product returns	(1,837)	(1,278)
Total	$35,193	$20,793

The following table provides a reconciliation of the change in estimated allowance for doubtful accounts for the years ended December 31, 2018, 2017 and 2016 (in thousands):

	Allowance for Doubtful Accounts
Balance at December 31, 2015	$ 221
Provision for doubtful accounts	632
Write-offs and adjustments, net of recoveries	(118)
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

Inventory

Inventory consisted of the following at (in thousands):

	December 31,	
	2018	2017
Raw materials	$6,622	$10,328
Work-in-process	2,710	3,812
Finished goods	10,564	12,853
Total	$19,896	$26,993

Property and Equipment

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

	December 31,	
	2018	2017
Leasehold improvements	$11,313	$13,924
Computer equipment and software	8,745	9,040
Office furniture and equipment	4,415	4,686
Manufacturing and scientific equipment	18,306	17,505
	42,779	45,155
Less accumulated depreciation and amortization	(25,628)	(25,524)
Total	$17,151	$19,631

Depreciation and amortization expense related to property and equipment was $5.5 million, $6.5 million, and $5.2 million for the years ended December 31, 2018, 2017, and 2016, 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. The following represents the capitalized patents at December 31, 2018 and 2017 (in thousands):

	December 31,	
	2018	2017
Gross amount	$3,247	$3,247
Accumulated amortization	(2,117)	(1,790)
Total	$1,130	$1,457
Weighted average remaining amortization period (in months)	42	54

Amortization expense related to intangible assets subject to amortization amounted to $0.3 million for each of the years ended December 31, 2018, 2017, and 2016. The amortization expense is recorded in cost of sales in the consolidated statement of operations. The estimated annual amortization is $0.3 million for periods 2019 through 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, 2018 and 2017, 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, 2018		
	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

	Fair Value Measurements at December 31, 2017		
December 31, 2017	Level 1	Level 2	Level 3

Assets				
Cash equivalents [1]	$ 23,700	$23,700	$ —	$—
Mutual funds held for nonqualified deferred compensation plan participants [2]	479	479	—	—
Total assets	$ 24,179	$24,179	$ —	$—
Liabilities				
Common stock warrants	$ 5,432	$—	$ —	$5,432
Deferred compensation [2]	479	$479	$ —	$—
Total liabilities	$ 5,911	$479	$ —	$5,432

(1) Cash equivalents included money market funds and commercial paper with a maturity of three months or less from the date of purchase. As of December 31, 2017, $13.7 million was included as a component of cash and cash equivalents on the balance sheet, and $10.0 million was classified as restricted cash – long-term.

(2) The deferred compensation plan was directed by the Company and structured as a Rabbi Trust for the benefit of certain executives and non-employee directors. The investment assets of the Rabbi Trust were valued using quoted market prices multiplied by the number of shares held in each trust account. The related deferred compensation liability at December 31, 2017 represented the fair value of the investment assets. The Company cancelled the deferred compensation plan in 2017 and all deferred compensation amounts were distributed to participants during the second quarter of 2018.

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, 2018 and 2017.

Level 3 liabilities at December 31, 2018 and 2017 include the Series A and Series B common stock 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 B warrants had a term of six months 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 and Series B warrants were initially valued in the aggregate amount of $6.5 million on the date of issuance utilizing a Black-Scholes pricing model. As of December 31, 2018, there were Series A warrants to purchase 510,785 shares of common stock outstanding and no Series B warrants outstanding.

The Company reassesses the fair value of the outstanding Series A and Series B 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 common stock warrants at December 31, 2018 and 2017 are presented below:

	Series A Warrants	
	December 31, 2018	December 31, 2017
Risk-free interest rate	3.0 %	2.2 %
Expected dividend yield	0.0 %	0.0 %
Expected volatility	78.3 %	63.5 %
Expected term (in years)	3.8	4.8

	Series B Warrants	
	December 31, 2018	December 31, 2017

Risk-free interest rate	N/A	1.4	%
Expected dividend yield	N/A	0.0	%
Expected volatility	N/A	80.3	%
Expected term (in years)	N/A	0.3	

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, 2018 and 2017:

	2018	2017
Balance at beginning of period	$5,432	$6,453
Increase (decrease) in fair value included in change in fair value of common stock warrants	66,494	(1,021)
Decrease in fair value from warrants exercised during the period	(54,000)	—
Balance at end of period	$17,926	$5,432

5. Term Loan Agreement

In August 2018, the Company fully repaid the term loan made by CRG pursuant to the Term Loan Agreement and terminated the agreement. The term loan was collateralized by all assets of the Company. The balance of the outstanding debt at the time of repayment was $82.7 million. The repayment included approximately $1.1 million in accrued interest and $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, 2018. The Company had aggregate borrowings under the Term Loan Agreement of $82.7 million as of December 31, 2017. Notes payable-long term on the accompanying consolidated balance sheet reflected these aggregate borrowings, offset by a $6.2 million debt discount associated with the financing fees and certain debt issuance costs at December 31, 2017. 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 balance 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.

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 or the PIK Loan to be added to the principal of the loan and subject to accruing interest. Interest-only payments were due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period, which would have ended on December 31, 2019. The principal balance was due in full at the end of the term of the loan, which was March 31, 2020, or the Maturity Date. The Company had elected to pay interest in cash at a rate of 11.5% per annum through September 30, 2015. From October 1, 2015 through December 31, 2017, the Company elected to pay interest in cash at a rate of 9.5% per annum and for a rate of 2.0% per annum to be added to the principal of the loan. As a result, $2.7 million was added to the principal of the loan during that time period, collectively, the PIK Loans.

The Company entered into a series of amendments to the Term Loan Agreement in 2016, 2017 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. The Company treated the execution of each of the Third, Fourth and Fifth Amendments as a modification for accounting purposes. The present value of the future cash flows under these amendments did not exceed the present value of the future cash flows under the previous terms by more than 10%.

At December 31, 2017, the Company had accrued $4.1 million for the financing fee of 5%, which was subsequently increased to $5.0 million, or 6%, in February 2018. These fees were included in other long-term liabilities and as contra-debt in notes payable-long term on the accompanying consolidated balance sheet.

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. 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.

Stock Plans

In September 2006, the Company adopted the Company's 2006 Stock Incentive Plan, or the 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 Stock 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 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.

The Company issued 8,603,321 shares of common stock upon the exercise of warrants, and 136,042 shares of common stock upon the exercise of stock options during the year ended December 31, 2018. The Company did not issue any shares of common stock upon the exercise of warrants, and issued 24,406 shares of common stock upon the exercise of stock options during the year ended December 31, 2017.

As of December 31, 2018, 969,445 shares were available for future issuance under the 2013 Plan, and options to purchase 5,763,192 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, 2016	822,265	$ 84.05	7.92	$ 1,593
Granted	615,067	$ 4.69		
Exercised	(24,406)	$ 11.06		$ 338
Canceled/forfeited/expired	(81,657)	$ 110.21		
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
Vested and expected to vest at December 31, 2018	5,643,473	$ 23.73	8.94	$ 114,547
Exercisable at December 31, 2018	1,215,287	$ 43.40	7.34	$ 25,852

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 (1%) 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, 2017 and 2018, the number of shares of common stock reserved for issuance under the ESPP was automatically increased by 101,194 and 31,096 shares respectively. In the years ended December 31, 2018 and 2017, 80,581 shares and 38,929 shares of our common stock, respectively, were purchased under the ESPP.

The Company announced the suspension of the ESPP as of May 16, 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 as of the suspension date of $2.4 million was fully expensed during the second quarter of 2017. In June 2018, the Company received approval from its stockholders to increase the number of shares reserved for issuance under the ESPP by an additional 2,000,000 shares and to remove the evergreen provision.

In the years ended December 31, 2018 and 2017, 80,581 shares and 38,929 shares of our common stock, respectively, were purchased under the ESPP. As of December 31, 2018, 2,020,626 shares remained available for issuance under the ESPP.

Stock-Based Compensation.

The compensation cost that has been included in the consolidated statement of operations for all stock-based compensation arrangements was as follows (in thousands):

	Year Ended December 31,		
	2018	2017	2016
Cost of sales	$2,581	$1,360	$1,016
Selling, general & administrative	16,824	10,020	9,360
Research and development	4,331	1,248	1,284
Total	$23,736	$12,628	$11,660

The total stock-based compensation capitalized as part of the cost of the Company’s inventory was $0.2 million and $0.2 million at December 31, 2018 and 2017, respectively.

There were no stock option grants to non-employees and no expense during the years ended December 31, 2018, 2017 and 2016.

At December 31, 2018, the total unamortized stock-based compensation expense of approximately $45.3 million will be recognized over the remaining weighted average vesting term of approximately 1.7 years.

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

	Stock Option Year Ended December 31,		
	2018	2017	2016
Weighted average grant date fair value (per share)	$12.94	$2.65	$24.30
Risk-free interest rate	2.8 %	2.1 %	1.7 %
Expected dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	71.4 %	60.8 %	57.5 %
Expected term (in years)	5.7	5.8	5.8

	ESPP Year Ended December 31,	
	2018	2017[1]
Weighted average grant date fair value (per share)	$13.48	N/A
Risk-free interest rate	2.5 %	N/A
Expected dividend yield	0.0 %	N/A
Expected volatility	81.2 %	N/A
Expected term (in years)	1.25	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 continues to use the historical volatility of peer entities 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. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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.

Common Stock Reserved for Future Issuance

The following shares of common stock were reserved for future issuance at December 31, 2018 (in thousands):

Common stock warrants outstanding	804
Stock options issued and outstanding	5,769
Authorized for future option grants	969
Employee stock purchase plan	2,021
	9,563

7. Income Taxes

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

	Year Ended December 31,[1]		
	2018	2017	2016
Income tax benefit at federal statutory rate	$(25,738)	$(24,829)	$(28,362)
State income tax, net of federal benefit	(1,649)	(2,034)	(2,393)
Warrants revaluation	13,964	(347)	—
Research and development credits	(1,425)	(480)	(720)
Stock-based compensation	1,362	3,214	1,686
Tax Cuts and Jobs Acts	—	51,577	—
Other	681	138	456
Change in valuation allowance	12,856	(27,231)	29,318
Income tax expense (benefit)	$51	$8	$(15)

(1) For the year ended December 31, 2018 as a result of the Tax Cuts and Jobs Act, the statutory rate was 21%. For the years ended December 31, 2017 and 2016, the statutory rate was 34%.

Significant components of the Company's net deferred income tax assets at December 31, 2018 and 2017 are shown below (in thousands). A valuation allowance has been recorded to offset the net deferred tax asset as of December 31, 2018 and 2017, as the realization of such assets does not meet the more-likely-than-not threshold.

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss (NOL) carryforwards	$85,761	$81,483
Research and development tax credits carryforwards	4,942	3,517
Capitalized research and development expenses	10,759	12,746
Accrued compensation	13,816	8,809
Other	8,238	4,139
Total deferred tax assets	123,516	110,694
Less valuation allowance	(123,516)	(110,694)
Net deferred tax assets	$—	$—

As of December 31, 2018, the Company has accumulated federal, state and foreign NOL carryforwards of approximately $352.7 million, $313.5 million, and $1.1 million, respectively, not considering the annual limitations of Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, as discussed below. The federal and state tax loss carryforwards begin to expire in 2026 and 2019, respectively, unless previously utilized. The remaining California NOL carry forwards of $183.9 million will expire beginning in 2028. The foreign tax loss carryforwards begin to expire in 2038, unless previously utilized.

The Company also has federal and California research credit carryforwards of approximately $5.7 million and $6.3 million, respectively. 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 Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Shared-Based Payment Accounting ("ASU 2016-09"). ASU 2016-09 simplifies how several aspects of share-based payments are accounted for and presented in the consolidated financial statements. ASU 2016-09 is effective for public companies and was adopted by the Company in 2017. The Company has excess tax benefits for which a benefit could not be previously recognized of approximately $1.8 million. Upon adoption, the balance of the unrecognized excess tax benefits 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 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 started but has not completed an analysis to determine whether its net operating losses and credits generated through December 31, 2018 are likely to be limited by Section 382. Based on preliminary results

of this analysis, the Company anticipates that an ownership change as defined under Section 382 may have occurred in 2018 and that the resulting limitation would significantly reduce the Company’s ability to utilize its net operating loss and credit carryovers before they expire. Additionally, future ownership changes under Section 382 may also limit the Company's ability to fully utilize any remaining tax benefits. The Company's net deferred income tax assets have been fully offset by a valuation allowance. Therefore, any resulting reduction to the Company's net operating loss and credit carryovers once the analysis is complete will be fully offset by a corresponding reduction of the valuation allowance and there would be no impact on the Company's balance sheet, statement of operations, or cash flows.

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, 2018, 2017 and 2016 (in thousands):

	Year Ended December 31,

	2018	2017	2016
Gross unrecognized tax benefits at the beginning of the year	$8,121	$8,167	$7,594
Increases related to current year positions	644	411	580
Increases (decreases) related to prior year positions	59	(457)	(7)
Gross unrecognized tax benefits at the end of the year	$8,824	$8,121	$8,167

As of December 31, 2018, the Company had $7.3 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 statements of operations for the years ended December 31, 2018 and 2017. 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 year ended December 31, 2018, the domestic and foreign components of loss before income taxes were $122.0 million and $1.0 million, respectively. Prior to 2018, 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 December 2017, the Tax Cuts and Jobs Act, or the 2017 Act, was enacted. The 2017 Tax Act includes a number of changes to existing U.S. tax laws that impact the company, most notably a reduction of the U.S. corporate income tax rate from 35 percent to 21 percent for tax years beginning after December 31, 2017. The 2017 Tax Act also provides 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 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, 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 Act will no longer allow 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.

The Act allows Companies to claim bonus depreciation to accelerate the expensing of the cost of certain qualified property placed in service after September 27, 2017 and before January 1, 2024. The Company recognized a provisional increase in net deferred tax liabilities attributable to the accelerated depreciation for certain assets placed into service after September 27, 2017. Due to the valuation allowance, the provisional adjustments have no impact on

income tax expense or income tax payable.

The company recognized the income tax effects of the 2017 Tax Act in its 2017 financial statements in accordance with Staff Accounting Bulletin No. 118, which provides SEC staff guidance for the application of ASC Topic 740, Income Taxes, in the reporting period in which the 2017 Act was signed into law. In accordance with Staff Accounting Bulletin No. 118, as of December 31, 2018, we have completed our accounting for the tax effects of enactment of the Act and no adjustments to the provisional income tax effects were required.

8. Collaborations

DexCom Development and Commercialization Agreement

In February 2012, the Company entered into a Development and Commercialization Agreement (the “DexCom Agreement”) with DexCom, Inc., or DexCom, for the purpose of collaborating on the development and commercialization of an integrated system which incorporates the t:slim Insulin Delivery System with DexCom’s proprietary CGM system.

Between 2012 and 2015, the Company paid to DexCom a total of $3.0 million in licensing fees. Additionally, upon commercialization of t:slim G4, and as compensation for non-exclusive license rights, under the original DexCom Agreement, the Company agreed to pay DexCom a royalty calculated at $100 per integrated system sold.

In September 2015, the Company entered into an amendment to the DexCom Agreement, or the Amendment. Pursuant to the Amendment, in lieu of the $100 royalty payment for each integrated system sold, the Company agreed to commit $100 of each t:slim G4 integrated system sold to incremental marketing activities associated with t:slim G4 integrated systems that are in addition to a level of ordinary course marketing activities or marketing activities to support other Company and DexCom jointly funded development projects. The committed marketing fund is recognized as cost of sales and other current liabilities in the period the related t:slim G4 Pump sale is recorded. The Company recorded such marketing fund commitment of $0.1 million and $1.1 million in the years ended December 31, 2018 and 2017, respectively.

9. Employee Benefits

Employee 401(k) Plan

The Company has a defined contribution 401(k) plan for employees 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

From time to time, the Company may be subject to legal proceedings or regulatory encounters or other matters arising in the ordinary course of business, including actions with respect to intellectual property, employment, product liability and contractual matters. In connection with these matters, the Company regularly assesses the probability and range of possible loss based on the developments in these 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 actions, the Company is currently unable to predict their ultimate outcome, and, with respect to any legal proceeding or claim where no liability has been accrued, to make a meaningful estimate of the reasonably possible loss or range of loss that could result from an adverse outcome. At December 31, 2018 and 2017, there were no legal proceedings, disputes, or other claims for which a material loss was considered probable or for which the amount or range of loss was reasonably estimable.

Operating leases

Under a noncancelable operating lease agreement, or the Existing Operating Lease, the Company leases manufacturing, laboratory and general office spaces in San Diego, California. On December 27, 2017, the Company entered into an amendment to the Existing Operating Lease which terminated the lease with respect to the building located at 11045 Roselle Street as of January 31, 2018, and extended the Existing Operating Lease term for the remaining buildings through May 2022. The building located at 11045 Roselle Street, which primarily housed the Company's manufacturing and related operations, was replaced by a facility located on Barnes Canyon Road in San Diego, California, collectively, the Barnes Canyon Lease. Pursuant to the amendment, the Company has the right to terminate the lease on the remaining buildings 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 the Existing Operating Lease, the Company has a $0.3 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.

On June 30, 2016, the Company entered into the Barnes Canyon Lease. The Barnes Canyon Lease is scheduled to expire in November 2023. The Company will also have a one-time option to extend the term of the lease for a period of not less than 36 months and not greater than 60 months, by delivering notice to the landlord at least nine months and not more than 12 months prior to the expiration of the lease.

The Barnes Canyon Lease allowed for a Tenant Improvement Allowance, or the TI Allowance of up to approximately $3.4 million to be applied to non-structural improvements to the building. Amounts utilized by the Company from the TI Allowance are subject to an interest accrual at a rate of 8.0% per annum and must be repaid in full during the lease term in monthly installments, or the TI Rent concurrently with the base rent. During the years ended December 31, 2017 and 2016, costs incurred for non-structural improvements to the facility were $3.9 million and $1.0 million, respectively, of which $2.6 million and $0.7 million, respectively, were funded by the landlord. The Company retains the right at any time during the lease term to prepay all or any portion of the TI Allowance drawn and outstanding without penalty, in which case the outstanding TI Rent would be reduced to reflect the TI Allowance prepayment and interest would cease to accrue on the prepaid portion of the TI Allowance.

The monthly rent, except TI Rent mentioned above, increases by a fixed percentage each year on the anniversary of the respective rent commencement date of the Existing Operating Lease and Barnes Canyon Lease. The difference between the straight-line expense over the term of the lease and actual amounts paid are recorded as deferred rent. Deferred rent arising from rent escalation provisions and lease incentives totaled $4.8 million and $5.6 million at December 31, 2018 and 2017, respectively. Rent expense for the three years ended December 31, 2018, 2017 and 2016, was $2.6 million, $3.5 million, and $3.1 million, respectively.

Future minimum payments under the aforementioned noncancelable operating leases for each of the five succeeding years following December 31, 2018 are as follows (in thousands):

2019	$2,743
2020	2,858
2021	2,944
2022	1,644
2023	642
Thereafter	—
	$10,831

Not included in the table above is the Barnes Canyon Lease TI Rent, which totaled $0.7 million and $0.4 million during the years ended December 31, 2018 and 2017, respectively. TI Rent will be approximately $0.7 million for each of the years ended December 31, 2019 through 2023.

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 2018 and 2017 is presented in the following table, in thousands, except per share data:

	For the Quarter Ending			
	March 31	June 30	September 30	December 31
2018:				
Revenue	$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]	$(1.82)	$(1.17)	$ (0.62)	$ 0.06
Diluted net income (loss) per share [1]	$(1.82)	$(1.17)	$ (0.62)	$ 0.02
2017:				

Revenue	$18,977	$21,327	$ 27,003	$ 40,294
Gross profit	$6,753	$8,001	$ 11,873	$ 17,468
Operating expenses	$27,979	$26,970	$ 25,039	$ 27,050
Operating loss	$(21,226)	$(18,969)	$ (13,166)	$ (9,583)
Net loss	$(23,792)	$(21,801)	$ (16,034)	$ (11,406)
Basic and diluted net loss per share [1]	$(7.46)	$(4.36)	$ (3.09)	$ (1.23)

(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.

12. Subsequent Event

In January 2019, the Company entered into a lease agreement for 25,332 square feet of additional general administrative office space located at 10935 Vista Sorrento Parkway, San Diego, California. Subject to limited exceptions, the initial lease term is expected to commence on the later of (i) March 1, 2019, or (ii) the date on which the landlord substantially completes certain specified work related to tenant improvements, such date the Commencement Date, and will expire 42 months from the first day of the first full month following the Commencement Date. The Company also has a one-time option to extend the term of the lease for a period of five years by delivering prior written notice to the Landlord in accordance with the terms of the lease. Future minimum payments under the lease, which include reimbursement of certain landlord operating expenses, are approximately $3.5 million.

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, 2018, 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, 2018.

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, 2018, 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, 2018, 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, 2018 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, who is expected to commence serving as our principal executive officer as of March 1, 2019, and Ms. Vosseller, who is currently serving as our principal financial and accounting officer, have informed us that they are involved in a personal relationship. 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, 2018, 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, 2018, 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, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, cash flows and changes in stockholders' equity (deficit) for each of the three years in the period ended December 31, 2018, and the related notes, and our report dated February 26, 2019 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 26, 2019

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 2019 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, 2018, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement 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 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 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 and is incorporated herein by reference.

PART IV

Item 15. Exhibits, 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:

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Report of Independent Registered Public Accounting Firm	79
Consolidated Balance Sheets	80
Consolidated Statements of Operations and Comprehensive Loss	81
Consolidated Statements of Stockholders' Equity (Deficit)	82
Consolidated Statements of Cash Flows	83
Notes to Consolidated Financial Statements	84

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.

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
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	Form of Common Stock Certificate.	S-1/A	333-191601	1-Nov-13	4.1	
4.2	Third Amended and Restated Investors' Rights Agreement, dated August 30, 2012.	S-1	333-191601	7-Oct-13	4.2	
4.3	Form of Warrant to Purchase Stock	S-1	333-216531	8-Mar-17	4.3	
4.4	Form of Preferred Stock Warrant.	S-1	333-191601	7-Oct-13	4.4	
4.5	Form of Series A Warrant to Purchase Common Stock	8-K	001-36189	13-Oct-17	4.1	
4.6	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	10-Q	001-36189	30-Apr-15	10.1	

10.5	Opportunities Partners II L.P. 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*	Retirement and Separation Agreement, dated December 7, 2017, by and between Tandem Diabetes Care, Inc. and John Cajigas.	S-1	333-222553	16-Jan-18	10.24
10.23*	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

10.24*	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-2018	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-2018	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	
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 Kim D. Blickenstaff, 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 Kim D. Blickenstaff, 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/ Kim D. Blickenstaff
Kim D. Blickenstaff
President, Chief Executive Officer and Director
(Principal Executive Officer)

Dated: February 26, 2019

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Kim D. Blickenstaff 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/ KIM D. BLICKENSTAFF Kim D. Blickenstaff	President, Chief Executive Officer and Director (Principal Executive Officer)	February 26, 2019
/s/ LEIGH A. VOSSELLER Leigh A. Vosseller	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 26, 2019
/s/ DICK P. ALLEN Dick P. Allen	Director and Chairman of the Board	February 26, 2019
/s/ EDWARD L. CAHILL Edward L. Cahill	Director	February 26, 2019
/s/ FRED E. COHEN	Director	February 26, 2019

Fred E. Cohen, M.D., D.Phil.		
/s/ HOWARD E. GREENE, JR.	Director	February 26, 2019
Howard E. Greene, Jr.		
/s/ REBECCA ROBERTSON	Director	February 26, 2019
Rebecca Robertson		
/s/ DOUGLAS A. ROEDER	Director	February 26, 2019
Douglas A. Roeder		
/s/ CHRISTOPHER J. TWOMEY	Director	February 26, 2019
Christopher J. Twomey		
/s/ RICHARD VALENCIA	Director	February 26, 2019
Richard Valencia		