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, 2017

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	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 30, 2017, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $30.7 million based on the closing price for the common stock of $8.00 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 23, 2018, there were 44,699,404 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2018 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, 2017, or this Annual Report, contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to considerable risks and uncertainties. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Annual Report, other than statements of historical fact, are forward-looking statements. You can identify forward-looking statements by the use of words such as "may," "will," "could," "anticipate," "expect," "intend," "believe," "continue" or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements. In particular, forward-looking statements contained in this Annual Report relate to, among other things, our future or assumed financial condition, results of operations, liquidity, 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 and sales activities primarily focus on our flagship product, the t:slim X2 Insulin Delivery System, or t:slim X2, which is based on our proprietary technology platform. The simple-to-use t:slim X2 is the smallest durable insulin pump available, and the only pump currently available 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 five insulin pumps since inception, all of which have been developed using our proprietary technology platform. Two of these pumps have featured continuous glucose monitoring technology, or CGM. Since the launch of our first product in August 2012, through December 2017, we have shipped nearly 68,000 pumps to customers in the United States. In 2017, we announced plans to begin commercialization of t:slim X2 in select geographies outside the United States, including Canada, during 2018.

We began commercial sales of our first insulin pump, the t:slim Insulin Delivery System, or t:slim, in August 2012. During 2015, we commenced commercial sales of two additional insulin pumps: t:flex in May 2015 and t:slim G4 in September 2015. In October 2016, we commenced commercial sales of t:slim X2 and discontinued new sales of t:slim. In September 2017, we commenced commercial sales of t:slim X2 integrated with the Dexcom G5 Mobile CGM system, which is manufactured by Dexcom, and discontinued new sales of t:slim G4. In 2017, t:slim X2 represented approximately 95% of our new pump shipments. In September 2017, we also commenced commercial sales of cartridge and infusion set products using our custom t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to our cartridge.

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 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 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 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 beginning in 2018, 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. Although we commenced commercial sales of t:lock in September 2017, we continue to offer cartridges and infusion sets with a standard Luer-lok connector on a limited basis to facilitate customer transition to our new t:lock products.

Each of our insulin pump products is compatible with the Tandem Device Updater, a unique tool that allows our pump users to update their pumps' software quickly and easily from a personal computer. The Tandem Device Updater provides our customers access to new and enhanced features and functionality faster than the industry has been able to in the past. Its first cleared use by the U.S. Food and Drug Administration, or the FDA, was to update t:slim pumps purchased before April 2015 to the latest software. In September 2017, we set a new standard of care in our industry by offering all existing t:slim X2 customers integration with the Dexcom G5 Mobile CGM system through a software update using the Tandem Device Updater. Within the first 30 days following the FDA approval of this update, more than 30% of t:slim X2 customers who purchased their pump prior to its availability had updated their pump. By the end of 2017 more than 40% of t:slim X2 customers had updated their pump and now have access to Dexcom G5 Mobile CGM integration. In October 2017, we announced that, subject to FDA approval, we intend to make any new features approved by the FDA in 2018 available to all in-warranty users of t:slim X2 at no cost through the Tandem Device Updater. In the future, this tool has the potential to enable users to add other new features and functionality to their pumps, such as automated insulin delivery algorithms, or AID algorithms, independent of the typical four-year insurance pump replacement cycle.

Our innovative approach to product design and development is consumer-focused and based on our extensive market research, as we believe the user is the primary decision maker when purchasing an insulin pump. Our market 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. By doing so, we seek to optimize our products, which allows for them to be successfully operated by users in their intended environment.

We have developed our products to provide the specific features people with insulin-dependent diabetes and healthcare providers seek in a next-generation insulin pump. Our use of modern consumer technologies, and a proprietary pumping technology, has allowed us to design the slimmest and smallest durable insulin pump on the market, without sacrificing insulin capacity. t:slim X2 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 lead screw driven syringe mechanism. It also features an easy-to-navigate software architecture, a vivid color touchscreen, an advanced Bluetooth radio capable of communicating with multiple compatible devices, such as a CGM sensor, blood glucose meter or mobile applications, and a micro-USB connection that supports a rechargeable battery, software updates through the Tandem Device Updater, as well as uploads to the t:connect Diabetes Management Application, or t:connect. t:connect is our custom cloud-based data management application that provides our customers and healthcare providers a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters.

Based on customer surveys, approximately half of our customers are new to insulin pump therapy, and the average age of our existing customers is 31 years old, with relatively equal distribution between men and women. Of the customers who converted from another manufacturers' pump, the greatest percentage converted from Medtronic, followed by Animas. However, in the fourth quarter of 2017, we did see a meaningful increase in our sales to former Animas pump users.

Between July 2016 and September 2017, we offered a Technology Upgrade Program to provide eligible customers a pathway to ownership of a t:slim X2. During the term of the Program, depending on the type of pump sold, we were required under accounting principles generally accepted in the United States of America, or GAAP, and related guidelines to defer some or all of the sales and cost of sales until a later date. This prevented us from recognizing up to 100% of the sales and cost of sales associated with the sale of our t:slim and t:slim G4 insulin pumps to eligible customers at the time of shipment. In general, the deferrals required by the Program had the effect of initially decreasing our sales, particularly in the second half of 2016, even when the number of our pump shipments increased, then benefiting our sales at the conclusion of the Program in 2017.

For the years ended December 31, 2017, 2016 and 2015, our sales were $107.6 million, $84.2 million, and $72.9 million, respectively. For the years ended 2017, 2016 and 2015, our net loss was $73.0 million, $83.4 million, and $72.4 million, respectively. For the year ended December 31, 2017, we recorded incremental net sales of $5.0 million with a corresponding increase in gross profit of $3.1 million as a result of our Technology Upgrade Program. For the year ended December 31, 2016, we recorded net sales deferrals of $4.3 million and recognized an additional net cost of sales of $0.3 million as a result of our Technology Upgrade Program. Pump sales accounted for 66%, 74%, and 83% of sales, respectively, for the years ended December 31, 2017, 2016 and 2015, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in any of these periods. Our accumulated deficit as of December 31, 2017 and December 31, 2016 was $477.6 million and $404.6 million, respectively.

We have rapidly increased sales since our commercial launch by expanding our sales, clinical and marketing infrastructure, by developing, commercializing and marketing multiple differentiated products that utilize our proprietary technology platform and consumer-focused approach, and by providing strong customer support. In our research, approximately 86% of healthcare providers surveyed believe that providing great customer support is the most important attribute in an insulin pump manufacturer. 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. 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 a pathway to our future innovations through the Tandem Device Updater, as they are approved by the FDA. As we continue to develop differentiated products based on our proprietary technology platform, our strategy is to leverage a single sales, marketing and clinical organization, a shared manufacturing and supply chain infrastructure, and the expertise of our customer support services.

Our headquarters and our manufacturing facility are located in San Diego, California and we employed 574 full-time employees as of December 31, 2017.

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. Insulin injections are often referred to as MDI and involve the use of syringes or insulin pens to inject insulin into the person's body. Insulin pumps are used to perform what is often referred to as continuous subcutaneous insulin infusion, or insulin pump therapy, and typically use a programmable device and an infusion set to administer insulin into the person's body.

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. Insulin pump therapy, by comparison, 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 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
Multiple Daily Injection, or MDI	• Less training and shorter time to educate • Less cost • Lower risk of technological malfunction	• Requires injections up to seven times per day • Delivers insulin less accurately than insulin pumps • 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 • Delivers insulin more accurately and precisely than injections • Often improves HbA1c, a common measure of blood glucose levels over time • Fewer large swings in blood glucose levels • 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	• Requires intensive education on insulin pump therapy and management • Wearing a pump can be bothersome • More costly • Risk of diabetic ketoacidosis if the catheter comes out and insulin infusion is interrupted

According to the American Diabetes Association, it is estimated that 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.

Insulin pump therapy can provide a person with insulin-dependent diabetes with benefits when used independently or in conjunction with CGM. A pump featuring integrated 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.

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 market research, through which we seek to better understand the opportunity within the insulin-dependent diabetes market. 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, as we believe the user is the primary decision-maker when purchasing an insulin pump. 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, such as a pager, 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.

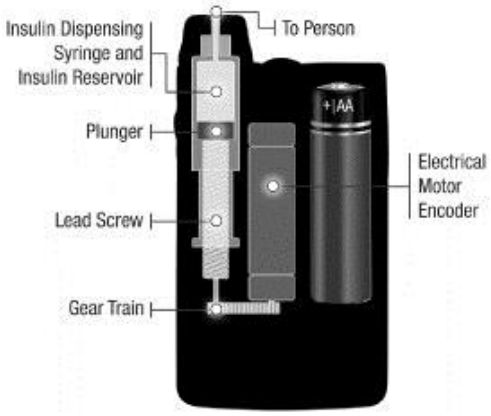
Not adaptable. Traditional pumps are typically sold as a single-product offering that are then iterated to add features, rather than being designed as a technology platform that is easily updatable to support new features and functionality as they are developed and approved by the FDA. We believe this 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, leading 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. 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 advanced pump 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 extensive market 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 those specific demands. 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. We believe this approach is fundamentally different from the historical approach applied to the traditional medical device development process. 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 t:lock. We expect to continue to utilize this approach as we develop new product offerings and innovations.

Our next generation flagship product, 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.

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

Adaptable platform. The 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. t:slim X2 is also compatible with the Tandem Device Updater, which is a tool that allows pump users to update their pumps' software quickly and easily from a personal computer. This tool uniquely positions us to bring new features and benefits, such as CGM integration or AID algorithms, to customers within their typical four-year insurance pump replacement cycle. 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, 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, t:slim X2 is at least 25% smaller than all other durable insulin pumps available in the United States, and 38% smaller than the newest insulin pump form factor offered by one of our leading competitors. t:flex offers a similar sleek pump form factor, while utilizing a cartridge with 480 units of insulin, providing enhanced flexibility to people with greater insulin needs. The size and shape of our products are 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. 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.

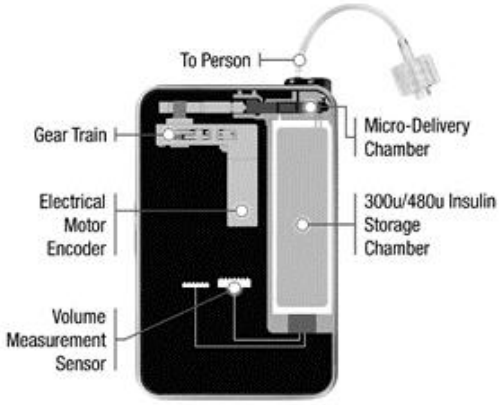
t:simulator App Accessible Through Mobile Device

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. We believe these features 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

Our insulin pumps feature 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 advancements in AID and the potential for further 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. By continually conducting market research to determine what people with insulin-dependent diabetes and healthcare providers desire from insulin therapy, and offering an adaptable insulin pump that can provide features and functionality to respond to evolving needs and preferences, we believe we are uniquely positioned to address differentiated segments of the insulin-dependent diabetes market. At the same time, by rapidly innovating and offering new product features and benefits through the t:slim X2 platform, and Tandem Device Updater, we are also able to leverage a single sales, marketing and clinical organization, a shared manufacturing and supply chain infrastructure, and the expertise of our customer support services.

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

Drive adoption of our products through our sales, marketing and clinical infrastructure. We have achieved commercial success by investing in the development of our 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 Dexcom G5 Mobile CGM integration, to primarily the same healthcare providers as our previous pump products, thereby increasing our efficiency. We are also leveraging our infrastructure to launch reusable supplies that utilize the t:lock, which has substantially increased our sales of infusion sets over the past year. We believe our early 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.

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 sales and marketing force, together with our clinical 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 analyzed from t:connect suggests that use of our pump products may provide users with improved clinical outcomes. For example, in a recent study, we compared retrospective user data from 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. Another recent study demonstrated a reduced risk of hypoglycemia associated with use of our pumps compared to other methods of diabetes therapy, as well as a statistically significant reduction in ambulance rides due to severe hypoglycemia and in days spent at the hospital due to severe hypoglycemia. In addition, we are actively involved in multiple clinical trials supporting the use of our AID products in development, which were 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 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. Subject to obtaining future FDA approvals, we intend to leverage the t:slim X2 platform to allow users to update their pumps' software to include AID algorithms, which also eliminates the need for disruptive and costly trade-in programs to upgrade hardware to newer platforms. We also intend 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 to allow the integration of our insulin pumps with Dexcom's CGM systems, and a license agreement with TypeZero Technologies, LLC, or TypeZero, to allow the integration of TypeZero's inControl 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 market 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 science of human factors throughout the design, development and continuous improvement of our products to optimize our products for intended users. 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 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 doubles our previous manufacturing capacity for both insulin pumps and cartridges and expands warehousing for additional infusion set supplies related to the launch of our t:lock. The facility is also designed to maximize efficiencies in our manufacturing processes and workflows, and allow us to further expand our production capacity by replicating our production lines, without significantly increasing the cost of overhead from our facilities. 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 to support new features as they are approved by the FDA, which we expect will create additional manufacturing efficiencies.

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 unique compared to traditional pumps. Our miniaturized pumping mechanism allows us to reduce the size of the pump as compared to traditional pumps. Reducing the size of the pumping mechanism also allows us to support various insulin cartridge capacities. It was 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. The flexible software architecture also facilitates updates to the software through the Tandem Device Updater 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 we provide with the pump. 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 at least 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 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. Our 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. Additionally, our platform enables rapid data uploads through a micro-USB connection, without interrupting insulin delivery.

Our Products

We have commercially launched five insulin pumps since inception, all of which have been developed using our proprietary technology platform. We began commercial sales of our first insulin pump, t:slim, in 2012. During 2015, we commenced commercial sales of t:flex and t:slim G4. In 2016, we commenced commercial sales of t:slim X2 and discontinued new sales of t:slim. In September 2017, we commenced commercial sales of t:slim X2 integrated with the Dexcom G5 Mobile CGM system and discontinued new sales of t:slim G4.

Commercial Products

Our Insulin Pump Products

Since the launch of our first product in August 2012, through December 2017, we have shipped nearly 68,000 pumps to customers in the United States. Today, our commercial efforts primarily focus on the manufacturing and sale of t:slim X2, although we continue to offer t:flex for people with greater insulin needs. Our insulin pumps feature 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. Our insulin pumps also feature a Home Screen button that immediately returns the user 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, our insulin pumps allow 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, our insulin pumps share important common features, including a black aluminum case and chrome trim, that give them the look and feel of a modern consumer electronic device, such as a smartphone. Our insulin pumps are also watertight, with an IPX7 rating, eliminating concerns about accidentally getting it wet. Each device also features a micro-USB connection that supports charging the lithium-polymer battery, software updates through the Tandem Device Updater, and rapid data uploads to t:connect.

t:slim X2 Insulin Delivery System

Our next-generation flagship product, the t:slim X2 Insulin Delivery System, is comprised of a t:slim X2 pump, its 300-unit disposable insulin cartridge and an infusion set. 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. t:slim X2 features new hardware advancements, including a two-way Bluetooth wireless technology radio for communicating with more than one external device at a time.

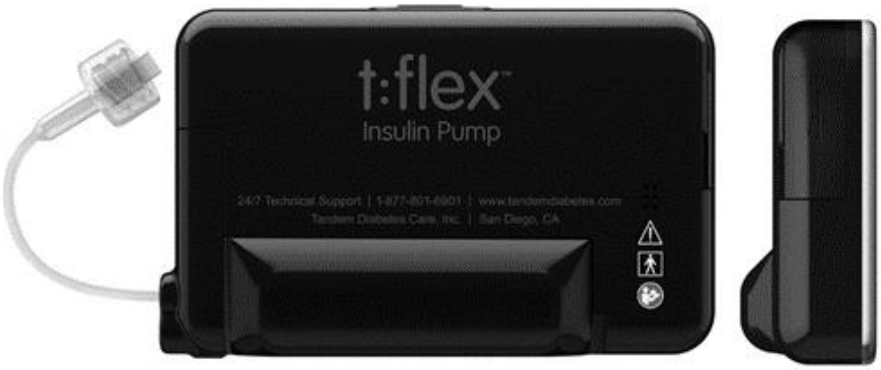
300-unit Insulin Cartridge being inserted into t:slim X2 Pump

We have a development and commercialization agreement with Dexcom, which provides us a non-exclusive license to integrate our product platform with the Dexcom G5 Mobile CGM System. CGM is a therapy that provides users with real-time access to their glucose levels as well as trend information. Following approval by the FDA, we began offering Dexcom G5 Mobile CGM integration on the t:slim X2 platform, or t:slim with G5, in the third quarter of 2017, at which point we ceased sales of t:slim G4. t:slim X2 with G5 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.

t:slim X2 with G5 is the only insulin pump available with Dexcom G5 Mobile CGM integration and is the first SAP approved to let users make treatment decisions without pricking their finger. We believe that these advancements, together with future anticipated applications of the Tandem Device Updater, have the potential to enable users to add new features and functionality, such as AID algorithms, to their pumps independent of their typical four-year insurance pump replacement cycle.

t:flex Insulin Delivery System

The t:flex Insulin Delivery System is comprised of a t:flex pump, its 480-unit disposable insulin cartridge and an infusion set. We began commercial sales of t:flex in the United States in the second quarter of 2015.



t:flex Insulin Pump

People with insulin-dependent diabetes require different amounts of insulin based on their level of insulin sensitivity, which can vary significantly from person to person. t:flex is designed for individuals who require more than 100 units of U-100 insulin per day on MDI or more than 80 units per day using a pump, such as teenagers with type 1 diabetes and many people with type 2 diabetes. t:flex incorporates the same technology platform as the original t:slim, but offers a 480-unit insulin reservoir, the largest capacity currently approved in the United States. This provides users the benefits of pump therapy without the frequent cartridge changes required by 200- and 300-unit capacity pumps. The insulin cartridge used in t:flex extends out slightly on one side to accommodate the extra volume while maintaining all of the other benefits of t:slim, including its slim and sleek appearance.

In our market research, two-thirds of endocrinologists cited limited volume capacity as the number one barrier to pump adoption for their patients with type 2 diabetes who use daily rapid-acting insulin. Our research also has shown that the appearance and bulky size of traditional pumps is a deterrent to pump adoption for people with greater insulin needs We believe that offering a 480-unit cartridge, combined with the other features and benefits offered by our technology platform, addresses many of the common barriers to pump therapy for a person with type 2 diabetes who is insulin-dependent.

Our Complementary Products

Tandem Device Updater

Our insulin pumps are compatible with the Tandem Device Updater, a revolutionary new 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 works with our insulin pumps 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 our pump products.

The first use of our Tandem Device Updater was for deployment of the latest t:slim software to in-warranty t:slim pumps purchased before April 2015. In September 2017, we set a new standard of care in our industry by offering all existing t:slim X2 customers integration with the Dexcom G5 Mobile CGM system through a software update using the Tandem Device Updater. Within the first 30 days following the FDA approval of this update, more than 30% of t:slim X2 customers who purchased their pump prior to its availability had updated their pump. By the end of 2017 more than 40% of t:slim X2 customers had updated their pump and now have access to Dexcom G5 Mobile CGM integration.

In October 2017, we announced that, subject to FDA approval, we intend to make any new features approved by the FDA in 2018 available to all in-warranty users of t:slim X2 at no cost through the Tandem Device Updater. In the future, this tool has the potential to enable users to add other new features and functionality to their pumps, such as 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 as we obtain regulatory approval for their commercialization.

t:connect Diabetes Management Application

We commercially introduced the t:connect Diabetes Management Application, or t:connect, our cloud-based data management application, in the first quarter of 2013. It provides users, their caregivers and their healthcare providers a fast, easy and visual way to display 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 for marketing purposes and third-party payors. 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 smart 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. While our insulin pumps hold the data generated over a period of up to 90 days, once a user uploads their therapy management information to t:connect, the information is retained in their account. t:connect maintains the highest standards of patient data privacy and is hosted on secure servers that are compliant with the Health Insurance Portability and Accountability Act of 1996, or HIPAA.

In 2017, we launched 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, which we refer to as t:connect HCP. This application allows a healthcare provider to establish a separate account that centralizes t:connect data from all of their enrolled patients.

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 was designed to address the most requested improvement to our products that we have received from customers. It 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. We are offering our customers the same choice in infusion set configurations as they were able to purchase from us previously, but with the added benefits associated with our t:lock. We continue to offer both the original Luer-lok connector and our t:lock concurrently for a period of time to facilitate the transition, and by the end of 2017 our infusion sets and cartridges were being sold on a one-to-one basis. The transition to our t:lock resulted in a substantial increase in our sales of infusion sets in 2017, particularly in the third and fourth quarters, which we anticipate will continue in 2018. We intend to continue to invest in the development of enhancements to 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, 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: 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.

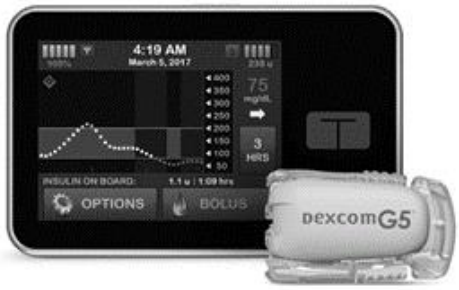
Automated Insulin Delivery Systems

An AID system generally involves an external device, or combination of devices, intended to aid a person with insulin-dependent diabetes by automatically testing and controlling their blood glucose through the administration of insulin by itself or in combination with a second hormone. This may be achievable by combining an insulin pump and a CGM with computer software that allows the two devices to automatically communicate to determine and provide the right amount of insulin, or insulin plus another hormone, at the correct time.

We have supported leading researchers at facilities such as the University of Virginia, Boston University, Massachusetts General Hospital and Stanford University by providing pump hardware and software to advance development of AID solutions. More recently, we commenced clinical trials of our own products under development with embedded AID systems.

t:slim X2 with Basal IQ

The t:slim X2 with Basal IQ is designed to utilize Dexcom G5 sensor values to adjust the rate of insulin delivery to help minimize the frequency and/or duration of hypoglycemic events. The algorithm was developed internally in consultation with clinical thought leaders in AID research. In our market research, a predictive low glucose suspend, or PLGS, algorithm was reported as the most valuable AID feature among people with insulin-dependent diabetes and their healthcare providers.



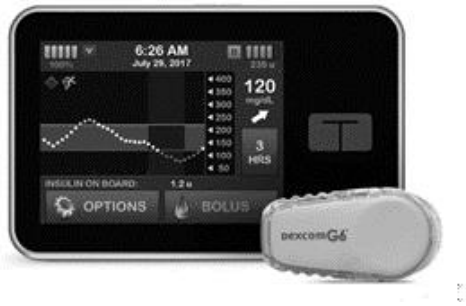
t:slim X2 with Basal IQ

We previously referred to this system under its development name, the t:slim X2 with PLGS and, following FDA approval, intend to market this product under the name t:slim X2 with Basal IQ. During 2016, we completed a feasibility study of our PLGS algorithm. The data from this feasibility study was used in an IDE submission for a pivotal study, which was approved by the FDA in May 2017. We completed a pivotal study for our t:slim X2 with Basal IQ in January 2018. Results from this study 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 results of the pivotal study were used in our PMA that was submitted to the FDA in late February 2018. Subject to future FDA approval, our goal is to launch the t:slim X2 with Basal IQ in the summer of 2018.

t:slim X2 with Control IQ

Our second generation AID system is expected to integrate the t:slim X2 pump with a combination of Dexcom's G6 sensor and AID technology that we licensed from TypeZero. TypeZero's technology includes a series of algorithms developed from research initially conducted at the University of Virginia. To date, this technology has been used in more than 30 clinical studies including more than 450 participants and the data has been referenced in a number of journal articles.

We previously referred to this system under its development name, the t:slim X2 with TypeZero and, following FDA approval, intend to market the product under the name t:slim X2 with Control IQ. This hybrid closed loop product will be differentiated from competing products, as we expect it will provide automated correction boluses, which we believe will bring additional benefits to our customers. In our market research, people with insulin-dependent diabetes and their healthcare providers reported a strong preference for t:slim X2 with Control IQ as compared to a competitive AID system.



t:slim X2 with Control IQ

In November 2016, we announced that we are working with Dexcom and TypeZero on the integration of our technologies into the IDCL Trial. We anticipate that a portion of the trial will utilize a t:slim X2 integrated with TypeZero's inControl AID algorithms, which is designed to automatically adjust a person's insulin based on information received from a Dexcom G6 sensor. We intend to use the results from this portion of the trial in a PMA submission with the FDA. We also anticipate conducting one or more targeted pediatric studies in a summer or winter camp setting for a future regulatory submission. Subject to both the timely completion of the IDCL Trial with a satisfactory outcome and future FDA approval, our goal is to launch this product in the first half of 2019.

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 low-cost 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 in 2018 we plan to conduct research on the use of insulin concentrates to provide people with greater insulin needs an alternative to t:flex. We are also evaluating offering a 300-unit cartridge alternative. We anticipate that t:sport will utilize a pumping mechanism that differs from our current Micro-Delivery technology and will be controlled through a separate controller or mobile device application.

t:sport Shown with Touchscreen Controller

In 2016, we began 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 believe that controlling a pump via an unrestricted mobile device will be a longer path to market, and as a result, 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 conducting clinical trials in 2019 and our goal is to launch this product in 2020 or 2021.

Connected (Mobile) Health Offerings

We are currently developing a mobile application designed to utilize the capability of the Bluetooth radio, which is already built into our pumps, 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. We intend to launch the first generation of our mobile application in mid-2018, with a subset of these features.

Mobile Application

Sales and Marketing

Our sales and marketing objectives are to:

- generate demand and acceptance for our current product offerings and future products developed with 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, 2017, 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 endocrinologists, nurse practitioners, primary care physicians, certified diabetes educators and potential customers. Where appropriate, some territories are supported by multiple clinical diabetes specialists. Our 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 a new pump purchasing decision. Typically, 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. 2017 was our first full year with customers eligible for renewal. Trend data suggests that we will achieve our renewal rate goal in the longer term, based on renewal purchases by our earliest customers. However, factors such as the timing of competitive product launches, regulatory approvals, advancements in diabetes therapy alternatives, and other market dynamics may impact the rate of renewal purchases.

As our market penetration continues to build momentum, and as we launch new products into the market, we may consider further expanding our sales, clinical and marketing infrastructure in the United States; however, no territory expansions are anticipated in 2018. We plan to begin commercialization of t:slim X2 outside the United States in select geographies, including Canada, during 2018. Unlike our approach domestically, with the exception of Canada, we currently plan to partner with distributors who will carry out the selling efforts, as well as the service and support of customers in geographies outside the United States. Currently, we anticipate having a direct sales and clinical infrastructure in Canada beginning in 2018, with customer support and services shared with our domestic organization. We may also elect to partner with distributors in Canada as needed.

For the year ended December 31, 2017, we made sales to approximately 35 independent distributors in the United States, with sales to Edgepark Medical Supplies, Inc. and Byram Healthcare accounting for 21.5% and 14.0% of our sales, respectively. For the year ended December 31, 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.

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

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;

- 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

- partnerships with third-party diabetes management systems for the display of Tandem pump data, including diasend Clinic and Tidepool.

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 launch of t:slim X2 with G5, our marketing also emphasizes the greater accuracy of the Dexcom G5 Mobile CGM over competitive products. Some of our recent consumer-focused marketing initiatives include:

- participation at consumer-focused regional diabetes conferences and events including the 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. Our “touch simplicity” marketing campaign highlights the slim touchscreen design and easy-to-navigate software associated with our pump products. 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 will Discontinue the Manufacture and Sale of Insulin Pumps

In October 2017, Johnson & Johnson announced that it intends to discontinue the operations of Animas, and exit 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. As part of this transition, Medtronic is offering a portion of Animas customers the option of acquiring a prior-generation Medtronic insulin pump, the 630G, 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. While this announcement represents a significant change within our industry, it is too early to know how it will influence our business or the competitive landscape in which we operate over the longer term. More recently, in the fourth quarter of 2017 we experienced an increase in our percentage of sales to people who reported switching from using an Animas pump. However, the largest 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. The potential impact on our business of this announcement is uncertain, although we expect it may be dependent on one or more of the following factors:

- The offer to Animas customers for a free Medtronic 630G pump is currently limited to customers with a warranty expiration date later than September 30, 2019, and the offer is not available until May 2018. 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. According to recent surveys from dQ&A, when making renewal decisions, Animas customers have historically chosen their pump or a Tandem pump rather than a Medtronic offering. Recent surveys from dQ&A have also shown that only 9% of patients acquiring a Medtronic pump during the past six quarters were previous Animas customers, and 79% of new purchasers of Medtronic pumps were customers who upgraded from a current Medtronic pump rather than switching from an alternative brand. For these reasons, and based on our own customer data that shows a high number of customers switching to our products from an Animas pump, 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.

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 consists of individuals focused on training, technical services and insurance verification. 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 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. 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 G5, we offer online training on the use of the 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. We anticipate using similar online training modules for t:slim X2 with Basal IQ. 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 for t:slim X2 with Basal IQ. 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 our t:slim X2 with Basal IQ 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 our AID systems will be 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 we may see similar trends as we launch our new AID systems in the future.

Our customer-focused technical services team provides support seven days a week, 24 hours a day by answering questions, troubleshooting and addressing issues or concerns for both the pump and CGM components of our systems. 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.

Insurance Verification. Our insurance verification team provides support to help 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 distributors, ongoing supplies are typically also arranged through the distributor.

Third-Party Reimbursement

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. We currently bill for all of 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. 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.

As of December 31, 2017, we had entered into commercial contracts with approximately 176 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, 2017, approximately 25% of our sales 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, 2017, we had executed distributor agreements with approximately 35 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, effective July 1, 2016, UnitedHealthcare designated one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18. 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.

Manufacturing and Quality Assurance

We currently manufacture our products at our facilities 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. We expect this facility will double our manufacturing capacity for insulin pumps and cartridges, provide additional production capacity for new products under development and expand warehousing for additional infusion set supplies related to the launch of our t:lock, 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 do not expect significant capital expenditures in our manufacturing operations.

Site inspections of the Barnes Canyon facility by the FDA and the California State Food and Drug Branch were completed in 2017. Following the FDA inspection, we received 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 review the observations during its next regularly scheduled inspection of our facilities. It is possible that the FDA will conclude that our corrective and preventive actions are inadequate.

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. Disposable cartridges are manufactured on a production line that requires 12 manufacturing operators and limited support staff, and reaches a maximum output of approximately 1.0 million cartridges per year on a single shift. We continue to improve the efficiency of our disposable cartridge manufacturing process. For instance, in 2017, we began manufacturing t:flex cartridges primarily using the same semi-automated manufacturing equipment used in the manufacture of t:slim X2 cartridges, and reduced the number of operators required to operate a production line.

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. 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. Typically, our outside vendors produce components to our specifications and in many instances to our designs.

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 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. The agreement is effective until the patents covered by the agreement have expired, but also contains customary provisions for termination in the event of an uncured material breach.

Research and development costs were $20.7 million, $18.8 million, and $17.0 million for the years ended 2017, 2016 and 2015, respectively.

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, 2017 our patent portfolio consisted of approximately 58 issued U.S. patents and 49 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 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, 2017, 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 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 is currently undergoing 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. In October 2017, Johnson & Johnson announced that it intends to discontinue the operations of Animas and exit the insulin pump business entirely, and that it has designated Medtronic as a preferred partner to facilitate the transition of Animas insulin pump customers. Most recently, in late 2017, Eli Lilly & Co. announced that it is developing an insulin pump with AID technology that it intends to launch in the next two to three years. However, it is difficult to predict the potential impact of these changes on our competitive landscape.

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, corresponding state regulatory authorities and, if we commence international sales, other regulatory bodies in other countries. 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 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 received FDA approval as a Class III device.

We first obtained 510(k) clearance for t:slim in November 2011. Subsequently, in October 2014, we received 510(k) clearance for the updated t:slim, which included software modifications for feature enhancements. t:slim is one of the first insulin pumps to be cleared under the FDA’s Infusion Pump Improvement Initiative. Infusion pumps are one of the most commonly recalled categories of medical devices, often as a result of deficiencies in device design and engineering. The Infusion Pump Improvement Initiative is intended to improve the current pre-market and post-market regulatory processes and requirements associated with infusion pumps and other home use medical devices. As part of this effort, the FDA continuously reviews adverse event reporting and recall processes for insulin pumps.

We obtained 510(k) clearance for t:connect in February 2013 and for t:flex in January 2015. In September 2015, we received approval of our PMA for t:slim G4. In July 2016, we received FDA clearance for the Tandem Device Updater. Also in 2016, we received FDA clearance for an expanded pediatric indication for t:slim and t:slim X2, lowering its use to children ages six and older from children ages 12 and older.

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;

- 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, also 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. 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 compliance with applicable state regulations regarding licensure requirements, if we were found to be noncompliant, we could 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 compliance with all 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 anti-kickback laws and physician self-referral 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.

Federal Anti-Kickback and Self-Referral Laws. The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, 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. The definition of "remuneration" has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at less than its fair market value. HHS has issued regulations, commonly known as safe harbors, that set forth certain provisions which, if fully met, will result in the transaction or arrangement being exempt from scrutiny under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued, but that the facts and circumstances of such arrangement or transaction may be reviewed on a case by case basis to determine if an intent to violate the Anti-Kickback Statute is present. Thus, arrangements and transactions that do not fully satisfy each element of an applicable safe harbor carry an increased risk of scrutiny by government enforcement authorities.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to five years, criminal fines of up to $25,000 per violation, civil fines of up to $50,000 per violation plus treble damages, and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare, Medicaid and other federal healthcare programs. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or PPACA, amends the intent requirement of the federal Anti-Kickback Statute and certain other criminal healthcare fraud statutes. An individual or entity no longer is required to have actual knowledge of a particular statute or specific intent to violate it. PPACA also provides that claims submitted in violation of the Anti-Kickback Statute automatically constitute false claims for purposes of the False Claims Act.

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.

Federal law also includes a statute commonly known as the "Stark Law," which 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. The term "financial relationship" is very broadly defined to include ownership or investments interests, as well as compensation arrangements. CMS has issued numerous exceptions to the Stark Law. The prohibition on referrals of designed health services does not apply when the financial relationship created by an arrangement or transaction meets all of the requirements of an applicable exception. Many states have also enacted statutes similar to the federal 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.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. As a result, our provider and training arrangements may ultimately be found to not comply with applicable federal 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 Federal False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits under the Federal False Claims 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.

On November 2, 2015, President Obama signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which provides for adjustments to civil money penalties. In particular, the 2015 legislation provided for an initial "catch up" adjustment, followed by annual adjustments thereafter. For violations of the False Claims Act that occurred on or before November 2, 2015, and for violations of the False Claims Act occurring after November 2, 2015 for which civil money penalties were assessed prior to August 1, 2016, penalties include fines ranging from $5,500 to $11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the false claim. For civil money penalties assessed after August 1, 2016, and on or before February 3, 2017, for violations of the False Claims Act occurring after November 2, 2015, penalties include fines ranging from $10,781 to $21,563 per claim, plus three times the amount of damages that the federal government sustains because of the false claim. Finally, for civil money penalties assessed after February 3, 2017 for violations of the False Claims Act that occurred after November 2, 2015, penalties include fines ranging from $10,957 to $21,916.

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 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.

Civil Monetary Penalties Law. The Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from federal healthcare programs. We believe that our arrangements comply with the requirements of the Federal Civil Monetary Penalties Law.

State Fraud and Abuse Provisions. Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act. We believe that we are in 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.

Health Insurance Portability and Accountability Act of 1996. HIPAA is commonly referred to in reference to the rules pertaining to security and privacy of protected health information. However, 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.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also set forth privacy and security rules. The privacy rules protect medical records and other personal health information (known as protected health information or PHI) by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own PHI and limiting most use and disclosures of PHI to the minimum amount reasonably necessary to accomplish the intended purpose. The security rule protects PHI by requiring appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity and security of such PHI. If we, or any of our service providers who have access to our PHI, are found to be in violation of the privacy and security rules under HIPAA and HITECH, 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 rules under HIPAA. However, even HIPAA compliant entities can experience security breaches resulting in potential liability under 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.

U.S. Foreign Corrupt Practices Act. The U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making corrupt payments, gifts or transfers to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA would include interactions with certain healthcare professionals in many countries.

International Regulation

We are evaluating international expansion opportunities. 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.

During the fourth quarter of 2017, we completed both the self-assessment and the third-party assessment of our operations by a Notified Body. Based on the outcome of those assessments, we anticipate receiving CE marking of our existing products in the first half of 2018, and beginning the commercialization of products outside the United States in the second half of 2018. This includes beginning direct commercial activities in Canada. Marketing our products in Canada requires regulatory approval of our products from Health Canada. We filed our medical device license application with Health Canada in February 2018. The timing of our international launch will remain dependent on other activities, including our completion of appropriate translations for our products and associated materials, software updates to our pump products to allow for alternative units of measurement and a 24 hour clock, our ability to commence manufacturing of our products for use outside the United States, and our entering into distribution agreements with third party distributors in the relevant geographies.

Employees

As of December 31, 2017, we had 574 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.

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.

Our filings may also be read and copied at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an internet site at *www.sec.gov* that contains periodic and current reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

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, 2017, we had an accumulated deficit of $477.6 million. To date, we have financed our operations primarily through public and private sales of our equity securities, debt financing with Capital Royalty Partners II, L.P. and its affiliated funds, or Capital Royalty Partners, and sales of our products. We have devoted substantially all of our resources to the 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. We began commercial sales of t:flex in the second quarter of 2015 and t:slim G4 in the third quarter of 2015. In October 2016, we discontinued new shipments of t:slim and launched t:slim X2, our next-generation flagship pump. In August 2017, we commenced commercial sales of t:slim X2 with G5 integration and discontinued new sales of t:slim G4. 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, 2017 and 2016, our gross profit was $44.1 million and $23.6 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 at least the next two years.

To implement our business strategy 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, improve our manufacturing capabilities, and obtain regulatory clearance or approval to commercialize our products currently under development. 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 new products. 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 pumps to generate a significant portion of our revenue, and any factors that negatively impact sales of our insulin pump products may adversely affect our business, financial condition and operating results.

We generate a significant majority of our revenue from the sale of our insulin pump products. During 2017, our insulin pump products included our t:slim X2, t:flex and t:slim G4 products. In August 2017, we discontinued sales of t:slim G4 in connection with our commercial launch of t:slim X2 with G5 during the third quarter of 2017. Sales of our insulin pumps 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 other technological 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 during 2016 that restricted 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, 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, 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.

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, recent changes in and volatility of our stock price, concerns regarding our ability to maintain the continued listing of our common stock on the NASDAQ Global Market, or NASDAQ, perceptions about the dilutive impact of our financing transactions, our current level of indebtedness and debt service costs, 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 insulin pump 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 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. If demand for our products fluctuates, including as a result of the introduction of competitive products or technologies, changes in reimbursement policies, manufacturing problems, perceived safety or reliability issues with our or our competitors' products, the failure to secure regulatory clearance or approvals, or for other reasons, our ability to attract and retain customers could be harmed. In addition, the retention of current customers may be 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. The failure to retain a high percentage of our customers would negatively impact our revenue growth, which could 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, Inc., 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 2016, Roche Diabetes Care, a division of F. Hoffman-La Roche, discontinued sales of new insulin pumps in the United States. In October 2017, Johnson & Johnson announced its plans to discontinue the operations of Animas and to exit the insulin pump business entirely. Both Roche and Animas designated Medtronic as a preferred partner to facilitate the transition of their respective insulin pump customers. Most recently, in late 2017, Eli Lilly & Co. announced that it is developing an insulin pump with AID technology that it intends to launch in the next two to three years. There are also a number of other companies developing and marketing their own insulin delivery systems, 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 influence 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 financial resources 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 diabetes industry;
- 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 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. Abbott Laboratories recently launched a new blood glucose monitoring system, which competes with the Dexcom technology. Competitive pressures within our industry could negatively impact the financial condition of our business partners, impact their ability to fulfil their 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, medical researchers and pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any technological 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 that companies will continue to dedicate significant resources to developing competitive products and technologies. The frequent 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 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 products achieving and maintaining market acceptance. Our products include t:slim X2 with G5 integration and t:flex. 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 insulin treatment 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 fail to increase our sales in line with our forecasts.

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

- the failure of our products to achieve and maintain wide acceptance among people with insulin-dependent diabetes, their caregivers, healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;
- the failure of our products to provide the features and functionality that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in an insulin pump, and to incorporate those features into our products in a timely, cost-effective and user-friendly manner;
- 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;
- the introduction of competitive products, technologies or treatment techniques and the rate of their acceptance as compared to our insulin pump products;
- adverse regulatory or legal actions relating to our insulin pump products or similar products or technologies;
- discounts, rebates and other financial incentives that our competitors may offer for competitive products that make them more attractive than our products; and
- results of clinical studies relating to our existing products or products under development or similar competitive products.

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

Furthermore, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements, or the perception that advancements 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 at or above our projections. If our sales do not meet our sales projections, 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, including by reducing raw material, labor, product-training, expected warranty and manufacturing overhead costs per unit.

We believe that our ability to reduce the per unit cost of our insulin pump products and related cartridges will have a significant impact on our ability to achieve profitability. Our cost of sales includes raw material procurement costs, labor costs, product training expenses, warranty, scrap and inventory excess and obsolescence. It also includes manufacturing overhead costs, including expenses relating to quality assurance, inventory 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 improved pricing, 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. The per unit cost of our products is significantly impacted by our overall production volumes, and any factors that cause our production volumes to decline, or to grow at a slower rate than we expect, would significantly impact our expected per unit costs. 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, such as any accelerated development of our next generation t:sport product, will reduce the efficiencies gained through our platform and could increase our per unit costs. 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 associated supplies 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. In addition, those 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, effective July 1, 2016, UnitedHealthcare designated one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18. 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 176 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 in securing reimbursement in international markets. Also, any negative perceptions among third-party payors regarding our financial stability, including our ability to continue to sell and service our products, may make it more difficult to enter into contracts for reimbursement with additional third-party payors. 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 only limited experience marketing and selling our products as well as training new customers on their use. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have only limited experience marketing and selling our products to customers with type 2 diabetes. As a result, we expect to continue to face unexpected challenges marketing and selling t:flex, which is designed to meet the needs of customers with type 2 diabetes and/or higher insulin requirements.

We expect to derive nearly all of our revenue from the sale of t:slim X2 with G5 and t:flex, as well as pump-related supplies, 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 the ability of our sales and marketing organization to adequately promote, market and sell our insulin pumps 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 rapidly 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 light of negative perceptions regarding our financial stability, and the decline in our stock price, especially over the past two years, which may make it more difficult to motivate and retain key personnel. 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, 2017, sales to approximately 35 independent distributors represented approximately 75% of our sales. While our goal in the United States is to ultimately reduce the percentage of our sales to independent distributors over time as we enter into contracts with additional third-party payors, we believe that 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 and Canada. For example, our dependence upon independent distributors 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 has also increased following our launch of the t:lock for our insulin cartridge, which may continue to result in greater sales of our infusion sets to distributors. 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. However, negative perceptions among independent distributors regarding our financial stability, and our ability to sustain our business operations on a long-term basis, may negatively impact the willingness of our distributors to continue to do business with us. None of our independent distributors in the United States 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. 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, 2017, our two largest independent distributors collectively comprised approximately 35.5% 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 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 National Institute of Health-funded International Diabetes Closed Loop Trial, or IDCL Trial, to support our development of t:slim X2 with Control IQ. 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 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. 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 have a limited operating history upon which to evaluate our business and forecast our future sales and operating results and may face difficulties frequently encountered by companies in competitive and rapidly-evolving markets.

We have a limited operating history upon which to evaluate our business and forecast our future sales and operating results. We began commercial sales of t:slim in the third quarter of 2012, of t:flex in the second quarter of 2015 and of t:slim G4 in the third quarter of 2015. More recently, our commercial launch of t:slim X2 with G5, 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, combine to make it more difficult for us to predict our future sales and operating results. 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 infrastructure to grow sales of our existing and proposed products;
- gain 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.

Due to our limited operating history, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. 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, 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.

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 our stock price to decline. For example, any revenue growth in 2018 on a GAAP basis is expected to be lower than the rate of growth on a product volume basis. In addition, the complexities associated with the Program may cause investors to avoid investing in our common stock until our financial results and trends are more predictable, which may also 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.

These risks are likely to be exacerbated by our limited experience with our current products, manufacturing processes and manufacturing facilities.

As demand for our products increases, and as the number of our commercial products expands, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. Over the past two years we have implemented several new pieces of equipment that are intended to improve our manufacturing capacity and efficiency. However, it is possible that we may not achieve the anticipated improvements from these investments.

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, implementation of additional equipment and procedures, obtaining new regulatory approvals, or the development of 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 product components, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of components, 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 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. For example, we have implemented a business strategy intended to increase our future sales of infusion sets, and any increase in the sales of our infusion sets could strain the ability of our suppliers to deliver products in a manner that meets our various requirements.

We do not have long-term supply agreements with many of our suppliers and, in many cases, we make our purchases on a purchase order basis. Under most of our supply agreements, we 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. As a result, our ability to purchase adequate quantities of our components or products may be limited. Additionally, 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. 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 or products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, 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 would limit our ability to meet our sales commitments, which could harm our reputation and 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 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. Our supplier of infusion sets must manufacture a variety of lengths and styles of infusion sets with t:lock that matches 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.

In addition, our independent distributors will need to continue to purchase the compatible infusion sets from us to provide to their customers. We anticipate the transition period for our direct customers and distributors to utilize their inventory on hand before transitioning to t:lock is substantially complete; however, we are aware of circumstances that may require additional time for some direct customers and distributors to complete the transition. Accordingly, we still anticipate offering both styles of cartridges and infusion sets to facilitate the transition of customer supplies early in 2018. However, 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 Luer-lok style insulin cartridges that we cannot sell at standard prices or at all.

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, substantially all of our inventory of component supplies and finished goods are held at these locations. We take precautions to safeguard our facilities, including 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 or other disaster, such as an earthquake, fire or flood, 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 may not cover our losses in any particular case. Regardless of the level of insurance coverage, 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.

We recently 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 as we commence manufacturing operations at the new facility. 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. It is possible that the FDA will conclude that our corrective and preventive actions are inadequate. 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.

We expect that the management and support of our new manufacturing facility 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.

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.

t:slim X2 and t:flex 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 G4 and t:slim X2 with G5 received FDA approval under a PMA. However, there are no published studies to evaluate the safety or effectiveness of t:slim G4 or t:slim X2 with G5 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 recall may negatively impact our financial results and business prospects depending on 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 generations of Dexcom CGM technology with our insulin pump products. Our agreements with Dexcom currently run until June 2020 with automatic one-year renewals. Under certain circumstances, these agreements may be terminated by either party without cause or on short notice. Termination of any of our agreements with Dexcom could 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.

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. 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.

In the third quarter of 2017, Hurricane Irma and Hurricane Harvey adversely impacted our business operations in Texas, Florida and other nearby regions. These hurricanes directly and significantly affected our sales force, healthcare providers and potential customers, as well as distribution centers operated by certain of our independent distributors. Although our business operations have resumed in these areas, it is difficult to assess the impact these hurricanes had or may continue to have on our customers, the demand for our products in the affected areas, the effectiveness of our sales force, and the ability of our distributors to meet their obligations to us.

These and 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, 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.

The failure of our or our service providers' information technology systems or our pumps' software to perform as we anticipate or our failure to effectively implement new information technology systems 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. This may be especially true during periods in which we face challenges such as financial difficulties or a reduced stock price. 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, the vast majority of our outstanding equity awards, which generally are 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, although some or all of these awards may be subject to conditions including the requirement to obtain the consent of our stockholders to an increase in the number of shares reserved for issuance under our equity plan. 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, 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 federal and state laws protecting the confidentiality and security of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated privacy and security rules under HIPAA, as amended by HITECH. The privacy rule protects medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. The security rule protects protected health information, or PHI, stored electronically by requiring appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity and security of such PHI. If we, or any of our service providers, are found to be in violation of the promulgated privacy and security rules under HIPAA and HITECH, 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 may also face new risks relating to security laws and privacy rights as we begin to commercialize our products outside the United States.

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.

We are planning to begin commercialization of the t:slim X2 in select geographies outside of the United States, including Canada, during 2018. We do not have experience in commercializing our products outside of the United States and expect that we will be subject to additional risks related to entering into 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;
- 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 Foreign Corrupt Practices Act;
- 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 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 will need to raise additional funds in the future. If these funds are not available to us, we will not have sufficient cash to fund our operations.

At December 31, 2017, we had $24.2 million in cash, cash equivalents and short-term investments, which included $10.0 million of restricted cash. In addition, in February 2018, we completed a registered public offering of 34.5 million shares of common stock that resulted in gross proceeds to us of $69.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. Although our management believes we have sufficient cash to fund our operations for at least the next twelve months, the continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers our plans to commence commercial sales of our products outside the United States and additional research and development activities, will continue to increase our expenses and capital needs. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our insulin pump products, infusion sets and insulin cartridges, and any other future products that we may develop and commercialize;
- the gross profits and gross margin we realize from the sales we generate;
- any proceeds we receive from the exercise of our outstanding warrants;
- the costs associated with maintaining an appropriate sales, clinical and marketing infrastructure;
- the expenses we incur in maintaining and enhancing our manufacturing infrastructure, including adding additional manufacturing equipment and capacity;
- the expenses associated with developing and commercializing our proposed products or technologies;
- the costs associated with maintaining and expanding our customer care 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;
- our compliance with the covenants in our Amended and Restated Term Loan Agreement with Capital Royalty Partners, which we refer to as the Term Loan Agreement;
    - 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, elect to restructure or refinance our existing indebtedness, or borrow additional 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 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 care 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, or satisfy covenants in the Term Loan Agreement. 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 introductions 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 of our insulin pump products and pump-related supplies, and to commercialize and sell our future products, and the number 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.

As a result of our recent and anticipated product launches, and due to the complexities of the industry in which we operate, it will continue to be difficult for us to forecast demand for our products with any degree of certainty. For example, our recent commercial launch of t:slim X2 with G5, 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, combine to make it more difficult for us to predict our operating results.

In addition, our operating expenses will continue to increase as we expand our business. Accordingly, we may experience substantial variability in our operating results from quarter to quarter. 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. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

We may not be able to generate sufficient cash to service our indebtedness, which currently consists of our Term Loan Agreement with Capital Royalty Partners.

At December 31, 2017, we had $82.7 million aggregate borrowings outstanding under the Term Loan Agreement with Capital Royalty Partners. Our ability to make scheduled payments or to restructure or refinance our debt obligations depends on numerous factors, including the amount of our cash reserves at the time a scheduled payment becomes due and our actual and projected financial and operating performance. The amount of our cash reserves and our financial and operating performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, or interest on our existing or future indebtedness.

If our cash balances or cash flows from operations are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell or license our assets, reduce our operations, seek additional capital on unfavorable terms, or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Our recent and projected financial results, the volatility in our stock price over the past two years, and general concerns among potential investors and creditors about our financial stability may make taking such actions on commercially reasonable terms especially difficult. If we are unable to generate sufficient cash flow or are otherwise unable to obtain the funds necessary to meet scheduled debt service obligations, we could be in default under the terms of the Term Loan Agreement.

The Term Loan Agreement contains restrictive and financial covenants that may limit our operating flexibility, and our potential inability to comply with such covenants puts us at risk of triggering an event of default under the Term Loan Agreement.

The Term Loan Agreement contains certain restrictive covenants that limit our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. We may not be able to engage in any of the foregoing transactions unless we obtain the consent of Capital Royalty Partners or terminate the Term Loan Agreement.

The Term Loan Agreement also contains certain financial covenants, including minimum revenue and cash balance requirements, and financial reporting requirements. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under the Term Loan Agreement. Further, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under the Term Loan Agreement.

The terms of the Term Loan Agreement also require that we deliver audited financial statements that include an unqualified audit report to Capital Royalty Partners. If the audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2017 included an explanatory paragraph that described conditions that raised substantial doubt about our ability to continue as a going concern, it could have constituted a potential event of default under the Term Loan Agreement. Accordingly, prior to the completion of our equity financing in February 2018, we entered into Waiver and Amendment No. 5 to Term Loan Agreement, or the Fifth Amendment, which included a limited advance waiver of such a potential event of default. The Fifth Amendment included a covenant requiring us to complete a financing in which our gross proceeds from the sale of equity securities is at least $20.0 million, no later than August 30, 2018. We satisfied this covenant with our recently completed equity financing that resulted in gross proceeds to us of $69.0 million.

In the event of a future default triggered by any violations of the covenants in the Term Loan Agreement, we will need to obtain additional waivers from Capital Royalty Partners to avoid being in default. If we are unable to obtain a waiver of any events of default, or an amendment to the Term Loan Agreement that would allow us to be in compliance with the terms of the agreement, an event of default would result.

In the event of our default under of the Term Loan Agreement, we may be required to repay any outstanding amounts earlier than anticipated and our capital resources may not be sufficient to meet those obligations. Further, if we are unable to repay our indebtedness and Capital Royalty Partners institutes foreclosure proceedings against our assets, we could be forced into bankruptcy or liquidation, and in such a scenario, the values that we receive for our assets could be significantly lower than the values reflected in our financial statements.

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, 2017, our patent portfolio consisted of approximately 58 issued U.S. patents and 49 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. Third parties also may 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 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 be expensive and time consuming and 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. Any intellectual property dispute 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;
- 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.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. Further, as the number of participants in the diabetes market increases, the possibility of intellectual property infringement claims against us increases.

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of 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 could become the subject of 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 following our January 2014 voluntary recall of cartridges used with t:slim. 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. 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. 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 an increase 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 Premarket Approval, or 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 t:slim X2 with G5 in August 2017. 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 a 510(k) may require a new 510(k). 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 initially received pre-market clearance for t:slim under Section 510(k) of the FDCA in November 2011. We obtained 510(k) clearances for t:connect and t:flex in February 2013 and January 2015, respectively. From time to time, we may make modifications to these products that may require a new 510(k). We have received 510(k) clearance for various modifications to t:slim and its associated cartridge. For instance, in July 2016, we received 510(k) clearance to reduce the age in our indications for use of t:slim to age six. 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 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.

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 are evaluating international expansion opportunities for a potential launch in 2018. If 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 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 Medical Device Reporting, or 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 and physician self-referral 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 federal "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 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 DOJ, has recently 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

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, or DGCL, 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, 2017, we had federal net operating loss, or NOL, carryforwards of approximately $335.3 million, not considering the limitation discussed below. The federal tax loss carryforwards begin to expire in 2026, unless previously utilized. In general, if there is an "ownership change" with respect to our company, as defined under Section 382 of the Internal Revenue Code of 1986, as amended, or 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 completed an update of our Section 382 analysis subsequent to December 31, 2017, the recent offerings of our securities, may have caused or could cause 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. 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. In addition, pursuant to our Term Loan Agreement with Capital Royalty Partners, we are precluded from paying any cash dividends. 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. Recent legislation permits "emerging growth companies" to implement many of these requirements over a period of up to five years after becoming subject to the requirements. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses.

In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, 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.

We are an "emerging growth company" and we do not know whether the reduced disclosure requirements and relief from certain other significant obligations that are applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act, and we have taken advantage of, and intend to continue to take advantage of certain exemptions from various reporting and compliance requirements that apply to other public companies that are not "emerging growth companies." These exemptions include the following:

- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act;
- less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements; and
- exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We intend to continue to take advantage of these exemptions but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. We cannot predict if investors will find our common stock less attractive because of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, which could result in a reduction in the price of our common stock or cause our stock price to be more volatile.

We are a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a "smaller reporting company" under applicable SEC rules and regulations. Similar to an "emerging growth company", a "smaller reporting company" is subject to scaled reporting and compliance obligations as compared to other public companies. Specifically, "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings, are exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and have certain other reduced disclosure obligations in their SEC filings. Reduced disclosures in our SEC filings due to our status as a "smaller reporting company" may make it harder for investors to analyze our financial condition, operating results and prospects. If investors find our common stock less attractive as a result of our reduced disclosures, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

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 after we no longer qualify as an "emerging growth company" or a "smaller reporting company", 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 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. However, for as long as we are an "emerging growth company" or a "smaller reporting company" under applicable SEC rules and regulations, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

The price of our common stock might fluctuate significantly.

Our common stock is listed for trading on NASDAQ under the symbol "TNDM." Our stock price could 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, and perceptions about the dilutive impact of our recent financing transactions;
- perceptions about our financial stability generally, and relative to our competitors, and our ability to sustain our business operations long term;
- overall performance of the equity markets;
- speculative trading practices of market participants;
- perceptions about the market acceptance of our products and the recognition of our brand;
- introduction of proposed products or technologies, or announcements of significant contracts, acquisitions or divestitures by us or our competitors;
- legislative, political or regulatory developments;
- issuance of securities analysts' reports or recommendations;
- additions or departures of key personnel;
- threatened or actual litigation and government investigations;
- sale of shares of our common stock by us or members of our management; and
- general economic conditions.

These and other factors might cause the market price of our common stock to fluctuate substantially, which may negatively affect the liquidity of our common stock. In addition, 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. The changes frequently appear to occur without regard to the 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.

Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in substantial costs, divert our management's attention and resources, and harm our business, operating results and financial condition.

If we are unable to comply with certain continued listing requirements of NASDAQ, our common stock would be delisted from NASDAQ, which could adversely affect the market price of our common stock.

Our common stock is currently listed on NASDAQ. In order to maintain this listing, we must satisfy minimum continued listing requirements and standards, including a minimum closing bid price requirement for our common stock. We have previously received a notice from NASDAQ indicating that we had failed to meet the minimum closing bid price requirement of $1.00 per share for 30 consecutive business days, which subjected our common stock to potential delisting. While we regained compliance under the NASDAQ minimum continued listing requirements, due to the recent volatility of our stock price we cannot assure you that we will continue to satisfy the NASDAQ continued listing requirements. If we cannot satisfy the continued listing standards going forward, NASDAQ may commence delisting procedures against us, which could result in our common stock being removed from listing on NASDAQ. If our common stock were to be delisted, the liquidity of our common stock could be adversely affected and the market price of our common stock could decrease.

We are at risk of securities class action litigation.

In the past, securities class action litigation has been brought against companies following a decline in the market price of their securities. This risk is particularly relevant to medical device companies, which 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.

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, 2017, we leased an aggregate of approximately 108,000 square feet of manufacturing, laboratory and office space on Roselle Street, San Diego, California. Effective as of January 31, 2018 we terminated our lease with respect to the building located at 11045 Roselle Street, which reduced our aggregate leased space on Roselle Street from 108,000 square feet to 88,000 square feet. All of our leases for facilities on Roselle Street are scheduled to expire in May 2022.

As of December 31, 2017, we also leased approximately 48,880 square feet of general office and manufacturing space located on Barnes Canyon Road in San Diego, California, or the Barnes Canyon Lease, which is scheduled to expire in November 2023. We also 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. The building located at 11045 Roselle Street, which primarily housed our manufacturing and related operations, was largely replaced by our Barnes Canyon facility.

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 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, 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
Year Ended December 31, 2016:		
First Quarter	$ 118.00	$ 65.90
Second Quarter	$ 113.00	$ 64.80
Third Quarter	$ 88.10	$ 60.40
Fourth Quarter	$ 81.00	$ 16.00

The last sale price for our common stock as reported by the NASDAQ Global Market on February 23, 2018 was $2.86 per share.

Holders of Record

As of February 23, 2018, there were approximately 68 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.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. At the present time, we have no plans to declare or pay any dividends and intend to retain all of our future earnings, if any, generated by our operations for the development and growth of our business. Any future decision to pay dividends will be made by our board of directors in its sole discretion and will depend upon our results of operations, financial condition, capital requirements and other factors that our board of directors deems relevant in its informed business judgment. In addition, the terms of the Term Loan Agreement restrict our ability to pay cash dividends.

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 Shares of Equity Securities

None.

Repurchases of Equity Securities

We did not repurchase any of our equity securities during 2017 or 2016.

Item 6. Selected Financial Data.

The selected financial data presented below under the heading "Statements of Operations Data" for the years ended December 31, 2017, 2016, and 2015 and the selected financial data presented below under the heading "Balance Sheet Data" as of December 31, 2017 and 2016 have been derived from our audited 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, 2014 and 2013 and the selected financial data presented below under the heading "Balance Sheet Data" as of December 31, 2015, 2014 and 2013 are derived from our audited 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 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.

Statements of Operations Data:

	Year Ended December 31,				
(in thousands, except per share data)	**2017**	**2016**	**2015**	**2014**	**2013**
Sales	$ 107,601	$ 84,248	$ 72,850	$ 49,722	$ 29,007
Cost of sales	63,507	60,656	46,270	34,474	22,840
Gross profit	44,094	23,592	26,580	15,248	6,167
Operating expenses:					
Selling, general and administrative	86,377	82,834	78,621	75,121	44,522
Research and development	20,661	18,809	16,963	15,791	11,079
Total operating expenses	107,038	101,643	95,584	90,912	55,601
Operating loss	(62,944)	(78,051)	(69,004)	(75,664)	(49,434)
Total other expense, net	(10,081)	(5,411)	(3,404)	(3,789)	(13,705)
Net loss before taxes	$ (73,025)	$ (83,462)	$ (72,408)	$ (79,453)	$ (63,139)
Provision for income tax expense (benefit)	8	(15)	10	71	—
Net loss	$ (73,033)	$ (83,447)	$ (72,418)	$ (79,524)	$ (63,139)
Net loss per share, basic and diluted:	$ (12.87)	$ (27.30)	$ (25.04)	$ (34.17)	$ (214.61)
Weighted average shares used to compute basic and diluted net loss per share	5,677	3,057	2,892	2,327	294

The issued and outstanding shares of common stock have been restated for all periods presented to reflect the effect of the 1-for-10 reverse stock split, which was effective on October 9, 2017.

Balance Sheet Data:

	As of December 31,				
(in thousands)	**2017**	**2016**	**2015**	**2014**	**2013**
Cash and cash equivalents	$ 13,700	$ 44,678	$ 43,088	$ 31,176	$ 124,385
Short-term investments	$ 479	$ 8,860	$ 28,018	$ 36,106	$ 5,095
Working capital	$ 28,071	$ 60,616	$ 80,464	$ 72,657	$ 134,390
Property and equipment, net	$ 19,631	$ 18,409	$ 15,526	$ 12,581	$ 9,886
Total assets	$ 95,346	$ 112,392	$ 124,725	$ 106,464	$ 162,215
Notes payable	$ 76,541	$ 78,960	$ 29,275	$ 29,440	$ 29,397
Total stockholders' equity (deficit)	$ (29,148)	$ (5,927)	$ 63,468	$ 54,572	$ 115,537

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 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 and sales activities primarily focus on our flagship product, t:slim X2, which is based on our proprietary technology platform. The simple-to-use t:slim X2 is the smallest durable insulin pump available, and 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 five insulin pumps since inception, all of which have been developed using our proprietary technology platform. Two of these pumps have featured CGM. Since the launch of our first product in August 2012 through December 2017, we have shipped nearly 68,000 pumps to customers in the United States. In 2017, we announced plans to begin commercialization of t:slim X2 in select geographies outside the United States, including Canada, during 2018.

We began commercial sales of our first insulin pump, t:slim, in August 2012. During 2015, we commenced commercial sales of two additional insulin pumps: t:flex in May 2015 and t:slim G4 in September 2015. In October 2016, we commenced commercial sales of t:slim X2 and discontinued new sales of t:slim. In September 2017, we commenced commercial sales of t:slim X2 integrated with the Dexcom G5 Mobile CGM system and discontinued new sales of t:slim G4. In 2017, t:slim X2 represented approximately 95% of our new pump shipments.

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 September 2017, we commenced commercial sales of cartridge and infusion set products using t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to our cartridge. However, we continue to offer cartridges and infusion sets with a standard Luer-lok connector on a limited basis to facilitate customer transition to our new t:lock products.

Our insulin pumps are compatible with the Tandem Device Updater, a revolutionary new tool that allows pump users to update their pumps' software quickly and easily from a personal computer. The Tandem Device Updater provides our customers 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 deployment of the latest t:slim software to in-warranty t:slim pumps purchased before April 2015. In September 2017, we set a new standard of care in our industry by offering all existing t:slim X2 customers integration with the Dexcom G5 Mobile CGM system through a software update using the Tandem Device Updater. Within the first 30 days following the FDA approval of this update, more than 30% of t:slim X2 customers who purchased their pump prior to its availability had updated their pump. By the end of 2017 more than 40% of t:slim X2 customers had updated their pump and now have access to Dexcom G5 Mobile CGM integration. In October 2017, we announced that, subject to FDA approval, we intend to make any new features approved by the FDA in 2018 available to all in-warranty users of t:slim X2 at no cost through the Tandem Device Updater. In the future, this tool has the potential to enable users to add other new features and functionality to their pumps, such as AID algorithms independent of the typical four-year insurance pump replacement cycle.

Between July 2016 and September 2017, we offered a Technology Upgrade Program to provide eligible customers a pathway to ownership of a t:slim X2. During the term of the Program, depending on the type of pump sold, we were required under accounting guidelines to defer some or all of the sales and cost of sales until a later date. This prevented us from recognizing up to 100% of the sales and cost of sales associated with the sale of our t:slim and t:slim G4 insulin pumps to eligible customers at the time of shipment. In general, the deferrals required by the Program had the effect of initially decreasing our sales, particularly in the second half of 2016, even when the number of pump shipments increased, then benefiting our sales at the conclusion of the Program in the second half of 2017.

For the years ended December 31, 2017, 2016 and 2015, our sales were $107.6 million, $84.2 million, and $72.9 million, respectively. For the years ended December 31, 2017, 2016, and 2015, our net loss was $73.0 million, $83.4 million, and $72.4 million, respectively. For the year ended December 31, 2017, we recorded incremental net sales of $5.0 million with a corresponding increase in gross profit of $3.1 million as a result of our Technology Upgrade Program. For the year ended December 31, 2016, we recorded net sales deferrals of $4.3 million and a decrease in gross profit of $4.6 million as a result of our Technology Upgrade Program. Pump sales accounted for 66%, 74%, and 83% of sales, respectively, for the years ended December 31, 2017, 2016 and 2015, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in any of these periods. Our accumulated deficit as of December 31, 2017 and December 31, 2016 was $477.6 million and $404.6 million, respectively.

We have rapidly increased sales since our commercial launch by expanding our sales, clinical and marketing infrastructure, by developing, commercializing and marketing multiple differentiated products that utilize our proprietary technology platform and consumer-focused approach, and by providing strong customer support. In our research, approximately 86% of healthcare providers surveyed believe that providing great customer support is the most important attribute in an insulin pump manufacturer. 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. 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 a pathway to our future innovations through the Tandem Device Updater, as they are approved by the FDA. As we continue to develop differentiated products based on our proprietary technology platform, our strategy is to leverage a single sales, marketing and clinical organization, a shared manufacturing and supply chain infrastructure, and the expertise of our customer support services.

Products under Development

Our products under development support our strategy of focusing on both consumer and clinical needs, and include 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 target people in differentiated segments of the insulin-dependent diabetes market.

Our current products under development include:

- *t:slim X2 with Basal IQ*: Utilizes Dexcom G5 sensor values and a predictive low glucose suspend, or PLGS, algorithm to adjust the rate of insulin delivery to help minimize the frequency and/or duration of hypoglycemic events.

- *t:slim X2 with Control IQ*: Our second generation AID system is expected to integrate the t:slim X2 pump with a combination of Dexcom's G6 sensor and AID technology that we licensed from TypeZero.

- *t:sport Insulin Delivery System:* 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.

- *Connected (Mobile) Health Offerings:* A mobile application designed to utilize the capability of the Bluetooth low energy radio, or BLE, already built into our pumps 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.

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. We consider the number of units shipped per quarter to be an important metric for managing our business. We have shipped nearly 68,000 insulin pumps since our initial launch in August 2012, of which over 60,000 pumps have been shipped within the four years ended December 31, 2017. Pump shipments are broken down by fiscal quarter as follows:

	Pump Units Shipped for Each of the Three Months Ended in Respective Years[1]				
	March 31	**June 30**	**September 30**	**December 31**	**Total**
2012	-	9	204	844	1,057
2013	852	1,363	1,851	2,406	6,472
2014	1,723	2,235	2,935	3,929	10,822
2015	2,487	3,331	3,431	6,234	15,483
2016	4,042	4,582	3,896	4,418	16,938
2017	2,816	3,427	3,868	6,950	17,061

(1) This table does not reflect returns or exchanges of pump products that occur in the ordinary course of business, nor does it reflect 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

In the third quarter of 2016, we launched a Technology Upgrade Program that provided eligible t:slim and t:slim G4 customers a path towards ownership of t:slim X2 or, as of August 2017, t:slim X2 with G5, by offering customers the right to exchange their t:slim or t:slim G4 for t:slim X2 or t:slim X2 with G5, under a variable pricing structure.

While our Technology Upgrade Program expired during 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, accounting guidelines 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. In general, the deferrals required by the Technology Upgrade Program had the effect of initially decreasing our sales, primarily in 2016, even when the number of our pump shipments increased.

We recognized the deferred amount of sales and cost of sales at the earlier of when the obligations under the Technology Upgrade Program were satisfied or upon the expiration of the Program. If a customer elected to participate in the Technology Upgrade Program, we recognized any upgrade fees that we received and the associated costs at the time of fulfilling the given obligation. The majority of deferred sales and cost of sales were recognized as of December 31, 2017 and we are no longer subject to these accounting deferrals.

Historical Financial Results

For the years ended December 31, 2017, 2016 and 2015, our sales were $107.6 million, $84.2 million and $72.9 million, respectively. For the year ended December 31, 2017, this included 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, this included 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. For the years ended December 31, 2017, 2016 and 2015, our net loss was $73.0 million, $83.4 million and $72.4 million, respectively. Our accumulated deficit as of December 31, 2017 was $477.6 million.

Trends Impacting Financial Results

Overall, we have experienced considerable sales growth since the commercial launch of t:slim 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. In particular, customers may defer a purchasing decision if they believe that a new product may be launched in the near future. For example, we believe that our pump shipments were negatively impacted during the second half of 2016 and first half of 2017, as we announced the launches of t:slim X2 and the Technology Upgrade Program in the third quarter of 2016, and one of our competitors announced the future availability of two new products with financial incentives for adoption.

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 associated with summer vacations, annual insurance deductibles, and coinsurance requirements associated with the medical insurance plans utilized by our customers and the customers of our distributors;
- 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 could materially impact our financial results going forward:

- continued increase in demand following the commercial launch of t:slim X2 with G5 and the demonstrated success of our Tandem Device Updater, which we expect will positively impact our sales;

- the anticipated launch of t:slim X2 with Basal IQ in the summer of 2018, subject to future FDA approval;

- increased opportunity to achieve customer renewals as customers become eligible for insurance reimbursement to purchase a new insulin pump, which we expect will positively impact our sales. Customers are typically eligible for insurance reimbursement once every four years. 2017 was our first full year with customers eligible for renewal. In 2018, renewal opportunities exist for some portion of the 6,472 and 10,822 pumps originally shipped in 2013 and 2014, respectively, based on the typical four-year insurance reimbursement cycle for insulin pumps. This opportunity may be limited by many factors, such as the ability to obtain approval for reimbursement from insurance payors and the potential for customers to choose competitive products, use their existing insulin pump on an out-of-warranty basis or discontinue insulin pump therapy;

- opportunity to attract Animas customers as their pumps come up for renewal, following the announcement by Johnson & Johnson that it intends to discontinue the operations of Animas and exit the insulin pump business entirely. We now offer the only alternative durable insulin pump to Medtronic in the United States. While it is too early to know how the announcement will influence our business or the competitive landscape in which we operate over the longer term, in the fourth quarter of 2017 we experienced an increase in our percentage of sales to people who reported switching from using an Animas pump;

- increased sales of infusion sets following the recent commercial launch of t:lock. In particular, the ratio of our sales volume of infusion sets relative to sales volume of cartridges during the third quarter was approximately 66%, as compared to 61% during the second quarter of 2017, 51% during the first quarter of 2017 and 31% for all of 2016. This ratio increased to 88% in the fourth quarter of 2017, and approached 100% during December 2017. We expect to maintain a ratio of approximately 100% in the full year of 2018;

- designation by UnitedHealthcare in July 2016 of one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18. We believe this decision has prevented and will continue to prevent a majority of UnitedHealthcare members from purchasing an insulin pump from us for the foreseeable future. However, in most other circumstances in which we do not have contracts established with third-party payors, we utilize our network of national and regional distributors to service our customers;

- international expansion in select geographies, including Canada, in the second half of 2018;

- due to seasonality factors impacting annual insurance deductibles, and the historical buying patterns of our customers, our sales will continue to be heavily weighted towards the second half of the year and product shipments from the fourth quarter to the following first quarter will decrease significantly; and

- negative perceptions regarding our financial stability relative to that of our competitors, including concerns among potential customers, healthcare providers, distributors and suppliers regarding our ability to sustain our business operations on a long-term basis. In some cases, we believe these perceptions have caused potential customers to delay the purchase of our products or purchase competitors' products and have negatively impacted the willingness of healthcare providers to recommend our products over those of our competitors.

Even with our growth expectations, in 2018 we intend to leverage our existing infrastructure investments and realize additional manufacturing cost improvements to increase our operating margins. Our operating expense goal for 2018, including our international launch plans, is to manage our operating expenses to less than 10% annual growth. We believe we can ultimately achieve profitability by driving incremental sales, achieving our pump renewal sales objectives, increasing gross profits from higher sales of infusion sets, maximizing manufacturing efficiencies on increased production volumes and the utilization of our new Barnes Canyon Facility, and leveraging the early investments made in our sales, clinical and marketing organization, as well as our customer support infrastructure.

Term Loan Agreement

We have entered into the Term Loan Agreement with Capital Royalty Partners. In the first quarter of 2016, we entered into Amendment No. 3 to the Term Loan Agreement, or the Third Amendment, which granted us the right to borrow up to an additional $50.0 million. We borrowed $15.0 million of this amount in January 2016, and the remaining $35.0 million in December 2016. At December 31, 2017, we had $82.7 million of aggregate borrowings outstanding under the Term Loan Agreement.

The Term Loan Agreement requires that we deliver audited financial statements that include an unqualified audit report to Capital Royalty Partners. As a result, we entered into Amendment No. 4 to the Term Loan Agreement, or the Fourth Amendment, in March 2017. The Fourth Amendment included a limited waiver of a potential event of default that could have resulted from the inclusion of an explanatory paragraph in the audit report of our independent registered public accounting firm included in our Annual Report on Form 10-K for the year ended December 31, 2016 that described conditions that raised substantial doubt about our ability to continue as a going concern. The Fourth Amendment also imposed additional restrictive and financial covenants on us, which may increase our risk of triggering defaults under the Term Loan Agreement.

On February 6, 2018, we entered into the Fifth Amendment, which included a limited advance waiver of a potential event of default that could have resulted from a qualification regarding our ability to continue as a going concern in the audit report for the year ended December 31, 2017. The Fifth Amendment included a covenant requiring us to complete a financing in which our gross proceeds from the sale of equity securities is at least $20.0 million, no later than August 30, 2018. We satisfied this covenant with our recently completed equity financing that resulted in gross proceeds to us of $69.0 million. The audit report included in this Annual Report does not include a qualification regarding our ability to continue as a going concern.

In the event of a future breach of any of the covenants in the Term Loan Agreement, we will need to obtain additional waivers from Capital Royalty Partners to avoid being in default. We may not be able to obtain such a waiver or amendment on favorable terms or at all.

For additional information about the Term Loan Agreement, see the section entitled “Indebtedness” below.

Leverage from Technology Platform

We believe we can ultimately achieve profitability because our proprietary technology platform will allow us to maximize efficiencies in the development, production, sale and marketing of multiple differentiated products. By offering products that are all based on our proprietary technology platform, in combination with the flexibility provided by the Tandem Device Updater, we believe we can develop and bring to market products and functionality more rapidly, while significantly reducing our per-unit design and development costs. Due to shared product design features, our production system is adaptable to new products and we intend to leverage our shared manufacturing infrastructure to drive operational efficiencies. Further, we expect to continue to increase production volume and to reduce the per-unit production overhead cost for our pump products and their associated disposable cartridges over time. We anticipate that the transition to our recently launched t:lock Connector will continue to increase our sales of infusion sets. By expanding our product offerings to address people in different segments of the large and growing insulin-dependent diabetes market, we believe we can increase the productivity of our sales, clinical and marketing organization, as well as our customer support infrastructure, thereby improving our operating margin over the long term.

Cash Flow Breakeven

Our goal is to reach the milestone of cash flow breakeven in the second half of 2019 when we expect to have an installed base of more than 80,000 customers and a gross margin of approximately 55%. However, our ability to achieve this milestone, and the timing of this achievement, is uncertain and subject to a number of variables. For example, the continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers, our plans to begin international sales activities in 2018 and additional regulatory approval and research and development activities, will continue to increase our expenses and capital needs, which could impact our results of operations and cash flow.

Subsequent Events

In February 2018, we completed a registered public offering of 34.5 million shares of common stock resulting in gross proceeds to us of $69.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by us, which we refer to as the February Financing.

Also in February 2018, we announced results from a pivotal study of the t:slim X2™ Insulin Pump with Basal-IQ technology, a predictive low glucose suspend (PLGS) feature. Data showed that the system achieved the primary outcome of reducing time spent in hypoglycemia compared to sensor-augmented pump therapy alone. The results of the pivotal study were used in our PMA that was submitted to the FDA in late February 2018. Subject to future FDA approval, our goal is to launch the t:slim X2 with Basal IQ in the summer of 2018.

Components of Results of Operations

Sales

We offer products for people with insulin-dependent diabetes. We commenced commercial sales of our first insulin pump, t:slim, in the United States in the third quarter of 2012. We have launched four additional insulin pump products since that time. Our current pump product offering includes t:flex, which was launched in the second quarter of 2015, and t:slim X2 with G5, which was launched in the third quarter of 2017, as well as disposable cartridges and infusion sets. We also offer accessories including protective cases, belt clips and power adapters. Sales of accessories since commercial launch have not been significant.

We primarily sell our products through national and regional distributors 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.

We expect that our sales will increase over time as we gain market acceptance for our current products and products under development. We believe the trends and factors discussed above under the heading “Trends Impacting Financial Results” have impacted and will continue to impact our product sales and operating results.

In general, as a result of these and other factors, 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. Consistent with prior results, we also expect product shipments from the fourth quarter to the following first quarter to decrease significantly.

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 the 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. For example, in 2015, we believe that the timing of the regulatory approval and commercial launch of t:slim G4 contributed to our product shipments being weighted heavily towards the fourth quarter of the year. Similarly, in 2016, we believe that our pump shipments were negatively impacted during the second half of 2016, as we announced the launches of t:slim X2 and the Technology Upgrade Program in the third quarter, and one of our competitors announced the future availability of two new products with financial incentives for adoption. 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 facilities 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, 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. Historically, cost of sales has also included royalty costs associated with sales of t:slim G4. In August 2017, we commenced commercial sales of t:slim X2 with G5, which has no royalty obligation, and discontinued new sales of t:slim G4. 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 we have more opportunities to spread our overhead costs over larger production volumes. We expect that 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. We also expect our warranty costs to decrease as we release product features and functionality utilizing the Tandem Device Updater.
In 2017, we transitioned our manufacturing operations to our Barnes Canyon facility, which we expect will double our previous manufacturing capacity for both insulin pumps and cartridges, and expand warehousing for additional infusion set supplies related to the launch of t:lock while maintaining approximately the same cost of facilities in manufacturing overhead. The transition to the new manufacturing facility took place primarily during 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. The transition to the Barnes Canyon facility was completed in early 2018.

We expect our overall gross margin to fluctuate in future quarterly periods due to fluctuating production volumes, as well as a result of numerous other factors. In general, we expect the gross margin on insulin pumps to be higher than the gross margin on pump-related supplies, which would be consistent with our historical experience. Other factors impacting our overall gross margin include the changing mix of products sold with different gross margins, the changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors, the timing and success of new regulatory approvals and product launches, warranty and training costs, and changes in our manufacturing processes, capacity or costs.

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, marketing, sales, clinical, customer care, technical services, insurance verification, regulatory affairs and administrative functions.

Our sales and clinical organization consisted of approximately 70 territories as of December 31, 2017. Territories are maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel. 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. Although we do not contemplate an increase in the number of sales territories in the near term or other significant infrastructure investments, we expect our SG&A expenses, including the cost of our customer care infrastructure, to moderately increase as our customer base grows and due to ordinary increases in employee compensation and benefits. Our SG&A expenses may also increase due to costs associated with additional compliance and regulatory reporting requirements, as well as in support of our planned international expansion in 2018.

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. Our R&D expenses are expected to moderately increase as we advance our products under development and develop new products and technologies and due to ordinary increases in employee compensation and benefits.

Other Income and Expense

Our other income (expense) primarily consists of interest expense and amortization of debt discount and issuance costs associated with the Term Loan Agreement. At December 31, 2017, there was $82.7 million of outstanding principal under the Term Loan Agreement, which accrues interest at a rate of 11.5% per annum. We expect interest expense to remain relatively flat in 2018 as compared to 2017 (see the section below entitled “Indebtedness”). Additionally, beginning in 2017, this amount includes changes in the fair value of the common stock warrants issued in October 2017.

Results of Operations

	Year Ended December 31,		
(in thousands, except percentages)	**2017**	**2016**	**2015**
Sales	$ 107,601	$ 84,248	$ 72,850
Cost of sales	63,507	$ 60,656	46,270
Gross profit	44,094	23,592	26,580
Gross margin	41%	28%	36%
Operating expenses:			
Selling, general and administrative	86,377	82,834	78,621
Research and development	20,661	18,809	16,963
Total operating expenses	107,038	101,643	95,584
Operating loss	(62,944)	(78,051)	(69,004)
Other income (expense), net:			
Interest and other income	239	296	337
Interest and other expense	(11,341)	(5,707)	(3,741)
Change in fair value of stock warrants	1,021	-	-
Total other expense, net	(10,081)	(5,411)	(3,404)
Net loss before taxes	$ (73,025)	$ (83,462)	$ (72,408)
Provision for income taxes (benefit)	8	(15)	10
Net loss	$ (73,033)	$ (83,447)	$ (72,418)

Comparison of Years Ended December 31, 2017 and 2016

Sales. For the year ended December 31, 2017, sales were $107.6 million, including 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 of the reported periods.

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. This includes 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. We borrowed $30.0 million under the agreement in January 2013, an additional $15.0 million in January 2016, and the remaining $35.0 million in December 2016. 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 gain from the change in fair value of the common stock warrants of $1.0 million. Other income for both periods presented was not significant.

Comparison of Years Ended December 31, 2016 and 2015

Sales. 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, compared to $72.9 million for the year ended December 31, 2015.

Sales of insulin pumps were $62.5 million and $60.8 million, respectively, for the years ended December 31, 2016 and 2015. 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. For the year ended December 31, 2015, sales of pump-related supplies were $11.9 million, of which $4.2 million were sales of infusion sets and $7.7 million were sales of cartridges. Sales of accessories were not significant in either of the reported periods.

The growth in sales was driven by a 9% increase in pump shipments from 15,483 in 2015 to 16,938 in 2016, offset in part by our deferral of sales of eligible insulin pumps due to the Technology Upgrade Program. We also experienced an increase in sales of pump-related supplies from our growing customer base.

Sales to distributors accounted for 74% and 77% of our total sales for the years ended December 31, 2016 and 2015, respectively. The percentage of sales to distributors decreased mainly due to UnitedHealthcare's decision to designate one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18, effective July 1, 2016. Previously, UnitedHealthcare's members accessed our products through one of our distributors.

Cost of Sales and Gross Profit. Our cost of sales in 2016 was $60.7 million, resulting in gross profit of $23.6 million, compared to $46.3 million cost of sales and gross profit of $26.6 million in 2015. The gross margin in 2016 was 28%, compared to 36% in 2015. The decrease in gross profit was primarily due to a net $4.6 million reduction in gross profit as a result of the deferral of sales due to the Technology Upgrade Program. The net reduction of gross profit associated with the Technology Upgrade Program negatively affected our gross margin for 2016 by four percentage points.

In addition, 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. For the first and second quarters in the year ended December 31, 2016, t:slim G4 shipments as a percentage of total pump shipments were 60% and 57%, respectively. By comparison, in the third and fourth quarters of the same year t:slim G4 shipments as a percentage of total pump shipments decreased to 40% and 7%, respectively. This inventory excess and obsolescence charge negatively affected our gross margin for 2016 by three percentage points.

The remaining decrease in gross margin was primarily due to an increase in warranty and other non-manufacturing costs, such as freight, training, and royalty costs, as a percentage of sales. The gross margin was further impacted by an increase in sales of pump-related supplies, which generally have lower gross margins than our insulin pumps. However, we continue to experience improvement in the gross margin associated with our pump-related supplies, achieving a positive gross margin for the first time in the second half of 2016. This improvement was primarily the result of significantly lower per-unit manufacturing costs for cartridges, driven by increased production volumes and manufacturing efficiencies, as well as increases in the volume of infusion sets sold to distributors.

Selling, General and Administrative Expenses. SG&A expenses increased 5% to $82.8 million in 2016 from $78.6 million in 2015. The increase was primarily the result of the expansion of our commercial operations during 2016. In particular, we expanded the number of our sales territories from 60 to 72 in early 2016, and also increased our customer and technical support personnel throughout the year to service our growing customer base.

Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. These expenses increased $4.4 million during 2016 compared to 2015, including an increase of $7.6 million in salaries and fringe benefits,

offset by a decrease in cash-based incentive compensation of $2.1 million and stock-based compensation of $1.2 million. We also experienced reduced costs for outside services, marketing and promotional activities, tradeshows and travel of $0.1 million.

Research and Development Expenses. R&D expenses increased 11% to $18.8 million in 2016 from $17.0 million in 2015. This increase was primarily the result of an increase of $2.3 million in clinical trial expenses, licensing fees, supplies and outside services, as well as an increase in employee-related expenses of $0.5 million. The increase was offset in part by a $1.0 million milestone payment made to DexCom in 2015 that did not recur in 2016.

Other Income (Expense). Other expense in 2016 was $5.4 million, compared to $3.4 million in 2015. Other expense in 2016 and 2015 primarily consisted of interest expense associated with the Term Loan Agreement. Other income for both periods presented was not significant.

Liquidity and Capital Resources

At December 31, 2017, we had $24.2 million in cash and cash equivalents and short-term investments, which included $10.0 million of restricted cash. In February 2018, we completed a registered public offering of 34.5 million shares of our common stock at a public offering price of $2.00 per share. The gross proceeds to us from the February Financing were approximately $69.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. We believe that our cash and cash equivalents and short-term investments balance, including proceeds from the February Financing, as well as additional proceeds that may be available through the exercise of outstanding warrants, will be sufficient to satisfy our liquidity requirements for at least the next 12 months.

Historically, our principal sources of cash have included private placements and public offerings of equity securities, debt arrangements, and cash generated from operations. In November 2013, we completed an initial public offering of common stock that resulted in net proceeds of approximately $125.0 million. In March 2015, we completed a public offering of common stock that resulted in net proceeds of approximately $64.9 million. During 2017, we completed the following financings:

- 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.

- During the three months ended September 30, 2017, we sold 464,108 shares of common stock under our “at-the-market” offering, or the ATM Offering, at prices ranging from $5.64 to $10.54. The gross proceeds to us from the ATM 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 October 2017, we completed a registered public offering 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, which we refer to as the October Financing. The gross proceeds to us from the October Financing were approximately $16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. Each of the two series of warrants, if exercised by all holders in full, may result in additional gross proceeds to us of $16.2 million.

Our historical cash outflows have primarily been associated with cash used for operating activities such as the expansion and support of our sales and marketing infrastructure, an increase in our R&D activities, the acquisition of intellectual property, expenditures related to equipment and improvements used to increase our manufacturing capacity and improve our manufacturing efficiency, overall facility expansion, and other working capital needs. Additionally, we have used cash for the interest expense associated with our Term Loan Agreement.

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 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 our recent financing transactions, concerns regarding our ability to maintain the continued listing of our common stock on NASDAQ, and our current level of indebtedness and debt service costs.

The following table shows a summary of our cash flows for the years ended December 31, 2017, 2016 and 2015:

(in thousands)	Year Ended December 31, 2017	2016	2015
Net cash provided by (used in):			
Operating activities	$ (66,136)	$ (61,173)	$ (58,764)
Investing activities	2,782	10,448	2,421
Financing activities	32,376	52,315	68,255
Total	$ (30,978)	$ 1,590	$ 11,912

Operating activities. Net cash used in operating activities was $66.1 million for the year ended December 31, 2017, compared to $61.2 million and $58.8 million for the same periods in 2016 and 2015, respectively.

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.

The increase in net cash used in operating activities for 2016 compared to 2015 was primarily associated with an increase in our operating loss, offset by changes in working capital. The changes in working capital were primarily due to greater cash collections from accounts receivable and an increase in deferred revenue and guarantee liability associated with the Technology Upgrade Program, offset by changes in employee-related liabilities, other current liabilities, accounts payable and prepaid expenses.

Investing activities. 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 $32.4 million for the year ended December 31, 2017, which was primarily due to net proceeds from the issuance of common stock in the amount of $40.4 million, partially offset by an increase in our restricted cash balance of $8.0 million as required by the Fourth Amendment to our Term Loan Agreement. 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 the exercise of outstanding stock options, and proceeds from employee contributions for the purchase of our common stock through our 2013 Employee Stock Purchase Plan.

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, and any exercise of the warrants issued in the October Financing;
- 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;
- payment of interest due under the Term Loan Agreement;
- acquisition of equipment and other fixed assets; and
- payments under our 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 short-term cash uses or the timing or amount of cash used. If cash generated from operations is insufficient to satisfy our working capital requirements, we may be required to sell additional equity or debt securities. There can be no assurance that equity or debt financing will be available on satisfactory terms, or at all. Further, any additional equity financing may be dilutive to stockholders, and debt financing may require debt service payments and include restrictive covenants. We may also seek to restructure or refinance our existing indebtedness, which could result in additional dilution, debt service costs and restrictive covenants.

Indebtedness

Term Loan Agreement

We had $82.7 million and $81.1 million of aggregate borrowings outstanding under the Term Loan Agreement at December 31, 2017 and December 31, 2016, respectively.

Under the Term Loan Agreement, interest is payable, at our option, (i) in cash at a rate of 11.5% per annum or (ii) at a rate of 9.5% with 2.0% added to the principal of the loan and subject to accruing interest. Interest-only payments are due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period, which ends on December 31, 2019. The principal balance is due in full on the maturity date of the Term Loan Agreement, which is March 31, 2020. We had elected to pay interest in cash at a rate of 11.5% per annum through September 30, 2015. Beginning October 1, 2015, we elected to pay interest in cash at a rate of 9.5% per annum and to have 2.0% per annum added to the principal of the loan. As a result, $2.7 million was added to the principal of the loan since October 1, 2015, which we refer to as PIK Loans.

The loan is collateralized by all of our assets. The principal financial covenants require that we attain minimum annual revenues of $95.0 million in 2018 and each year thereafter until the end of the term of the loan.

In connection with the Third Amendment, we previously agreed to pay, on the earlier of (i) the maturity date of the Term Loan Agreement, (ii) the date that the loan under the Term Loan Agreement becomes due, and (iii) the date on which we make a voluntary pre-payment of the loan, a financing fee equal to 3.0% of the sum of (x) the aggregate amount drawn under the Third Amendment, and (y) any PIK Loans issued in relation to the Third Amendment, which we refer to as the Back End Financing Fee.

Pursuant to the Fourth Amendment, we also agreed to increase the Back End Financing Fee to 5.0% of the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued, under the Term Loan Agreement. The Back End Financing Fee is payable at maturity of our loans and on the principal amount of any loans for which we make an optional prepayment, and may be payable in connection with asset sales not permitted under the Term Loan Agreement or in connection with a change of control. As of December 31, 2017, we had accrued $4.1 million for the Back End Financing Fee.

In February 2018, we entered into the Fifth Amendment, which included a limited advance waiver of a potential event of default in the event that the audit report and opinion of our independent registered public accounting firm contained in this Annual Report included an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. The Fifth Amendment also included a covenant requiring us to complete a financing in which our gross proceeds from the sale of equity securities is at least $20.0 million, no later than August 30, 2018. We satisfied this financing covenant with the completion of the February Financing. In connection with the Fifth Amendment, we also agreed to increase the Back End Financing Fee from 5.0% to 6.0% of the entire aggregate principal amount of borrowings outstanding under the Term Loan Agreement. The audit report included in this Annual Report does not include a qualification regarding our ability to continue as a going concern.

Contractual Obligations & Commitments

The following table summarizes our long-term contractual obligations as of December 31, 2017:

	Payments Due by Period				
(in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligation relating to our facility (1)	$ 13,586	$ 2,705	$ 5,630	$ 5,251	$ -
Term Loan Agreement, including interest (2)	109,400	9,647	99,753	-	-
Firm purchase commitments (3)	15,854	15,854	-	-	-
Total contractual obligations	$ 138,840	$ 28,206	$ 105,383	$ 5,251	$ -

(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. In 2017, we paid $0.5 million in TI Rent. TI Rent is expected to be $0.6 million for each of the years ended December 31, 2018 through 2023.

(2) The amounts indicated include principal, interest and other payments due under the Term Loan Agreement. These amounts assume that we will pay interest in cash at a rate of 11.5% per annum. These amounts also assume that the principal, as well as the full 6.0% Back End Financing Fee, will be paid in full at the maturity date.

(3) The amounts indicated are for purchase orders that are cancellable under the standard terms of our purchase order agreements.

Critical Accounting Policies Involving Management Estimates and Assumptions

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these 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 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 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 financial statements.

Revenue Recognition

Our revenue is generated from sales of our insulin pumps, disposable cartridges and infusion sets to customers in the United States. Our customers are comprised of individuals, and third-party distributors that resell our product to insulin-dependent diabetes customers. We are paid directly by customers who use our products, distributors and third-party payors.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title passed, the price is fixed or determinable, and collectability is reasonably assured.

Revenue Recognition for Arrangements with Multiple Deliverables

We consider the deliverables in our product offering to be separate units of accounting and recognize deliverables as revenue upon delivery only if (i) the deliverable has standalone value and (ii) the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is probable and substantially controlled by us. We allocate consideration to the separate units of accounting, unless the undelivered elements were deemed perfunctory and inconsequential. The amount of the determined guarantee fair value is allocated in full to the guarantee and the remaining allocable consideration is allocated to other separate units of accounting using the relative selling price method, in which allocation of consideration is based on vendor-specific objective evidence, or VSOE, if available, third-party evidence, or TPE, or if VSOE and TPE are not available, management's best estimate of a standalone selling price, or ESP, for the undelivered elements.

We offer a cloud-based data management application, t:connect, which is made available to customers upon purchase of any of our insulin pumps. In July 2016, we received clearance from the FDA to begin offering the Tandem Device Updater, which is a Mac and PC-compatible tool for the remote update of Tandem insulin pump software. Utilizing the Tandem Device Updater, we may from time to time provide future unspecified software upgrades to the insulin pumps' essential software. The t:connect service and the embedded right included with qualifying insulin pumps to receive on a when-and-if-available basis, future unspecified software upgrades relating to the product's essential software are deemed undelivered elements at the time of the insulin pump sale. Because we have neither VSOE nor TPE for these deliverables, the allocation of revenue is based on our ESP. We establish our ESP based on the estimated cost to provide such services, including consideration for a reasonable profit margin, which is then corroborated by comparable market data. We allocate fair value based on management's ESP to these elements at the time of sale and recognize the revenue over a four-year period, which is the hosting period for t:connect and the period that software upgrades are expected to be provided using the Tandem Device Updater. At December 31, 2017 and 2016, $2.0 million and $1.6 million were recorded as deferred revenue for these undelivered elements, respectively. All other undelivered elements at the time of sale are deemed inconsequential or perfunctory.

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 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 our balance sheet for product return allowance was $0.2 million and $0.2 million at December 31, 2017 and 2016, respectively. Actual product returns have not differed materially from estimated amounts reserved.

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. 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 liability. At December 31, 2017 and 2016, the warranty reserve was $5.6 million and $5.7 million, respectively.

Off-Balance Sheet Arrangements

As of December 31, 2017, we did not have any off-balance sheet arrangements.

JumpStart Our Business Startups Act of 2012 (JOBS Act)

The JOBS Act permits an "emerging growth company" such as ours to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We have chosen to "opt out" of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted. This decision to opt out of the extended transition period under the JOBS Act is irrevocable.

We completed our initial public offering in November 2013 and are currently in our fifth year as an "emerging growth company" under the JOBS Act. As such, we will be 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 financial statements for the fiscal year ending December 31, 2018, unless we continue to qualify as a "smaller reporting company."

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

We invest our excess cash primarily in commercial paper, 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, 2017, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

The interest rate under the Term Loan Agreement is fixed and not subject to changes in market interest rates.

Our operations are located in the United States, and nearly all of our sales since inception have been made in U.S. dollars. Accordingly, we have assessed that we do not currently have any material exposure to foreign currency rate fluctuations. 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. Financial Statements and Supplementary Data

Our financial statements as of December 31, 2017 and 2016 and for each of the three years in the period ended December 31, 2017, and the Report of the Independent Registered Public Accounting Firm are included in this report as listed in the index.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements
We have audited the accompanying balance sheets of Tandem Diabetes Care, Inc. (the Company) as of December 31, 2017 and 2016, the related statements of operations and comprehensive loss, stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we been engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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
March 1, 2018

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

	December 31, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 13,700	$ 44,678
Restricted cash	-	2,000
Short-term investments	479	8,860
Accounts receivable, net	20,793	11,172
Inventory, net	26,993	21,195
Prepaid and other current assets	2,191	4,187
Total current assets	64,156	92,092
Property and equipment, net	19,631	18,409
Patents, net	1,457	1,784
Restricted cash - long term	10,000	-
Other long-term assets	102	107
Total assets	$ 95,346	$ 112,392
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,150	$ 7,513
Accrued expense	2,832	1,629
Employee-related liabilities	14,488	10,183
Deferred revenue	2,526	5,208
Common stock warrants	5,432	-
Other current liabilities	5,657	6,943
Total current liabilities	36,085	31,476
Notes payable—long-term	76,541	78,960
Deferred rent—long-term	4,687	2,609
Other long-term liabilities	7,181	5,274
Total liabilities	124,494	118,319
Commitments and contingencies (Note 10)		
Stockholders' deficit:		
Common stock, $0.001 par value; 100,000 shares authorized as of December 31, 2017 and 2016, respectively, 10,119 and 3,110 shares issued and outstanding at December 31, 2017 and 2016, respectively[1]	10	3
Additional paid-in capital	448,455	398,651
Accumulated other comprehensive loss	-	(1)
Accumulated deficit	(477,613)	(404,580)
Total stockholders' deficit	(29,148)	(5,927)
Total liabilities and stockholders' deficit	$ 95,346	$ 112,392

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

(1) The issued and outstanding shares of common stock have been restated for all periods presented to reflect the effects of the 1-for-10 reverse stock split, which was effective on October 9, 2017.

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

	Year Ended December 31,		
	2017	2016	2015
Sales	$ 107,601	$ 84,248	$ 72,850
Cost of sales	63,507	60,656	46,270
Gross profit	44,094	23,592	26,580
Operating expenses:			
Selling, general and administrative	86,377	82,834	78,621
Research and development	20,661	18,809	16,963
Total operating expenses	107,038	101,643	95,584
Operating loss	(62,944)	(78,051)	(69,004)
Other income (expense), net			
Interest and other income	239	296	337
Interest and other expense	(11,341)	(5,707)	(3,741)
Change in fair value of stock warrants	1,021	—	—
Total other expense, net	(10,081)	(5,411)	(3,404)
Loss before taxes	(73,025)	(83,462)	(72,408)
Provision for income tax expense (benefit)	8	(15)	10
Net loss	$ (73,033)	$ (83,447)	$ (72,418)
Other comprehensive loss:			
Unrealized gain (loss) on short-term investments	$ 1	$ (21)	$ 12
Comprehensive loss	$ (73,032)	$ (83,468)	$ (72,406)
Net loss per share, basic and diluted[1]	$ (12.87)	$ (27.30)	$ (25.04)
Weighted average shares used to compute basic and diluted net loss per share[1]	5,677	3,057	2,892

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

(1) The issued and outstanding shares of common stock have been restated for all periods presented to reflect the effects of the 1-for-10 reverse stock split, which was effective on October 9, 2017.

TANDEM DIABETES CARE, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares(1)	Amount(1)	Capital(1)	Income	Deficit	Equity (Deficit)
Balance at December 31, 2014	2,366	$ 2	$ 303,277	$ 8	$ (248,715)	$ 54,572
Exercise of common stock warrants	2	—	122	—	—	122
Exercise of stock options	24	—	337	—	—	337
Issuance of common stock in public offering, net of underwriter's discount and offering costs	603	1	64,861	—	—	64,862
Issuance of common stock for Employee Stock Purchase Plan	31	—	2,934	—	—	2,934
Stock-based compensation	—	—	13,047	—	—	13,047
Unrealized gain on short-term investments	—	—	—	12	—	12
Net loss	—	—	—	—	(72,418)	(72,418)
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)

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

(1) The shares and amounts of common stock and amounts of additional paid-in capital have been restated for all periods presented to reflect the effects of the 1-for-10 reverse stock split, which was effective on October 9, 2017.

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

	Year Ended December 31,		
	2017	**2016**	**2015**
Operating activities			
Net loss	$ (73,033)	$ (83,447)	$ (72,418)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	6,866	5,489	4,829
Interest expense related to amortization of debt discount and debt issuance costs	1,883	274	138
Payment in kind interest accrual of notes payable	1,657	927	153
Provision for allowance for doubtful accounts	824	632	70
Provision for inventory reserve	26	3,343	404
Change in fair value of common stock warrants	(1,021)	—	—
Amortization of (discount) premium on short-term investments	(16)	(85)	4
Stock-based compensation expense	12,628	11,660	13,096
Other	159	(78)	(76)
Changes in operating assets and liabilities:			
Accounts receivable, net	(10,445)	2,251	(6,473)
Inventory, net	(5,894)	(6,904)	(6,084)
Prepaid and other current assets	1,831	(2,466)	(395)
Other long-term assets	4	(2)	131
Accounts payable	(1,953)	3,234	3,355
Accrued expense	1,203	(497)	(734)
Employee-related liabilities	3,873	(1,578)	2,039
Deferred revenue	(3,906)	4,610	981
Other current liabilities	260	573	1,924
Deferred rent	(692)	1	(631)
Other long-term liabilities	(390)	890	923
Net cash used in operating activities	(66,136)	(61,173)	(58,764)
Investing activities			
Purchase of short-term investments	—	(30,622)	(80,191)
Proceeds from sales and maturities of short-term investments	8,500	50,000	88,450
Purchase of property and equipment	(5,718)	(8,930)	(5,764)
Purchase of patents	—	—	(74)
Net cash provided by investing activities	2,782	10,448	2,421
Financing activities			
Issuance of notes payable, net of issuance costs	—	49,994	—
Restricted cash in connection with notes payable	(8,000)	—	—
Proceeds from public offering, net of offering costs	39,806	—	64,862
Proceeds from issuance of common stock	570	2,321	3,393
Net cash provided by financing activities	32,376	52,315	68,255
Net increase (decrease) in cash and cash equivalents	(30,978)	1,590	11,912
Cash and cash equivalents at beginning of period	44,678	43,088	31,176
Cash and cash equivalents at end of period	$ 13,700	$ 44,678	$ 43,088
Supplemental disclosures of cash flow information			
Interest paid	$ 7,876	$ 4,401	$ 3,345
Income taxes paid	$ 22	$ 23	$ 9
Supplemental schedule of noncash investing and financing activities			
Lease incentive - lessor-paid tenant improvements	$ 3,292	$ —	$ 933
Property and equipment included in accounts payable & other current liabilities	$ 92	$ 501	$ 1,457
Debt discount included in other long-term liabilities	$ 4,137	$ 1,509	$ —
Common stock warrants issued in connection with term loan	$ 3,331	$ —	$ —

The accompanying notes are an integral part of the 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 in the United States that are designed to address large and differentiated needs of the insulin-dependent diabetes market. The Company's pump products currently include:

- the t:slim X2 Insulin Delivery System, or t:slim X2, the next-generation flagship product that is updatable and designed to display Dexcom G5 continuous glucose monitoring, or CGM, sensor information directly on the pump Home Screen; and

- the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs.

The Company began commercial sales of its first product, t:slim, in August 2012. During 2015, the Company commenced commercial sales of two additional insulin pumps: t:flex in May 2015 and t:slim G4 in September 2015. In October 2016, the Company commenced commercial sales of t:slim X2 and discontinued new sales of t:slim. In September 2017, the Company commenced commercial sales of t:slim X2 with Dexcom G5 Mobile CGM integration, or t:slim X2 with G5, and discontinued new sales of t:slim G4. The Company will continue to provide ongoing service and support to existing t:slim and t:slim G4 customers.

In July 2016, the Company received clearance from the U.S. Food and Drug Administration ("FDA") to begin offering the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of Tandem insulin pump software.

In July 2016, the Company also announced and launched a Technology Upgrade Program that provided eligible t:slim and t:slim G4 customers a path to obtain t:slim X2, or, as of September 2017, t:slim X2 with G5. Participating customers had the right to exchange their original t:slim and t:slim G4 for a t:slim X2 or t:slim X2 with G5, under a variable pricing structure. The Technology Upgrade Program expired on September 30, 2017.

In September 2017, the Company commenced commercial sales of products using the t:lock Connector, or t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to the cartridge. t:lock incorporates a smaller inner cavity than the Luer-lok connector, which reduces the amount of insulin used in the cartridge fill process and reduces the time required to fill the infusion set tubing.

The 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.

The Company has incurred operating losses since its inception and as reflected in the accompanying financial statements, the Company had an accumulated deficit of $477.6 million as of December 31, 2017. The Company's ability to achieve profitable operations primarily depends upon achieving a level of revenues adequate to support its cost structure. The Company has relied on its ability to fund its operations through private and public equity and debt financing. Management expects operating losses and negative cash flows to continue for at least the next 12 months.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). The accompanying financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the Company's realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustments relating to the recoverability and classification of assets and liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent upon its ability to raise additional equity or refinance its existing debt and ultimately, to attain profitability. There is no assurance that the Company will be successful in raising additional funds or that, if it does raise additional funds, that it will be able to attain profitability or even continue in business.

At December 31, 2017, the Company had $24.2 million in cash and cash equivalents and short-term investments, which included $10.0 million of restricted cash. In February 2018 (see Note 12 "Subsequent Event"), the Company completed a registered public offering of 34,500,000 shares of its 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 the Company. Management evaluated the Company's ability to continue as a going concern within one year of the financial statements being issued and believes that the cash on hand and proceeds from the February financing will be sufficient to satisfy its liquidity requirements for at least the next 12 months.

The Company's ability to continue as a going concern, meet its minimum liquidity requirements in the future or satisfy the other covenants under the Term Loan Agreement is dependent on its ability to continue to grow the business by executing its strategy to achieve renewal pump sales objectives, develop and launch new products, increase gross profits from higher sales of infusion sets, maximize manufacturing efficiencies and leverage early investments made in the sales, clinical and marketing organization. If the Company does not achieve these objectives, it 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.

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 financial statements have been adjusted to reflect the reverse stock split. The number of authorized shares of common stock remains at 100 million shares.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the 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 financial statements and accompanying notes as of the date of the 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 segment discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and managed its business as one segment, operating in the United States.

Cash and 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) income as a separate component of stockholders' deficit on the balance sheets. Unrealized gains or losses on trading securities are reported as a component of other income or expense within the 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 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, no other than temporary declines in fair value have been identified.

Restricted Cash

As of December 31, 2017 and 2016 the Company recorded $10.0 million and $2.0 million of restricted cash, respectively, for the minimum cash balance requirement in connection with the Term Loan Agreement (see Note 5, "Term Loan Agreement").

Accounts Receivable

The Company grants credit to various customers in the normal 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, specific review of outstanding invoices or 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,	
	2017	2016
Edgepark Medical Supplies, Inc.	17.7%	15.2%
Byram Healthcare	17.2%	14.7%
CCS Medical, Inc.	16.2%	N/A

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

	December 31,		
	2017	2016	2015
Edgepark Medical Supplies, Inc.	21.5%	18.7%	17.8%
Byram Healthcare	14.0%	14.0%	17.2%
Solara Medical Supplies, Inc.	N/A	10.7%	N/A
CCS Medical	10.3%	N/A	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. Based on the borrowing rates currently available for loans with similar terms, the Company believes that the fair value of its long-term notes payable approximates its carrying value. The estimated fair value of certain of the Company's common stock warrants is determined by using the Black-Scholes pricing model as of December 31, 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 have been 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. For further details regarding our guarantees, see the following section "Revenue Recognition" within Note 2 and Note 4, "Fair Value Measurements."

Inventory, Net

Inventories are valued at the lower of cost or market (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 based on quantities on hand, expectations of future use, judgments based on quality control testing data and assessments of the likelihood of scrapping or obsoleting certain inventories.

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. 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, 2017.

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 was included in other current liabilities on the Company's 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. 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 is required to file federal and state income tax returns in the United States and various other state jurisdictions. 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 from sales in the United States 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.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title passed, the price is fixed or determinable, and collectability is 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 Pump. Upon expiration of the Program at September 30, 2017, the remaining guarantee liabilities of $1.1 were recognized as sales compared to $1.2 million recorded as guarantee liabilities in other current liabilities on the accompanying balance sheets as of December 31, 2016. There were no guarantee liabilities at 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, 2017 and 2016, $65,000 and $3.2 million, respectively, were recorded as a trade-in rights reserve in deferred revenue on the accompanying balance sheet.

Revenue Recognition for Arrangements with Multiple Deliverables

The Company considers the deliverables in its product offering as separate units of accounting and recognizes deliverables as revenue upon delivery only if (i) the deliverable has standalone value and (ii) if the arrangement includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is probable and substantially controlled by the Company. The Company allocates consideration to the separate units of accounting, unless the undelivered elements were deemed perfunctory and inconsequential. The amount of the determined guarantee fair value is allocated in full to the guarantee and the remaining allocable consideration is allocated to other separate units of accounting using the relative selling price method, in which allocation of consideration is based on vendor-specific objective evidence ("VSOE") if available, third-party evidence ("TPE"), or if VSOE and TPE are not available, management's best estimate of a standalone selling price ("ESP") for the undelivered elements.

The Company offers a cloud-based data management application, t:connect, which is made available to customers upon purchase of any of its insulin pumps. In July 2016, the Company received clearance from the FDA to begin offering the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of Tandem insulin pump software. Utilizing Tandem Device Updater, the Company may from time to time provide future unspecified software upgrades to the insulin pump's essential software. The t:connect service and the embedded right included with qualifying insulin pumps to receive, on a when-and-if-available basis, future unspecified software upgrades relating to the product's essential software are deemed undelivered elements at the time of the insulin pump sale. Because the Company has neither VSOE nor TPE for these deliverables, the allocation of revenue is based on the Company's ESP. The Company establishes its ESP based on the estimated cost to provide such services, including consideration for a reasonable profit margin, which is then corroborated by comparable market data. The Company allocates fair value based on management's ESP to these elements at the time of sale and recognizes the revenue over a four-year period, which is the hosting period for t:connect and the period that software upgrades are expected to be provided. At December 31, 2017 and 2016, $2.0 million and $1.6 million were recorded as deferred revenue for these undelivered elements, respectively. All other undelivered elements at the time of sale are deemed inconsequential or perfunctory.

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 balance sheets for product return allowance was $0.2 million and $0.2 million at December 31, 2017 and 2016, respectively. Actual product returns have not differed materially from estimated amounts reserved in the accompanying 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, 2017 and December 31, 2016, the warranty reserve was $5.6 million and $5.7 million, respectively. The following table provides a reconciliation of the change in estimated warranty liabilities for the years ended December 31, 2017 and 2016:

(in thousands)	December 31, 2017	2016
Balance at beginning of the year	$ 5,690	$ 3,547
Provision for warranties issued during the period	5,613	8,830
Settlements made during the period	(6,742)	(8,739)
Increases in warranty estimates	1,079	2,052
Balance at end of the year	$ 5,640	$ 5,690
Current portion	$ 2,596	$ 2,302
Non-current portion	$ 3,044	3,388
Total	$ 5,640	$ 5,690

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 ("2013 Plan") and shares issued under the Company's 2013 Employee Stock Purchase Plan ("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 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 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, 2017, 2016 and 2015, advertising costs were $1.1 million, $0.9 million, and $1.0 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 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 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. For all periods presented, 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.

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,		
	2017	2016	2015
Warrants for common stock	—	—	99
Common stock options	—	151	202
ESPP	—	2	—
	—	153	301

Reclassifications

Certain reclassifications of prior year amounts have been made to conform to the current year presentation.

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board ("FASB") issued new guidance that clarifies how entities should classify certain cash receipts and cash payments on the statement of cash flows. The guidance also clarifies how the predominance principle should be applied when cash receipts and cash payments have aspects of more than one class of cash flows. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and interim periods within those years. The Company does not believe the adoption of the standard, effective January 1, 2018, will have a material impact on the Company's statement of cash flow.

In June 2016, FASB issued a new credit loss standard that changes the impairment model for most financial assets and certain other instruments. The standard is effective for public business entities for annual periods beginning after December 15, 2019, and interim periods within those years. Early adoption is permitted for all entities for annual periods beginning after December 15, 2018, and interim periods within those years. The Company has not determined the impact of the adoption of the standard on its financial statements.

In March 2016, FASB issued ASU 2016-09, Compensation - Stock Compensation (Topic 718) ("ASU 2016-09"), which is intended to simplify several areas of accounting for share-based payment arrangements. The amendments in this update cover such areas as the recognition of excess tax benefits and deficiencies, the classification of those excess benefits on the statement of cash flows, an accounting policy election for forfeitures, the amount an employer can withhold to cover income taxes and still qualify for equity classification and the classification of those taxes paid on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, and interim periods within those annual periods. The Company adopted this standard in the first quarter of 2017. The Company has excess tax benefits for which a benefit could not previously be recognized of approximately $0.6 million. Upon adoption, the balance of the unrecognized excess tax benefits was reversed with the impact recorded to accumulated deficit, including any change to the valuation allowance as a result of the adoption. Due to the full valuation allowance on the U.S. deferred tax assets as of December 31, 2017 and 2016, there was no impact to the financial statements as a result of this adoption in 2017.

In February 2016, FASB issued final guidance for lease accounting. The new guidance requires lessees to recognize most lease liabilities and corresponding right-of-use assets with terms greater than twelve months on their balance sheet but to recognize expenses on their income statement in a manner similar to current accounting principles. The new guidance also eliminates the current real estate-specific provisions for all entities. The standard is effective for public companies for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. The Company believes the adoption will modify its analyses and disclosures of lease agreements since operating leases are a significant portion of the Company's total lease commitments. The Company is in the process of assessing the impact of the adoption of the standard on its financial statements.

In May 2014, FASB and the International Accounting Standards Board issued a comprehensive new revenue recognition standard ("Revenue from Contracts with Customers Standard") that will supersede existing revenue guidance under U.S. GAAP and International Financial Reporting Standards. The Revenue from Contracts with Customers Standard's core principle is that a company will recognize 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. In doing so, companies will need to use more judgment and make more estimates than under current guidance. The Revenue from Contracts with Customers Standard will be effective for the Company beginning in its first quarter of 2018, and early adoption is permitted.

Subsequently, FASB issued the following standards related to Revenue from Contracts with Customers Standard: Principal versus Agent Considerations; Identifying Performance Obligations and Licensing; and Narrow-Scope Improvements and Practical Expedients (collectively, the "new revenue standards"). The new revenue standards may be applied retrospectively to each prior period presented (full retrospective method) or retrospectively with the cumulative effect recognized as of the date of adoption (the modified retrospective method). The Company will adopt the new revenue standard in the first quarter of 2018 utilizing the modified retrospective method. This adoption will not have a material impact on the recognition of revenues for the sale of its products through third-party distributors and insurance payors with whom it has contractual arrangements, which generally comprise approximately 99% of its sales. For sales that are impacted by this adoption, revenue is currently recognized upon collection of cash at which time the price is considered determinable. Pursuant to this new standard, such revenue will be recognized upon delivery to the customer at the estimated transaction price, using the expected value method. As a result, on January 1, 2018, the Company will record a net adjustment to accumulated deficit in the amount of approximately $0.2 million, reflecting this accounting change. Additionally, the Company has given consideration to the accounting for warranty and commissions, for which there will not be a material change to its current method of expense recognition.

3. Financial Statement Information

Short-term investments

The Company invests in investment securities, principally debt instruments of financial institutions and corporations it evaluates to have strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at December 31, 2017 and 2016 (in thousands):

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

At December 31, 2016	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale investment securities:					
Commercial paper	Less than 1	$ 8,483	$ 1	$ (2)	$ 8,482
Trading securities:					
Mutual funds held for nonqualified deferred compensation plan participants		$ 354	$ 26	$ (2)	$ 378
Total		$ 8,837	$ 27	$ (4)	$ 8,860

Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	December 31,	
	2017	2016
Accounts receivable	$ 22,071	$ 12,112
Less allowance for doubtful accounts, and product returns	(1,278)	(940)
Total	$ 20,793	$ 11,172

The following table provides a reconciliation of the change in estimated allowance for doubtful accounts, and product returns for the years ended December 31, 2017, 2016 and 2015 (in thousands):

	Allowance for doubtful accounts
Balance at December 31, 2014	$ 253
Provision for doubtful accounts and return reserves	70
Write-offs and adjustments, net of recoveries	(102)
Balance at December 31, 2015	$ 221
Provision for doubtful accounts and return reserves	632
Write-offs and adjustments, net of recoveries	(118)
Balance at December 31, 2016	$ 735
Provision for doubtful accounts and return reserves	824
Write-offs and adjustments, net of recoveries	(524)
Balance at December 31, 2017	$ 1,035

Inventory

Inventory consisted of the following at (in thousands):

	December 31,	
	2017	2016
Raw materials	$ 10,328	$ 9,375
Work in process	3,812	4,395
Finished goods	12,853	7,425
Total	$ 26,993	$ 21,195

The increase in inventory at December 31, 2017 as compared to December 31, 2016 is primarily due to an increase in infusion set finished goods in connection with the commercial launch of the t:lock infusion set.

Property and Equipment

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

	December 31,	
	2017	2016
Leasehold improvements	$ 13,924	$ 8,851
Computer equipment and software	9,040	7,844
Office furniture and equipment	4,686	4,185
Manufacturing and scientific equipment	17,505	16,785
	45,155	37,665
Less accumulated depreciation and amortization	(25,524)	(19,256)
Total	$ 19,631	$ 18,409

Depreciation and amortization expense related to property and equipment amounted to $6.5 million, $5.2 million, and $4.5 million for the years ended December 31, 2017, 2016, and 2015, 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, 2017 and 2016 (in thousands):

	December 31,	
	2017	2016
Gross amount	$ 3,247	$ 3,247
Accumulated amortization	(1,790)	(1,463)
Total	$ 1,457	$ 1,784
Weighted average remaining amortization period (in months)	54	66

Amortization expense related to intangible assets subject to amortization amounted to $0.3 million for each of the years ended December 31, 2017, 2016, and 2015. The amortization expense is recorded in cost of sales in the statement of operations. The estimated annual amortization is $0.3 million for periods 2018 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, 2017 and 2016, 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, 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

	December 31, 2016	Fair Value Measurements at December 31, 2016		
		Level 1	Level 2	Level 3
Assets				
Cash equivalents (1)	$ 39,941	$ 39,941	$ —	$ —
Commercial paper	8,482	—	8,482	—
Mutual funds held for nonqualified deferred compensation plan participants (2)	378	378	—	—
Total assets	$ 48,801	$ 40,319	$ 8,482	$ —
Liabilities				
Deferred compensation (2)	$ 378	$ 378	$ —	$ —
Total liabilities	$ 378	$ 378	$ —	$ —

(1) Cash equivalents included money market funds and commercial paper with a maturity of three months or less from the date of purchase.

(2) Deferred compensation plans are compensation plans directed by the Company and structured as a Rabbi Trust for certain executives and non-employee directors. The investment assets of the Rabbi Trust are valued using quoted market prices multiplied by the number of shares held in each trust account. The related deferred compensation liability represents the fair value of the investment assets.

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, 2017 and 2016.

Level 3 liabilities at December 31, 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. These warrants were initially valued at $6.5 million on the date of issuance utilizing a Black-Scholes pricing model. The Series A warrants to purchase 4,630,000 shares of the Company's common stock have a contractual life of five years with an exercise price of $3.50 per share. The Series B warrants to purchase 4,630,000 shares of the Company's common stock have a contractual life of six months with an exercise price of $3.50 per share.

The Company reassesses the fair value of the 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, 2017 are presented below:

	Series A Warrants	Series B Warrants
Risk-free interest rate	2.2%	1.4%
Expected dividend yield	0.0%	0.0%
Expected volatility	63.5%	80.3%
Expected term (in years)	4.8	0.3

The following table presents a summary of changes in fair value of the Company's total Level 3 financial assets for the year ended December 31, 2017:

Balance at offering date	$ 6,453
Decrease in fair value included in change in fair value of common stock warrants	(1,021)
Balance at end of year	$ 5,432

As of December 31, 2016, the Company recorded a $1.2 million as a guarantee liability in other current liabilities on the accompanying balance sheet, and as a reduction of revenue in the statement of operations and other comprehensive loss. There were no guarantee liabilities at December 31, 2017. Guarantees are not measured at fair value on a recurring basis; they are not included in the tables above. Guarantees are classified within Level 3 of the fair value hierarchy. The estimated fair value of the guarantee is based on various economic and customer behavioral assumptions, including the probability that a trade-in right will 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 t:slim X2 (see Note 2, "Summary of Significant Accounting Policies – Revenue Recognition"). Changes in the probability of the trade-in have the most significant impact on the estimate of the fair value of the liability.

5. Term Loan Agreement

At December 31, 2017, the Company had $82.7 million of aggregate borrowings outstanding under the Term Loan Agreement. At December 31, 2016, the Company had $81.1 million of aggregate borrowings outstanding under the Term Loan Agreement. In January 2016, the Company entered into Amendment No. 3 to the Term Loan Agreement (the "Third Amendment") which allowed the Company to borrow up to an additional $50.0 million. The Company borrowed $15.0 million of this amount in January 2016 and the remaining $35.0 million in December 2016. The term loan is collateralized by all assets of the Company. The principal financial covenants require that the Company attain minimum annual revenues of $80.0 million in 2017 and $95.0 million each year thereafter until the Maturity Date.

Under the principal terms of the Term Loan Agreement, interest is 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 (the "PIK Loan") to be added to the principal of the loan and subject to accruing interest. Interest-only payments are due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period, which ends on December 31, 2019. The principal balance is due in full at the end of the term of the loan, which is March 31, 2020 (the "Maturity Date"). The Company had elected to pay interest in cash at a rate of 11.5% per annum through September 30, 2015. Beginning October 1, 2015, 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, $1.7 million and $0.9 million was added to the principal of the loan for the years ended December 31, 2017 and 2016, respectively, which the Company refers to as PIK Loans.

Pursuant to the Third Amendment, the Company agreed to pay, on the earlier of (i) the Maturity Date, (ii) the date that the loan under the Term Loan Agreement becomes due, and (iii) the date on which the Company makes a voluntary pre-payment of the loan, a financing fee equal to 3.0% of the sum of (x) the aggregate amount drawn under the Third Amendment, and (y) any PIK Loans issued in relation to the Third Amendment (collectively, the "Back End Financing Fee").

In March 2017, we entered into the Fourth Amendment to the Term Loan Agreement (the "Fourth Amendment"), which included a limited waiver of a potential event of default that could have resulted from the explanatory paragraph in the audit report of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016. In consideration for the waiver, we agreed to: (i) issue Capital Royalty Partners ten-year warrants to purchase an aggregate of 193,788 shares of our common stock at an exercise price equal to $23.50 per share, the closing price of our common stock on the NASDAQ Global Market on the date of the Fourth Amendment, (ii) increase our minimum cash balance requirement under the Term Loan Agreement from $2.0 million to $10.0 million, (iii) provide Capital Royalty Partners the same information we make available to our board of directors, subject to limited exceptions, and (iv) not incur additional third party indebtedness secured solely by accounts receivable, inventory and cash. In addition, the Fourth Amendment included a covenant which required us to complete a financing in which our gross proceeds from the sale of equity securities was at least $30.0 million, no later than January 15, 2018. As of December 31, 2017, the Company was in compliance with this covenant.

Furthermore, the Company agreed to increase the Back End Financing Fee to 5.0% of the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued, under the Term Loan Agreement, which was $82.7 million as of December 31, 2017. The Back End Financing Fee is payable at maturity of the Company's loans and on the principal amount of any loans for which it makes an optional prepayment, and may be payable in connection with asset sales not permitted under the Term Loan Agreement or in connection with a change of control. As of December 31, 2017, the Company had accrued $4.1 million for the Back End Financing Fee in other long-term liabilities and as contra-debt in notes payable-long-term on the accompanying balance sheet.

The Company treated the execution of both the Third Amendment and Fourth Amendment 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%. The Back End Financing Fee and the remaining balance of debt issuance costs and debt discount of the loan are amortized to interest expense over the remaining term using the effective interest method.

Future minimum principal payments under the Term Loan Agreement as of December 31, 2017, are as follows (in thousands):

Year ended December 31,		
2018	$	—
2019		—
2020		82,737
2021		—
2022		—
Thereafter		—
Total	$	82,737
Less current portion of notes payable		—
Notes payable, net of current portion	$	82,737

On February 6, 2018, the Company entered into the Fifth Amendment, which includes a limited advance waiver of a potential event of default that could have resulted from a qualification regarding the Company's ability to continue as a going concern in the audit report for the year ended December 31, 2017. The Fifth Amendment includes a covenant requiring the Company to complete a financing in which gross proceeds from the sale of equity securities is at least $20.0 million, no later than August 30, 2018, which was satisfied with the February 2018 financing (Note 12 "Subsequent Event"). In addition, the Company agreed to increase the Back End Financing Fee from 5.0% to 6.0% of the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued, under the Term Loan Agreement.

6. Stockholders' Equity (Deficit)

Public Offerings

In the first quarter of 2015, the Company completed a public offering of 603,750 shares of its common stock at a public offering price of $115.00 per share. Gross cash proceeds from the public offering were approximately $69.4 million, after deducting underwriting discounts, commissions and offering expenses payable by the Company.

In March 2017, the Company 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 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 October 2017, the Company completed the October Financing, pursuant to which it 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 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. Each series of warrants, if exercised by all holders in full, may result in additional gross proceeds to us of $16.2 million.

In February 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.

Stock Plans

In September 2006, the Company adopted the Company's 2006 Stock Incentive Plan (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 Incentive Plan (the "2013 Plan") and no further options will be granted under the 2006 Plan.

In October 2013, the Company's board of directors approved the 2013 Plan. The 2013 Plan became effective immediately prior to the completion of the 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 shares available for issuance under the 2013 Plan were increased by 124,823 shares and 121,018 shares on January 1, 2017 and 2016, respectively, in accordance with an "evergreen" provision under the 2013 Plan.

As of December 31, 2017, zero shares were available for future issuance under the 2013 Plan, and options to purchase 1,331,269 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, 2015	574,607	$ 107.22	7.99	$ 19,158
Granted	316,316	$ 45.75		
Exercised	(14,866)	$ 11.49		$ 1,049
Canceled/forfeited/expired	(53,792)	$ 126.19		
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	$ -
Vested and expected to vest at December 31, 2017	1,313,053	$ 47.55	8.07	$ -
Exercisable at December 31, 2017	602,646	$ 84.93	6.39	$ -

This table does not include 811,800 shares granted pursuant to the 2013 Plan that are expressly subject to and conditioned upon the approval by our stockholders of an increase to the number of shares authorized under the 2013 Plan.

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 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 increases on January 1 of each calendar year, from January 1, 2014 through January 1, 2023, 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. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. In the years ended December 31, 2017 and 2016, 38,929 shares and 69,233 shares of our common stock, respectively, were purchased under the ESPP. As of December 31, 2017, 13 shares remained available for issuance under the ESPP. On January 1, 2017 and 2016, the number of shares of common stock reserved for issuance under the ESPP was automatically increased by 31,096 shares and 30,255 shares, respectively.

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.

Prior to the suspension of the ESPP, eligible employees could 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.

Stock-Based Compensation.

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

	Year Ended December 31,		
	2017	2016	2015
Cost of sales	$ 1,360	$ 1,016	$ 1,162
Selling, general & administrative	10,020	9,360	10,517
Research and development	1,248	1,284	1,417
Total	$ 12,628	$ 11,660	$ 13,096

This table does not include value for 811,800 shares granted pursuant to the 2013 Plan that are expressly subject to and conditioned upon the approval by our stockholders of an increase to the number of shares authorized under the 2013 Plan.

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, 2017 and 2016, respectively.

There was no expense for stock option grants to non-employees for the years ended December 31, 2017 and 2016. For the year 2015, the expense for stock option grants to non-employees was $35,000, and is included in the table above as a component of selling, general and administrative expenses.

At December 31, 2017, the total unamortized stock-based compensation expense of approximately $6.0 million will be recognized over the remaining weighted average vesting term of approximately 1.9 years.

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

	Stock Option		
	Year Ended December 31,		
	2017	2016	2015
Weighted average grant date fair value (per share)	$ 2.65	$ 24.30	$ 71.50
Risk-free interest rate	2.1%	1.7%	1.7%
Expected dividend yield	0.0%	0.0%	0.0%
Expected volatility	60.8%	57.5%	64.7%
Expected term (in years)	5.8	5.8	6.0

	ESPP	
	Year Ended December 31,	
	2017(1)	2016
Weighted average grant date fair value (per share)	N/A	$ 17.80
Risk-free interest rate	N/A	0.7%
Expected dividend yield	N/A	0.0%
Expected volatility	N/A	62.7%
Expected term (in years)	N/A	1.3

(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. Prior to January 1, 2016, the expected volatility is estimated based on volatilities of a peer group of similar companies whose share prices are publicly available. Since January 1, 2016, 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 are reserved for future issuance at December 31, 2017 (in thousands):

Common stock warrants outstanding	9,553
Stock options issued and outstanding	1,331
Authorized for future option grants	—
Employee stock purchase plan	—
	10,884

This table does not include 811,800 million shares granted pursuant to the 2013 Plan that are expressly subject to and conditioned upon the approval by our stockholders of an increase to the number of shares authorized under the 2013 Plan.

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,		
	2017	2016	2015
Income tax benefit at federal statutory rate	$ (24,829)	$ (28,362)	$ (24,616)
State income tax, net of federal benefit	(2,034)	(2,393)	(2,285)
Warrants revaluation	(347)		
Research and development credits	(480)	(720)	(1,796)
Uncertain tax position		—	3,154
Stock-based compensation	3,214	1,686	1,904
Tax Cuts and Jobs Acts	51,577		
Other	(7)	456	550
Removal of net operating losses and research and development credits	145	—	8,344
Change in valuation allowance	(27,231)	29,318	14,755
Income tax expense (benefit)	$ 8	$ (15)	$ 10

Significant components of the Company's net deferred income tax assets at December 31, 2017 and 2016 are shown below (in thousands). A valuation allowance has been recorded to offset the net deferred tax asset as of December 31, 2017 and 2016, as the realization of such assets does not meet the more-likely-than-not threshold.

	December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss (NOL) carryforwards	$ 81,483	$ 100,251
Research and development tax credits carryforwards	3,517	2,543
Capitalized research and development expenses	12,746	16,673
Deferred rent	170	537
Accrued compensation	8,809	11,332
Other	3,969	5,931
Total deferred tax assets	110,694	137,267
Less valuation allowance	(110,694)	(137,267)
Net deferred tax assets	$ —	$ —

The remaining California NOL carry forwards of $181.3 million will expire beginning in 2028.

As of December 31, 2017, the Company has accumulated federal and state NOL carryforwards of approximately $335.3 million and $306.0 million, respectively, not considering the annual limitation of Section 382 of the Internal Revenue Code of 1986, as amended (the "Code") discussed below. The federal and state tax loss carryforwards begin to expire in 2026 and 2018, respectively, unless previously utilized. The Company also has federal and California research credit carryforwards of approximately $4.4 million and $5.3 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 financial statements. ASU 2016-09 is effective for public companies for and adopted by the Company in 2017. The Company adopted this ASU 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 were reversed with the impact recorded to retained earnings which was fully offset by a change to the valuation allowance.

Utilization of the NOLs and R&D credit carryforwards are subject to annual limitations due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 of the Code, as well as similar state and foreign provisions. These ownership changes may limit the amount of NOLs and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an “ownership change,” as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders.

Although the Company determined that it is more likely than not that an ownership change had occurred in March 2015, the Company has not completed a formal update of its Section 382 analysis subsequent to December 31, 2013. Until this analysis has been updated, the Company has removed deferred tax assets for NOLs of $16.0 million and research and development credits of $2.9 million from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. The amount presented as a deferred tax asset with respect to losses and credits after the removal of potentially limited amounts reflects the estimated asset value using the Section 382 limitation criteria as of the date of the March 2015 public offering of 603,750 shares of common stock, given that it is possible that this transaction may have triggered the limitation. When this analysis is finalized, the Company will reassess the amount of NOLs and credits subject to limitation under Section 382. Due to the existence of the valuation allowance, future changes in the deferred tax assets related to these tax attributes will not impact the Company’s effective tax rate.

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.

In December 2017, the Tax Cuts and Jobs Act (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 of 35% to a 21% flat tax. As a result of the tax rate, our deferred tax assets were decreased by $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 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 tax effects of these provisions requires further analysis which is expected to be completed in the second half of 2018.

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. As such, the Company's financial results reflect the provisional income tax effects of the 2017 Tax Act for which the accounting under ASC Topic 740 is incomplete but a reasonable estimate could be determined.

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, 2017, 2016 and 2015 (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Gross unrecognized tax benefits at the beginning of the year	$ 8,167	$ 7,594	$ 3,539
Increases related to current year positions	411	580	474
Increases (decreases) related to prior year positions	(457)	(7)	3,581
Expiration of unrecognized tax benefits	—	—	—
Gross unrecognized tax benefits at the end of the year	$ 8,121	$ 8,167	$ 7,594

As of December 31, 2017, the Company had $6.7 million of unrecognized tax benefits that, if recognized and realized would impact the effective tax rate.

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 balance sheets and has not recognized interest and penalties in the statements of operations for the years ended December 31, 2017 and 2016. The Company does not expect any significant increases or decreases to its unrecognized tax benefits within the next 12 months.

The Company is subject to taxation in the United States and state jurisdictions. 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.

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. ("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 the 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 (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 recorded as an increase to cost of sales and current liability in the period that the related t:slim G4 Pump sale is recorded. The Company recorded such marketing fund commitment of $1.1 million and $0.7 million in the years ended December 31, 2017 and 2016, 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 quarter following their date of hire. 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 assesses, on a regular basis, the probability and range of possible loss based on the developments in these matters. A liability is recorded in the financial statements if it is believed to be probable that a loss has been incurred and the amount of the loss can be reasonably estimated. Because of the uncertainties related to the occurrence, amount, and range of loss on any pending actions, the Company is currently unable to predict their ultimate outcome, and, with respect to any pending litigation 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 unfavorable outcome. At December 31, 2017 and 2016, there were no material matters for which a negative outcome was considered probable or estimable.

Operating leases

Under a noncancelable operating lease agreement ("Existing Operating Lease"), the Company leases manufacturing, laboratory and office space in San Diego, California. On December 27, 2017, the Company entered into an amendment to the Existing Operating Lease which terminates the lease with respect to the building located at 11045 Roselle Street as of January 31, 2018 and extends the remaining Existing Operating Lease term through May 2022. The building located at 11045 Roselle Street, which primarily housed the Company's manufacturing and related operations, was largely replaced by a facility located on Barnes Canyon Road in San Diego, California (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 $419,000.

In connection with the Existing Operating Lease, the Company has a $0.5 million unsecured standby letter of credit arrangement with a bank under which the landlord of the building is the beneficiary. The expiration of the standby letter of credit is July 14, 2019.

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 allows for a Tenant Improvement 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 (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 $5.6 million and $3.7 million at December 31, 2017 and 2016, respectively. Rent expense for the three years ended December 31, 2017, 2016 and 2015, was $3.5 million, $3.1 million, and $2.6 million, respectively.

Future minimum payments under the aforementioned noncancelable operating leases for each of the five succeeding years following December 31, 2017 are as follows (in thousands):

2018	$ 2,705
2019	2,757
2020	2,873
2021	2,959
2022	1,650
Thereafter	642
	$ 13,586

Not included in the table above is the Barnes Canyon Lease TI Rent, which totaled $0.4 million during the year ended December 31, 2017. No TI Rent was due as of December 31, 2016. TI Rent will be approximately $0.6 million for each of the years ended December 31, 2018 through 2023.

11. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for fiscal 2017 and 2016 is presented in the following table, in thousands, except per share data:

	For the Quarter Ending			
	March 31	June 30	September 30	December 31
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)
2016:				
Revenue	$ 20,058	$ 22,985	$ 12,293	$ 28,912
Gross profit	$ 6,927	$ 8,176	$ (1,577)	$ 10,065
Operating expenses	$ 26,166	$ 25,229	$ 26,837	$ 23,411
Operating loss	$ (19,239)	$ (17,053)	$ (28,414)	$ (13,346)
Net loss	$ (20,485)	$ (18,326)	$ (29,815)	$ (14,822)
Basic and diluted net loss per share (1)	$ (6.80)	$ (6.00)	$ (9.70)	$ (4.80)

(1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per-share calculations will not necessarily equal the annual per share calculation. The issued and outstanding shares of common stock have been restated for all periods presented to reflect the effects of the 1-for-10 reverse stock split, which was effective on October 9, 2017.

12. Subsequent Event

In February 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 February 2018, the Company entered into the Fifth Amendment to its Term Loan Agreement, which includes a limited advance waiver of a potential event of default that could have resulted from a qualification regarding the Company's ability to continue as a going concern in the audit report for the year ended December 31, 2017. The Fifth Amendment includes a covenant requiring the Company to complete a financing in which gross proceeds from the sale of equity securities is at least $20.0 million, no later than August 30, 2018, which was satisfied with the February 2018 financing. In addition, the Company agreed to increase the Back End Financing Fee from 5.0% to 6.0% of the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued, under the Term Loan Agreement.

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. In designing and evaluating the disclosure 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 of December 31, 2017, 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, 2017.

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 financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2017, 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, 2017, our internal control over financial reporting was effective based on those criteria.

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.

Item 9B. Other Information.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item and not set forth below will be set forth in our definitive Proxy Statement for our 2017 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC pursuant to Schedule 14A not later than 120 days after the end of the fiscal year ended December 31, 2017, and is incorporated herein by reference.

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.

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:

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 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 October 9, 2017 and currently in effect)	S-1/A	333-222553	29-Jan-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 between 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 between 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 between 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 between Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P., Capital Royalty Partners II—Parallel Fund "B" (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.	10-Q	001-36189	30-Apr-15	10.1	
10.5	Amendment No. 3 to Term Loan Agreement, dated January 8, 2016, by and between 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 between 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 between 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. 2013 Stock Incentive Plan.	S-1/A	333-191601	1-Nov-13	10.6
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. 2013 Employee Stock Purchase Plan.	S-1/A	333-191601	1-Nov-13	10.9
10.15*	Tandem Diabetes Care, Inc. 2015 Cash Bonus Plan.	10-K	001-36189	24-Feb-15	10.25
10.16*	Tandem Diabetes Care, Inc. 2016 Cash Bonus Plan.	10-K	001-36189	24-Feb-15	10.14
10.17*	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
10.18*	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
10.19*	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
10.20*	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
10.21*	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
10.22*	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	
10.25*	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	
10.26*	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	
10.27	Form of Indemnification Agreement.	S-1	333-191601	7-Oct-13	10.11	
10.28**	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	
10.29**	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	
10.30**	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	
10.31	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	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	
10.33	Lease Agreement, dated June 30, 2016, by and between Tandem Diabetes Care, Inc. and ARE-SD REGION NO. 36, LLC.	10-Q	001-36189	28-Jul-16	10.3	
10.34	Development Agreement, dated June 4, 2015, by and between Tandem Diabetes Care, Inc. and DexCom, Inc.	10-Q	001-36189	26-Oct-17	10.1	
10.35	Fourth Amendment to Lease, dated December 27, 2017, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC.	8-K	001-36189	3-Jan-18	10.2	
10.36	First Amendment to Lease, dated December 27, 2017, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC.	8-K	001-36189	3-Jan-18	10.1	
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: March 1, 2018

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)	March 1, 2018
/s/ LEIGH A. VOSSELLER Leigh A. Vosseller	Senior Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 1, 2018
/s/ DICK P. ALLEN Dick P. Allen	Director and Chairman of the Board	March 1, 2018
/s/ EDWARD L. CAHILL Edward L. Cahill	Director	March 1, 2018
/s/ FRED E. COHEN Fred E. Cohen, M.D., D.Phil.	Director	March 1, 2018
/s/ HOWARD E. GREENE, JR. Howard E. Greene, Jr.	Director	March 1, 2018
/s/ DOUGLAS A. ROEDER Douglas A. Roeder	Director	March 1, 2018
/s/ CHRISTOPHER J. TWOMEY Christopher J. Twomey	Director	March 1, 2018

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:
(1) Registration Statement (Form S-3 No. 333-333-222143) of Tandem Diabetes Care, Inc.,
(2) Registration Statement (Form S-8 No. 333-192406) pertaining to the 2006 Stock Incentive Plan, 2013 Stock Incentive Plan, and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care Inc.,
(3) Registration Statement (Form S-8 No. 333-202254) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc., and
(4) Registration Statement (Form S-8 No. 333-209685) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc.;
of our report dated March 1, 2018, with respect to the financial statements of Tandem Diabetes Care, Inc. included in this Annual Report (Form 10-K) of Tandem Diabetes Care, Inc. for the year ended December 31, 2017.

/s/Ernst & Young LLP

San Diego, California
March 1, 2018

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kim D. Blickenstaff, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tandem Diabetes Care, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Tandem Diabetes Care, Inc.

By: /s/ Kim D. Blickenstaff
Kim D. Blickenstaff
President, Chief Executive Officer and Director

Dated: March 1, 2018

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Leigh A. Vosseller, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tandem Diabetes Care, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Tandem Diabetes Care, Inc.

By: /s/ Leigh A. Vosseller
Leigh A. Vosseller
Senior Vice President, Chief Financial Officer and Treasurer

Dated: March 1, 2018

Exhibit 32.1

CERTIFICATION
Pursuant to U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Tandem Diabetes Care, Inc. (the "Company") for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kim D. Blickenstaff, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: March 1, 2018

/s/ Kim D. Blickenstaff
Kim D. Blickenstaff
President, Chief Executive Officer and Director

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
Pursuant to U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Tandem Diabetes Care, Inc. (the "Company") for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leigh A. Vosseller, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: March 1, 2018

/s/ Leigh A. Vosseller
Leigh A. Vosseller
Senior Vice President, Chief Financial Officer and Treasurer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.