

TANDEM DIABETES CARE INC
Form 10-K
March 08, 2017

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, 2016

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.

Edgar Filing: TANDEM DIABETES CARE INC - Form 10-K

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation or organization)	20-4327508 (I.R.S. Employer Identification No.)
11045 Roselle Street San Diego, California (Address of principal executive offices)	92121 (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

Edgar Filing: TANDEM DIABETES CARE INC - Form 10-K

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, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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

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, 2016, the aggregate market value of the registrant's common stock held by non-affiliates was approximately \$140.5 million based on the closing price for the common stock of \$7.54 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 March 6, 2017, there were 31,335,891 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2017 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.

TABLE OF CONTENTS

Part I	
Item 1	<u>Business</u> 3
Item 1A	<u>Risk Factors</u> 33
Item 1B	<u>Unresolved Staff Comments</u> 64
Item 2	<u>Properties</u> 64
Item 3	<u>Legal Proceedings</u> 65
Item 4	<u>Mine Safety Disclosures</u> 65
Part II	
Item 5	<u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> 66
Item 6	<u>Selected Financial Data</u> 68
Item 7	<u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u> 69
Item 7A	<u>Quantitative and Qualitative Disclosure About Market Risk</u> 84
Item 8	<u>Financial Statements and Supplementary Data</u> 86
Item 9	<u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u> 112
Item 9A	<u>Controls and Procedures</u> 113
Item 9B	<u>Other Information</u> 113
Part III	
Item 10	<u>Directors, Executive Officers and Corporate Governance</u> 114
Item 11	<u>Executive Compensation</u> 114
Item 12	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u> 114
Item 13	<u>Certain Relationships and Related Transactions, and Director Independence</u> 114
Item 14	<u>Principal Accounting Fees and Services</u> 114
Part IV	
Item 15	<u>Exhibits, Financial Statement Schedules</u> 115
	<u>Signatures</u> 119

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2016, 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 financial condition (including our ability to continue as a going concern, to raise additional capital and to succeed in our future operations), 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, 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 that our competitive advantage is rooted in our unique consumer-focused approach and proprietary technology platform. This allows us to deliver innovative hardware and software solutions to meet the various needs and preferences of people with diabetes and their healthcare providers. We manufacture and sell insulin pump products in the United States that are designed to address large and differentiated segments of the insulin-dependent diabetes market. Our insulin pump products include:

- the t:slim X2 Insulin Delivery System, or t:slim X2, our next-generation flagship product,
- the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs, and
- the t:slim G4 Insulin Delivery System, or t:slim G4, the first continuous glucose monitoring, or CGM, enabled pump with touchscreen simplicity.

From the launch of our first product in August 2012, through December 2016, we have shipped more than 50,000 pumps. For the past three consecutive years, our company and our products have been ranked #1 by insulin pump users in the United States for customer support, product features and ease of training in an independent survey by dQ&A, a leading diabetes research firm.

According to the Centers for Disease Control and Prevention, or CDC, in 2016, approximately 22 million people in the United States had diagnosed diabetes. Close Concerns, Inc., an independent consulting and publishing company that provides diabetes advisory services, or Close Concerns, estimated in 2015 that there are approximately 1.6 million people with type 1 diabetes in the United States and 1.7 million people with type 2 diabetes in the United States who require daily administration of rapid acting insulin. 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. Our target market consists of the approximately 3.3 million people in the United States who require daily rapid acting insulin.

We began commercial sales of our first insulin pump product, 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. Each of our insulin pump products is compatible with the Tandem Device Updater, a 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 faster than the industry has been able to in the past. Its

first cleared use by the U.S. Food and Drug Administration, or FDA, was to update t:slim Pumps purchased before April 2015 to the latest software. In the first quarter of 2017, we filed a regulatory submission with the FDA to permit t:slim X2 customers to update their pumps' software using the Tandem Device Updater to allow integration with the DexCom G5 Mobile CGM system, which is manufactured by DexCom, Inc., or DexCom. Subject to FDA approval, we intend to offer this update to t:slim X2 customers free of charge. 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, 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, which seeks to optimize our devices, allowing users to successfully operate our devices in their intended environment.

We developed our products to provide the specific features that people with insulin-dependent diabetes seek in a next-generation insulin pump. Our proprietary pumping technology allows us to design the slimmest and smallest durable insulin pumps on the market, without sacrificing insulin capacity. Our insulin pump platform features our patented Micro-Delivery technology, and a miniaturized pumping mechanism that draws insulin from a flexible bag within the pump's cartridge, rather than relying on a syringe and plunger mechanism. It also features an easy-to-navigate software architecture, a vivid color touchscreen and a micro-USB connection that supports a rechargeable battery, software updates through the Tandem Device Updater, and uploads to t:connect Diabetes Management Application, or t:connect. t:connect is our custom cloud-based data management application that provides customers and healthcare providers a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters. Our next generation pump, t:slim X2, also features an advanced Bluetooth radio capable of communicating with multiple compatible devices.

Based on customer surveys, approximately half of our customers are new to insulin pump therapy, and the average age of our existing customers is 32 years old, with relatively equal distribution between men and women. By offering multiple differentiated products that are all 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.

In the third quarter of 2016, we launched a Technology Upgrade Program that provides eligible t:slim and t:slim G4 customers a path towards ownership of a t:slim X2 by providing customers the right to exchange their t:slim or t:slim G4 for a t:slim X2, under a variable pricing structure. The Technology Upgrade Program expires on September 30, 2017.

The Technology Upgrade Program results in complex accounting treatment of sales and cost of sales, including deferral of amounts from the time of initial sale to the earlier of the date that we complete the upgrade of the original pump and when the program ends. In general, the deferrals required by the Technology Upgrade Program have the effect of initially decreasing our GAAP sales even where the number of our pump shipments increases. When a customer elects to participate in the Technology Upgrade Program, we recognize upgrade fees that we receive, if any, and the associated costs, at the time of fulfilling the given obligation. At this time, we are not able to estimate when we will recognize deferred sales or costs of sales as a result of the Technology Upgrade Program, nor are we able to estimate the amount of upgrade fees or associated costs for a customer's election to participate in the Technology Upgrade Program.

For the years ended December 31, 2016, 2015 and 2014, our sales were \$84.2 million, \$72.9 million and \$49.7 million, respectively. For the years ended December 31, 2016, 2015 and 2014, our net loss was \$83.4 million, \$72.4 million, and \$79.5 million, respectively. 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. Our accumulated deficit as of December 31, 2016 was \$404.6 million. Pump sales accounted for 74%, 83% and 86% of sales, respectively, for the years ended December 31, 2016, 2015 and 2014, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in any of these years.

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 technology platform and consumer-focused approach, and by providing strong customer support. 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.

Our headquarters and our manufacturing facility are located in San Diego, California and we employed 591 full-time employees as of December 31, 2016.

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 International Diabetes Federation estimates that in 2015 approximately 415 million people had diabetes worldwide and that by 2040, this number will increase to 642 million people worldwide. According to the Center for Disease Control and Prevention, or CDC, in 2016 approximately 22 million people in the United States had diagnosed diabetes.

There are two primary types of diabetes:

Type 1 diabetes is caused by an autoimmune response in which the body attacks and destroys the insulin-producing cells of the pancreas. As a result, the pancreas can no longer produce insulin, requiring patients to administer daily insulin to survive. According to Close Concerns, in 2015, approximately 1.6 million people had type 1 diabetes in the United States.

Type 2 diabetes occurs when the body does not produce enough insulin to regulate the amount of glucose in the blood, or cells become resistant to insulin and are unable to use it effectively. 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. According to Close Concerns, in 2015, approximately 1.7 million people in the United States with type 2 diabetes required daily administration of rapid acting insulin.

Our target market consists of approximately 3.3 million people in the United States who require daily administration of insulin, which includes approximately 1.6 million people with type 1 diabetes and approximately 1.7 million people with type 2 diabetes who require daily rapid acting insulin. 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.

There are two primary therapies practiced 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 multiple daily injection, or 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. By comparison, insulin pump therapy uses only rapid acting insulin to fulfill both mealtime (bolus) and background (basal) requirements. Insulin pump therapy allows a person to customize their bolus and basal insulin doses to meet their insulin needs throughout the day, and is intended to more closely resemble the physiologic function of a healthy pancreas.

Insulin pump therapy 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	Requires injections up to seven times per day
	Lower upfront and ongoing supply costs	Delivers insulin less accurately than insulin pumps
	Lower risk of technological malfunction	Results in greater variability in blood glucose levels or less accurate glycemic control
		Requires more planning around and restrictions regarding meals and exercise
Insulin Pump	Eliminates individual insulin injections	Requires intensive education on insulin pump therapy and management
	Delivers insulin more accurately and precisely than injections	Wearing a pump can be bothersome
	Often improves HbA1c, a common measure of blood glucose levels over time	More costly
	Fewer large swings in blood glucose levels	Risk of diabetic ketoacidosis if the catheter comes out and insulin infusion is interrupted
	Provides greater flexibility with meals, exercise and daily schedules	
	Can improve quality of life	

Reduces severe low blood glucose episodes

Eliminates unpredictable effects of intermediate or long-acting insulin

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

According to Close Concerns estimates in 2015, approximately 425,000 people with type 1 diabetes in the United States use an insulin pump, or approximately 27% of the type 1 diabetes population. In addition, approximately 125,000 people with type 2 diabetes in the United States use an insulin pump, or approximately 7% of the type 2 diabetes population who are insulin-dependent.

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. 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.

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 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 therapy features, or even discourage use entirely.

Pump mechanism limitations. Traditional pumps utilize a syringe and plunger mechanism 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 plunger. The design also potentially exposes the user to the unintended delivery of the full volume of insulin within the pump, which can cause hypoglycemia or death. This effect is well documented and can occur when traditional pumps are elevated above the user's infusion site, referred to as siphoning, or when the user experiences changes in air pressure, such as during air travel. Our research has shown that the fear of adverse health events due to technical malfunctions related to traditional pump mechanism limitations deters the adoption of insulin pump therapy.

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.

Our Solution

We developed our proprietary technology platform using a consumer-focused approach by first utilizing 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 product features they seek and in a manner that makes the features usable. We believe this approach is fundamentally different from the approach applied to the traditional medical device development process. All of our insulin pump products were developed using this approach, as were our complementary offerings, the Tandem Device Updater and the t:connect Data Management Application.

Our insulin pump products, which we believe address the shortcomings of traditional pumps, include:

Contemporary style. Our current products, as well as our products under development, have the look and feel of a modern consumer electronic device, such as a smartphone. Relying on significant consumer input and feedback during the development process, we believe the aesthetically-pleasing, modern 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 our products unique in the insulin pump market.

Our Insulin Pump Form Factor (Actual Size of All Tandem Pump Products)

Adaptable platform. Our products share a pump form factor, as well as an updatable, easy-to-navigate software architecture combined with a touchscreen user interface. This enables us to offer differentiated features and functionality while on a shared technology platform, which allows us to execute on our strategy of leveraging a single sales, marketing and clinical organization, as well as a shared manufacturing and supply chain infrastructure. It also creates efficiencies when training healthcare providers as our products' user interface operations are the same across all products, subject only to slight differences that relate to specific features such as a large volume cartridge or CGM integration. t:slim, t:slim X2 and t:flex are also compatible with the Tandem Device Updater, a new 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, our products can easily and discreetly fit into a pocket. t:slim X2 and t:slim G4 are the slimmest and smallest durable insulin pumps on the market, while still offering a cartridge with 300 units of insulin. More specifically, t:slim X2 and t:slim G4 are 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 pump 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 touch-screen 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

Next generation technology platform. 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 plunger mechanism. The pump is specifically designed to help prevent the unintentional delivery of insulin from the reservoir by limiting the volume of insulin that can be delivered to a person at any one time and to reduce fear associated with using a pump. Our technology was tested under both typical and extreme operating conditions and is designed to last for at least the anticipated four-year warranty life of the pump. Our technology allows us to reduce the size of the device as compared to traditional pumps, which allows our pumps to be the slimmest and smallest durable insulin pumps on the market. In addition, our technology is capable of delivering the smallest increment of insulin to users of any pump currently available, which allows insulin therapy to be individualized for each user.

Quick Access to Pump History

Our Insulin Pump Mechanism

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

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

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 desire from their insulin therapy, and by offering insulin pump products with different features and functionality, we believe we are uniquely positioned to provide a broad range of insulin pump products that allow us to address multiple segments of the diabetes market. At the same time, by offering multiple pump products that are based on our proprietary technology platform, 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 expanded sales, marketing and clinical infrastructure and multiple product offerings. We have achieved commercial success since the launch of our first commercial product, t:slim, by investing in the development of our sales, marketing and clinical infrastructure. We believe we are now in a position to leverage this infrastructure to increase access to our products by more people with insulin-dependent diabetes, their caregivers and healthcare providers. For example, we are leveraging this infrastructure by marketing our new products, including t:slim X2, to primarily the same healthcare providers as our previous pump products, thereby increasing the efficiency of new product launches. We believe that our investment in our sales, marketing and clinical infrastructure, combined with the launch of additional product offerings through the same infrastructure and the marketing of new products to our existing customers, will drive continued adoption of our products, while efficiently increasing our revenues over the long-term.

Promote awareness of our differentiated 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 broaden our direct-to-consumer marketing to promote the insulin therapy features and functionality offered by our products through our website, the use of social media tools, our t:imulator 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 that we will attract users of 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 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. We plan to continue to invest in clinical activities intended to demonstrate that the use of our pump products contributes to improved clinical outcomes.

Advance our platform of innovative, consumer-focused products to address the unmet needs of people in the insulin-dependent diabetes market. We believe that our proprietary technology platform allows us to provide the most sophisticated and intuitive insulin pump therapy products on the market. In addition, our FDA-cleared Tandem Device Updater is a new tool that is designed to allow pump users to quickly and easily update their pump's software from a personal computer. For example, subject to obtaining FDA approvals, we intend to leverage our technology platform to allow t:slim X2 users to update their pumps' software to include CGM integration and AID algorithms. We also intend to leverage our platform to continue to pursue advances in the automated delivery of insulin, 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 with t:slim X2. In addition, we intend to continue to explore further advancements in our technology platform to expand our product offerings, as well as the features and functionality associated with our products, in order to address different segments of the large and growing insulin-dependent diabetes market.

Invest in our consumer-focused approach. We believe that 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 current 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 that third-party reimbursement is an important determinant in driving consumer adoption of insulin pump therapy. We also believe that 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 headquarters 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 intend to relocate our manufacturing operations to a new larger facility, which will allow us to expand our production capacity further by replicating our production lines and gaining efficiencies from the operation of a facility designed to maximize our manufacturing processes and workflows. Because each of our products is based on our proprietary technology platform, the products have shared product design features, making our production system highly adaptable to new products. As demand for our products increase, 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.

Our Technology Platform

Utilizing our unique consumer-focused approach, which is based on our extensive market research and the science of human factors, we have developed an innovative technology platform that is fundamental to the design of our existing products and provides the foundation for development of future products. The key elements of our 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 up to seven days. 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 has been tested to last for at least the four-year warranty life of the pump. Our battery also allows for accessible monitoring of the current charge level on the device's Home Screen.

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

In 2016, we introduced to the market t:slim X2, the next generation of our flagship t:slim product that originally launched in 2012. In 2016, we also launched the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of our insulin pumps' software. In 2015, we launched two additional pumps, t:flex and t:slim G4, which were each designed to address different needs of people with insulin-dependent diabetes. In 2013, we launched t:connect, a companion diabetes management application for use with our pumps. We believe our unique products address the significant and fundamental shortcomings of traditional pumps and will allow people to manage their diabetes more efficiently.

Commercial Products

Our Insulin Pump Products

All of our insulin pump products 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 insulin remaining 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 pump products 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 pump products 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 a rechargeable battery, software updates through the Tandem Device Updater, and uploads to t:connect.

t:slim X2 Insulin Delivery System

Our next-generation flagship product, 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. t:slim X2 replaced t:slim, which was originally commercialized in the third quarter of 2012. 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. 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 CGM integration or AID algorithms, to their pumps independent of their typical four-year insurance pump replacement cycle. Measuring 2.0 x 3.1 x 0.6 inches, t:slim X2 (and t:slim G4) is the slimmest and smallest durable insulin pump on the market.

In the third quarter of 2016, we launched a Technology Upgrade Program that provides eligible t:slim and t:slim G4 customers a path towards ownership of t:slim X2 by providing customers the right to exchange t:slim or t:slim G4, under a variable pricing structure. The Technology Upgrade Program expires on September 30, 2017.

300-unit Insulin Cartridge being inserted into Pump

t:flex Insulin Delivery System

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 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. We believe that offering a 480-unit cartridge addresses the typical insulin needs of a person with type 2 diabetes who is insulin-dependent. Our research has also shown that the appearance and bulky size of traditional pumps is a deterrent to pump adoption for people with greater insulin needs. We believe the combination of t:flex's larger insulin reservoir, combined with the other features and benefits offered by our technology platform, provides us with an opportunity to expand the current insulin pump market to address the unmet needs of individuals with greater insulin requirements.

t:slim G4 Insulin Delivery System with Integrated CGM

t:slim G4 Insulin Delivery System includes the first and only touchscreen pump with CGM integration. It combines features of a t:slim and DexCom G4 PLATINUM CGM System, both devices that have consistently ranked #1 in independent surveys, into a single device that is simple to use. We began commercial sales of t:slim G4 in the United States in the third quarter of 2015.

We have a development and commercialization agreement with DexCom, which provides us a non-exclusive license to integrate our product platform with the DexCom G4 PLATINUM CGM System. t:slim G4 incorporates the same pump technology and user interface as t:slim, but also provides the added convenience of allowing CGM information to be displayed on the pump, 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.

CGM is a therapy used in conjunction with blood glucose testing, and provides users with real-time access to their glucose levels as well as trend information. Notwithstanding the significant potential benefits associated with using CGM technology as a component of diabetes management therapy, Close Concerns estimates that approximately only 10% of people with type 1 diabetes currently use CGM. We believe that CGM utilization may be significantly increased by offering an accurate CGM sensor in combination with an innovative and consumer-focused insulin pump, such as t:slim. t:slim G4 is designed to meet these requirements for the diabetes market.

We commenced commercial sales of t:slim G4 in September 2015. During the fourth quarter of 2015, and in the first half of 2016, t:slim G4 represented the majority of our insulin pump shipments. However, following our announcement of the commercial launch of t:slim X2, sales of t:slim G4 decreased and began to represent the smallest percentage of our pump shipments compared to our other insulin pump products.

Our Complementary Products

Tandem Device Updater

Our Tandem Device Updater was cleared by the FDA in the third quarter of 2016 and is a Mac and PC-compatible tool for the remote update of Tandem insulin pump software. Our pump software may be updated in a manner similar to how a user would update software on a smartphone. We are uniquely positioned to offer this capability due to the intuitive software architecture and convenient micro-USB connection included within our pump products. This tool allows us to provide our customers access to new and enhanced pump features and functionality faster than the industry has been able to in the past, and separate from the typical four-year insurance pump replacement cycle.

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. This updated software began shipping on new t:slim Pumps as of April 2015 and includes a variety of product enhancements that offer convenience and flexibility. 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 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 providing clinical outcomes data for marketing purposes and to payors. We also believe that t:connect can serve as a key component of mobile health applications that are currently under development.

We developed t:connect to be intuitive, with 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 2016, we initiated the launch of an enhanced version of t:connect that we expect will simplify the ability of patients to share their t:connect data with their healthcare providers, which we refer to as t:connect HCP. We expect to make t:connect HCP available to all interested healthcare providers in 2017. This application will allow 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

We offer our customers various infusion set choices for use with our insulin pump products. During 2015, we launched a Tandem-branded infusion set under the t:90 brand name. The t:90 offers a 90-degree soft cannula and comes pre-loaded in an automatic spring inserter, making one-handed insertions quick and easy, even in hard-to-reach areas. During 2016, we launched the second Tandem-branded infusion set under the t:30 brand name. The t:30 offers the same features and benefits as the t:90, but with a 30-degree soft cannula, which is often preferred by users who are lean or lead an active lifestyle. Both the t:90 and t:30 infusion sets come in a wide variety of tubing lengths to fit customers' individual needs.

Beginning in the second half of 2017, we intend to replace the standard Luer-lok connector that currently joins an infusion set to our cartridge with a custom connector, the t:lock™ Connector. Our t:lock Connector was designed to address the most requested improvement to our products that we have received from customers. It will be similar in its design to that of a standard Luer connector, but will, on average, reduce the time required to fill tubing by more than 30 seconds and reduce the amount of insulin used in the process by four and a half units. It will also reduce the likelihood that air bubbles will become trapped in the connector. We intend to offer our customers the same choice in infusion set configurations as they are able to purchase from us today, but with the added benefits associated with our t:lock Connector. However, we expect to offer customers both the original Luer-lok connector and our t:lock Connector concurrently for a period of time to facilitate the transition, and by year end we intend to only offer our t:lock Connector. We anticipate that the transition to our t:lock Connector will also result in an increase in our sales of infusion sets beginning in the second half of 2017. 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. These accessories include different color casings, belt clips, and leather cases.

Insulin Pump Accessories

Products under Development

Our products under development support our strategy to focus on both consumer and clinical needs. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionality that will allow us to target people in different segments of the insulin-dependent diabetes market. In addition, we are evaluating the potential benefit of our technology platform when used to administer alternative therapies for diseases outside of diabetes.

t:slim X2 with G5 integration

The first new feature that we plan to roll out on t:slim X2 is the display of DexCom G5 CGM sensor information directly on the pump's Home Screen. In our market research, t:slim X2 with G5 integration was shown to be highly competitive when compared to alternative pump offerings, including pumps featuring AID algorithms. We filed a PMA supplement for this feature in the first quarter of 2017 and we are preparing to launch t:slim X2 with G5 integration in mid-2017 pending FDA approval. Subject to FDA approval, we also intend to offer customers who purchase a t:slim X2 prior to the availability of G5 CGM integration the ability to quickly update their pump software using the Tandem Device Updater to add this feature for no charge.

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. Within t:slim, t:slim X2 and t:flex there is a Bluetooth low energy radio, or BLE, that is not presently enabled. In July 2013, we submitted a Master File to the FDA, allowing researchers to use t:slim technology with the BLE enabled. This device provides researchers wireless use of our device with their selected algorithm and CGM for single hormone or dual hormone clinical studies.

t:slim X2 with PLGS

Our first generation AID system is expected to include a predictive low glucose suspend, or PLGS, algorithm. The algorithm will be integrated with t:slim X2 and use DexCom G5 CGM sensor data to help predict future hypoglycemia before it happens. This product will be designed 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 PLGS algorithm was reported as the most valuable AID feature among people with insulin-dependent diabetes and their healthcare providers. During 2016, we completed a pilot study of our PLGS algorithm. We expect to begin a pivotal study for t:slim X2 with PLGS in the first half of 2017, the results of which could then be used to prepare a PMA supplement that we intend to file with the FDA by the end of 2017.

t:slim X2 with TypeZero

We expect our second generation AID system will also involve t:slim X2, will use DexCom's G6 CGM technology, and will feature inControl 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 28 clinical studies including more than 475 participants and the data has been referenced in a number of journal articles. This product will be differentiated from competing products, as we expect it will include automated correction boluses, which we believe will bring additional benefits to our customers.

In November 2016, we announced that we are working with DexCom and TypeZero on the integration of our technologies into the National Institute of Health funded International Diabetes Closed Loop Trial, or IDCL Trial. The IDCL Trial is expected to enroll 240 adults with type 1 diabetes and enrollment began in late 2016.

The IDCL trial is structured in two phases:

- 1) The first phase will use a modified t:slim and DexCom's G5 sensor as part of an AID system that combines these devices with a smartphone running TypeZero's inControl AID algorithms. The system will predict high and low blood sugar levels and adjust the rate of insulin delivery throughout the day in order to try to keep a user's blood sugar levels within a predetermined range, while still allowing the user to administer a bolus manually for meals.
- 2) In the second phase, we anticipate the IDCL Trial will utilize a t:slim X2 integrated with a DexCom G6 sensor that will also incorporate TypeZero's inControl AID algorithms directly into the pump's touchscreen interface.

We anticipate that the integrated design used in the second phase of the IDCL Trial, together with data from the first phase of the trial, will be the primary basis for us to file a PMA submission with the FDA for the potential future commercial launch of t:slim X2 with TypeZero's inControl AID algorithms. We also anticipate conducting a smaller targeted pediatric study in a summer or winter camp setting for our planned PMA submission. In our market research, people with insulin-dependent diabetes and healthcare providers reported a strong preference for t:slim X2 with TypeZero as compared to a competitive AID system. Subject to the timely completion of a successful IDCL Trial, and subject to future FDA approval, we are currently planning to launch this product by the end of 2018.

t:sport Insulin Delivery System

The t:sport Insulin Delivery System, or t:sport, is currently about 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 and a Bluetooth radio. We also 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.

In 2016, we began discussions with the FDA on the t:sport controller, and whether it can be implemented as a mobile device application or if it needs to be a separate device. Based on their feedback and concerns regarding the use of mobile phones, we believe that controlling a pump via a mobile device will be a longer path-to-market, and so we plan to design the product so that it can be technically capable of being 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.

At this time, there is not a predicate device for an insulin pump wirelessly controlled through a mobile device application. The timing of the commercialization will be based on our ongoing dialogue with the FDA.

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, 2016, we had a sales, clinical and marketing team of approximately 200 full-time employees. In the first quarter of 2016, we expanded our sales and clinical organization from 60 to 72 territories. Each territory within our sales organization consists of 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. 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 customer sales support organization also contacts existing customers who are approaching their insurance renewal date to aid in the renewal process. 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 and may evaluate international commercialization opportunities.

In addition, as of December 31, 2016, we had executed agreements with approximately 40 independent distributors. 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. For the year ended December 31, 2015, Edgepark Medical Supplies, Inc., and Byram Healthcare accounted for 17.8%, and 17.2% of our sales, respectively. None of our independent distributors have been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements 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, and national tradeshows, including 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 G4, our marketing also emphasizes the greater accuracy of the DexCom G4 PLATINUM 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 webinars 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, Diabetes Hands Foundation, Students with Diabetes, College Diabetes Network, Diabetes Scholars; 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.

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.

In connection with t:slim G4, we also offer our customers 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 the location that they prefer, which offers them a convenient method to access the latest training available. We anticipate using similar online training modules for the CGM components of t:slim X2 with DexCom's G5 sensor integration, which is currently pending FDA review.

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.

Our customer-focused technical services team provides support seven days a week, 24 hours a day by answering questions, trouble-shooting and addressing issues or concerns. Our insulin pump products are covered by a four-year warranty that includes our product replacement program through which our technical services team members can provide a customer with a replacement device within as little as 24 hours to minimize the interruption of his or her therapy.

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, 2016, we had entered into commercial contracts with approximately 150 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, 2016, approximately 23% 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, 2016, we had executed distributor agreements with approximately 40 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 headquarters in San Diego, California, but will be transitioning the manufacturing operations to a nearby facility that will allow for future capacity expansion. 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 is expected to begin during the second quarter of 2017 and to be completed by the end of 2017. During the transition period, we expect to experience some temporary duplication of operations to support ongoing product requirements, as well as some incremental manufacturing costs.

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 1,000,000 cartridges per year on a single shift. We are actively working to improve the efficiency of our disposable cartridge manufacturing process. For instance, we are currently working towards manufacturing t:flex cartridges primarily using the same semi-automated manufacturing equipment used in the manufacture of t:slim X2 and t:slim G4 cartridges, as well as reducing 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.

We have significantly increased our manufacturing output since we began the commercialization of our first product and we will have the ability to expand our production capacity in the new facility by replicating our production lines. Our production system is also adaptable to new products due to shared product design features. We intend to drive operational efficiencies by leveraging our manufacturing infrastructure.

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 audited 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 includes design control requirements. 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.

We entered into a Development and Commercialization Agreement with DexCom, which provides us a non-exclusive license to integrate the DexCom G4 PLATINUM CGM System with t:slim G4 during the term of the agreement. The license covers the United States, and such other territories as may be added from time to time. We paid DexCom \$1.0 million at the commencement of the collaboration, and a \$1.0 million milestone payment in July 2014, and a final \$1.0 million payment in September 2015. The payments were recorded as research and development costs. We agreed to pay DexCom a royalty payment in the amount of \$100 for each integrated system sold. In September 2015, we amended the agreement with DexCom such that, in lieu of the \$100 royalty payment, we will commit \$100 for each t:slim G4 sold for incremental marketing activities associated with t:slim G4 that are in addition to a level of ordinary course marketing activities or marketing activities to support other jointly funded development projects. Our agreement with DexCom runs until January 4, 2019, with automatic one-year renewals. Either party may terminate the agreement without cause upon 18 months' prior notice. In addition, in the event of a change of control of either party, the other party may unilaterally elect to terminate the agreement, subject to limited ongoing obligations. The agreement also contains customary provisions for termination in the event of an uncured material breach or in the event of a dissolution of the other party.

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 continuous glucose monitoring 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 \$18.8 million, \$17.0 million, and \$15.8 million in 2016, 2015 and 2014, respectively. This includes the \$1.0 million milestone payments made to DexCom under the Development and Commercialization Agreement relating to t:slim G4, in each of the years ended December 31, 2015 and 2014.

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, 2016 our patent portfolio consisted of approximately 50 issued U.S. patents and 46 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2035. We are also seeking patent protection for our proprietary technology in other countries throughout the world. In addition, we also have one pending U.S. trademark applications as well as 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, 2016, 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, Inc., Animas Corporation, a division of Johnson & Johnson, 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, and in early 2017, Johnson & Johnson announced that it is evaluating strategic options for its diabetes business unit, including Animas. It is too early to evaluate 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 with significantly more market share and resources than we have. 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 threshold suspend feature and has FDA approval for a traditional insulin pump with a hybrid closed-loop AID algorithm that it intends to launch in 2017.

In addition, we face competition from a number of companies, medical researchers and existing pharmaceutical companies that are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and prevention of diabetes.

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

Government Regulation

Our products are medical devices subject to extensive regulation by the FDA, corresponding state regulatory authorities and, if we commence international sales, other regulatory bodies in other countries. The Federal Food, Drug and Cosmetic Act, or 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 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 received FDA approval as a Class III device. t:slim X2 is currently considered a Class II device, but upon approval by the FDA of t:slim X2 with DexCom's G5 sensor integration, we anticipate that t:slim X2 will thereafter also be considered 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 is reviewing the 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;

Medical Device Reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;

voluntary and mandatory device recalls to address problems when a device is defective and could be a risk to health; and

corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

Also, the FDA may require us to conduct post-market surveillance studies or establish and maintain a system for tracking our products through the chain of distribution to the patient level. The FDA and the Food and Drug Branch of the California Department of Health Services enforce regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

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

warning letters or untitled letters that require corrective action;

finest 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. The U.S. Department of Health and Human Services, or HHS, has issued regulations, commonly known as safe harbors, that set forth certain provisions which, if fully met, will result in parties to a transaction or arrangement being assured that the transaction or arrangement does not violate 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. However, conduct and business arrangements that do not fully satisfy each element of an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the HHS Office of Inspector General.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to five years, fines of up to \$25,000 per violation 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. The 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 law, 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 provision 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, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement. 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 exceptions 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 and \$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. 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 as inadvertent any billing errors that may be made, 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. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, 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 HIPAA.

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

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

Employees

As of December 31, 2016, we had 591 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

Edgar Filing: TANDEM DIABETES CARE INC - Form 10-K

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 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 Relating 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, 2016, we had an accumulated deficit of \$404.6 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, 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. 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, 2016 and 2015, our gross profit was \$23.6 million and \$26.6 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 the next several years.

To implement our business strategy we need to, among other things, increase sales and gross profits of our products, maintain an appropriate customer service and support infrastructure, fund ongoing research and development activities, improve and expand 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 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. In addition, our implementation of the Technology Upgrade Program makes forecasting our operating results more difficult, because such forecasts depend on customer behavioral assumptions, such as the likelihood that the trade-in rights will actually be exercised and the timing of any such decisions. 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, which currently include our t:slim X2, t:flex and t:slim G4 products. Sales of our insulin pumps may be negatively impacted by many factors, including:

the potential that other technological breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pump products 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 their 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 facility; 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 financial results, recent changes in our stock price, our current level of indebtedness, recent or anticipated competitive product launches, the impact of the Technology Upgrade Program, and uncertainties regarding the regulatory environment. Any such concerns, whether actual or perceived, could cause consumers to delay the purchase of our products or to 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, and negatively impact our ability to successfully launch future products currently under development.

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, or 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. Other significant insulin pump suppliers in the United States include Animas Corporation, a division of Johnson & Johnson, 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, and in early 2017, Johnson & Johnson announced that it is evaluating strategic options for its diabetes business unit, including Animas. It is too early to evaluate the potential impact of these changes on our competitive landscape. There are also newer companies entering the field.

Some of our competitors 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 and third-party payors;

established reputation and name recognition among healthcare providers and other key opinion leaders in the diabetes industry;

in some cases, 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 currently offers a traditional insulin pump that is integrated with a CGM system with a threshold suspend feature. In addition, Medtronic recently announced that it received FDA approval of a new insulin pump product with additional functionality and a new CGM system that it intends to launch during 2017. Furthermore, Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set. For these and other reasons, we may not be able to compete successfully against our current or potential future competitors. As a result, we may fail to meet our forecasted budget, and our sales and operating results may be negatively affected.

The administration of the Technology Upgrade Program may result in unanticipated difficulties or costs, which may harm our financial condition or operating results.

In July 2016, we announced the implementation of the Technology Upgrade Program that allows eligible t:slim and t:slim G4 customers the ability to trade in their existing pump for t:slim X2, subject to the conditions specified in the program. The Technology Upgrade Program is being offered to provide our existing customers the ability to upgrade to the features and capabilities of t:slim X2. However, we do not have experience implementing and administering trade-in programs of this type and we may encounter unexpected difficulties, costs or uncertainties in administering or fulfilling our obligations under the Technology Upgrade Program. For example, it is difficult to predict the impact of the adoption of the Technology Upgrade Program on the willingness of consumers to purchase our products compared to competitive products, or the timing of any purchase decisions. If we incur unexpected difficulties, costs or uncertainties in administering the Technology Upgrade Program, or if we do not derive the anticipated benefits to our business from offering the program to our customers, the program could have a material adverse effect on our financial condition and operating results.

The Technology Upgrade Program has resulted in accounting complexities that may be difficult for investors to understand and may lead to confusion when comparing our historical and future financial results.

The Technology Upgrade Program has resulted in a number of accounting complexities that will make comparisons of our historical and future financial results more difficult. In particular, United States generally accepted accounting principles, or GAAP, prevent us from recognizing, at the time of sale, up to 100% of the sales and cost of sales associated with the sale of t:slim and t:slim G4 made to eligible customers during the term of the Technology Upgrade Program. Instead, depending on the type of pump sold, we are required to defer some or all of the sales and cost of sales until a later date, which will generally be the earlier of when our obligations under the Technology Upgrade Program are satisfied or when the program expires. The amount and timing of the deferred sales and cost of sales will depend on multiple factors that are based on future events that are difficult to estimate or predict, especially because we have not offered a similar trade-in program in the past. For example, we do not currently have sufficient history to reasonably estimate the likelihood that the trade-in rights will be exercised, or the timing of any trade-in decisions. Accordingly, it is very difficult for us to estimate the amount of the deferrals with any level of certainty, which makes it very difficult for us to predict our GAAP results, including revenues and operating margins.

Despite our efforts to explain the required accounting treatment for the Technology Upgrade Program, it is possible that investors or analysts will view the accounting treatment or the resulting impact on our GAAP financial results negatively, and there may be confusion when comparing our historical and future financial results, which may cause our stock price to decline. In addition, the complexities associated with the accounting treatment, or with the Technology Upgrade Program generally, may cause investors to avoid purchasing our common stock until the impact of the program is better understood or our financial results and trends are more predictable, which also may adversely impact our stock price.

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit cost of our products 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 and expected warranty expenses. 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 experience disruption in our manufacturing productivity or incur duplicative or incremental costs as we manage the planned relocation of our manufacturing facility over the next 12 months. Furthermore, while we currently believe our proprietary technology platform will allow us to gain efficiencies in the design and development of new products, changes in the market that require us to modify or replace our existing platform will reduce the amount of efficiency gained through our platform and increase our per unit costs. If we are unable to effectively manage our overall costs, while increasing our production volumes, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results.

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, which currently include t:slim X2, t:flex and t:slim G4, achieving and maintaining market acceptance. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that it is 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 insulin pump

products, our sales may decline or we may fail to increase our sales in line with our forecasts.

Achieving and maintaining market acceptance of our products could be negatively impacted by many factors, including:

the failure of our products to achieve 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;

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, especially in light of our recent financial results and the recent decline in the market price of our common stock, 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. For example, we believe that during the second half of 2016, consumers interested in purchasing our insulin pump products may have delayed or changed their purchasing decisions in anticipation of the release of a new product by one of 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 projected amounts. If our sales do not meet our sales projections, our business, financial condition and operating results could be materially and adversely affected, and we may fail to meet our strategic objectives.

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. 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 is essential to the acceptance of our products by customers.

As guidelines in setting their coverage and reimbursement policies, many third-party payors 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. More recently, 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 150 national and regional third-party payors in the United States. While we anticipate entering into additional contracts 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, any negative perceptions among third-party payors regarding our financial stability and 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. This may be especially true in light of our conclusion that, if we do not successfully raise additional capital, there is substantial doubt about our ability to continue as a going concern and the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern included in the report of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016. 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.

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 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. 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 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.

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

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 may 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, t:flex, and t:slim G4 Pumps and 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 is the ability of our sales, clinical, marketing and customer service infrastructure to drive adoption of our products, which includes independent diabetes educators that train new customers on the use 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 recent decline in our stock price, 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 that 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 could even 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, 2016, sales to approximately 40 independent distributors represented approximately 74% of our sales. While our goal 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 meaningful percentage 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. 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 is also expected to increase following our launch of the t:lock Connector for our insulin cartridge, which we expect will 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, our conclusion that, unless we successfully raise additional capital, there is substantial doubt about our ability to continue as a going concern, together with the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in our independent registered public accounting firm's report contained in our financial statements for the year ended December 31, 2016, may negatively impact one or more of our distributors' interest in continuing to do business with us. None of our independent distributors has been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements generally have one-year initial terms with automatic one-year renewal terms, and are terminable in connection with a party's material breach. 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, 2016, our two largest independent distributors collectively comprised approximately 33% 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 such a situation, 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 that 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 cause 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 contract with or reach other mutually acceptable agreements with these third parties on a timely basis or on mutually acceptable terms, 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 IDCL Trial to support our development

of t:slim X2 with TypeZero inControl AID algorithms. 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 TypeZero 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 TypeZero. 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.

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, 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 and may have a material adverse effect on our business, financial condition and operating results.

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 early in their commercialization in competitive and rapidly-evolving markets.

We commenced operations in 2006, and 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. Accordingly, we have a limited operating history upon which to evaluate our business and forecast our future sales and operating results. More recently, our launch of t:slim X2, our adoption of the Technology Upgrade Program, the FDA approval and launch of new products by one of our competitors, and the use of aggressive pricing strategies by our competitors combine to make forecasting our future sales and operating results even more challenging. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization history in competitive and rapidly evolving markets, particularly companies that develop 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;

increase awareness of our brand and build loyalty among people with insulin-dependent diabetes, their caregivers and healthcare providers;

expand our commercial operations, including complying with a broad range of legal requirements within a highly regulated industry;

expand our manufacturing capabilities, including increasing production of current products efficiently while maintaining quality standards and adapting 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.

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 relating 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;

the challenge of 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 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 and manufacturing processes.

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 year we have implemented several new pieces of equipment that are intended to improve our manufacturing capacity and efficiency and we expect to implement additional equipment and procedures over the next 12-18 months. However, it is possible that we may not achieve the anticipated improvements from these investments. In addition, we recently entered into a new lease agreement for an additional facility to consolidate substantially all of our manufacturing, warehousing and other operational needs, and any transition of our current manufacturing, warehousing and other operations to a new facility is subject to additional risk and uncertainty, and may expose us to duplicative or incremental costs. Furthermore, 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 the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, the implementation of additional equipment and procedures, 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, complying with regulatory requirements and efficiently managing costs, our sales and operating margins could be negatively impacted.

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 of 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. Recently, we have implemented several business strategies intended to increase our future sales of infusion sets. Increases in any of our product sales, whether forecasted or unanticipated, could strain the ability of our suppliers to deliver an increasingly large supply of components in a manner that meets these 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. Our conclusion that, unless we successfully raise additional capital, there is substantial doubt about our ability to continue as a going concern, together with the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in our independent registered public accounting firm's report contained in our financial statements for the year ended December 31, 2016, 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 could have a material adverse effect on our business.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA, or other regulatory agencies, and the failure of our suppliers to comply with strictly-enforced 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 disruptions, 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 adversely affect our operating results.

If we cannot manufacture and sell our new infusion set connector when anticipated, or if it does not achieve market acceptance, we may not achieve our financial projections.

We intend to transition from the use of a standard Luer-lok connector on our proprietary disposable insulin cartridges to our new t:lock Connector. Concurrently, we intend to begin selling infusion sets that will be compatible with our t:lock Connector. We have filed for but not yet received regulatory approval to manufacture our insulin cartridges with the necessary modifications to change our infusion set connector from a standard Luer-lok to our t:lock Connector. In addition, our infusion set supplier intends to seek 510(k) clearance for its infusion sets with the companion to our t:lock Connector.

Our anticipated 2017 sales assume that our current and future customers will begin using our new cartridges and infusion sets with our t:lock Connector in significant quantities by the end of 2017. Any delay in obtaining regulatory approvals for our new insulin cartridge with the t:lock Connector or the compatible infusion sets would negatively impact our operating results and may harm our ability to meet our financial projections or those of our financial analysts. In order to manufacture our cartridges with the t:lock Connector, we must order and validate new molding equipment. Furthermore, our supplier of infusion sets must begin manufacturing a variety of lengths and styles of infusion sets with the t:lock Connector that matches our cartridges. Failure to do so, or to do so at the necessary production volumes, may result in our inability to launch our t:lock Connector or convert customers to our t:lock Connector when anticipated.

In addition, our independent distributors will need to agree 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 the t:lock Connector will be 90 to 120 days following its initial launch. During this period we anticipate offering both styles of cartridges and infusion sets to facilitate the transition of customer supplies. 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 the t:lock Connector was designed based on customer feedback, and while all standard Luer-lok infusion sets that we currently offer will initially be made available with the t:lock Connector, it is possible the t:lock Connector may not gain market acceptance by current or potential customers, their caregivers, or healthcare providers. Any negative market response to the t:lock Connector may impact a current customer's decision to purchase a new pump from us at the time of renewal. In addition, new potential customers may decide not to purchase our insulin pumps if they do not prefer our t:lock Connector, which may impede our ability to achieve our financial projections.

We currently operate primarily at a single location comprised of five buildings, and any disruption at this location could adversely affect our business and operating results.

Our principal offices are presently located in five buildings in San Diego, California. Substantially all of our operations are presently conducted at this location, 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 is held at this location. 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, 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.

The transition of our manufacturing operations to a new facility may result in unanticipated expenses or inefficiencies, which may increase our manufacturing and operating costs, and will require us to spend additional capital.

We manufacture our products at our headquarters in San Diego, California, but will be transitioning our manufacturing operations to a nearby facility that will allow for future capacity expansion. The transition to the new manufacturing facility is expected to begin during the second quarter of 2017 and be completed by the end of 2017. During the transition period we expect to experience some temporary duplication of operations to support ongoing product manufacturing, which will result in incremental costs. The transition remains subject to completion of ongoing construction, validation of newly installed equipment and our ability to receive numerous governmental approvals associated with the new facility. We may face significant challenges as we manage our proposed facility transition, such as unanticipated delays or expenses, and we will be required to make capital expenditures relating to the new facility. We also may experience unanticipated inefficiencies as we commence manufacturing operations at the new facility, particularly during the transition period. If we fail to achieve the operating efficiencies that we anticipate from the new facility, or if we incur substantial incremental costs during the transition, our manufacturing and operating costs may be greater than we anticipate.

We expect that the management and support of our transition to the new facility will place significant burdens on our management team, particularly in areas relating to operations, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage the completion of construction of the new facility or our transition and commencement of manufacturing operations when planned 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 or 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 we 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 received FDA approval under a PMA. However, there are no published studies to evaluate the safety or effectiveness of t:slim G4 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, that might have been generated in connection with other approval processes. 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 subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, significant legal liability, and harm to our business reputation.

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, degree of publicity, reaction of our customers, healthcare professionals, and collaborators, competitive reaction, and consumer attitudes overall. 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 or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues 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 entered into three separate development agreements with DexCom which provide us non-exclusive licenses to integrate various generations of DexCom CGM technology with our insulin pump products. We currently offer t:slim G4 under an agreement that runs until January 4, 2018, with automatic one-year renewals. Under certain circumstances, our agreements with DexCom 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.

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. As a result of the recent FDA clearance of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps, these risks are significantly increased.

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 we anticipate 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.

If we fail to properly manage our anticipated growth, our business could suffer.

Our rapid growth has placed, and we expect that it will continue to place, a significant strain on our management team and financial resources. For example, between December 31, 2015 and December 31, 2016 our employee base increased by approximately 23%. In addition, during 2015 and 2016 we experienced turnover among key employees in our sales, marketing, clinical, and research and development functions, including the hiring of a new Chief Commercial Officer and a new Vice President of Engineering. Our failure to manage growth effectively could cause us to misallocate management or financial resources, negatively impact our ability to attract and retain key employees, and result in losses or weaknesses in our infrastructure, which could materially adversely affect our business. Additionally, our anticipated growth and the projected evolution of our product portfolio will increase the demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our business objectives.

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, our Chief Executive Officer, as well as other key members of 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 difficulty 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.

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 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 patient privacy rules under HIPAA. These privacy rules protect 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. If we, or any of our service providers, are found to be in violation of the promulgated patient privacy rules under HIPAA, 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 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 through December 31, 2017.

At December 31, 2016, we had \$55.5 million in cash, cash equivalents and short-term investments, which included \$2.0 million of restricted cash. At the date our financial statements for the year ended December 31, 2016 were issued, we did not have sufficient cash to fund our operations through December 31, 2017 without additional financing and therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements were issued. As a result, the audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. Moreover, the continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers, additional research and development activities, and the transition to our new manufacturing facility, 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:

Edgar Filing: TANDEM DIABETES CARE INC - Form 10-K

the revenue generated by sales of our insulin pump products and pump-related supplies, and any other future products that we may develop and commercialize;

the costs associated with maintaining an appropriate sales, clinical and marketing infrastructure;

the gross profits we realize from the sales we generate and the expenses we incur in maintaining and expanding our manufacturing infrastructure, including opening our new manufacturing location and adding additional manufacturing equipment and capacity;

the cost associated with developing and commercializing our proposed products or technologies, including any costs to administer the Technology Upgrade Program;

the costs associated with maintaining and expanding our customer care infrastructure;

the cost of obtaining and maintaining regulatory clearance or approval for our current or future products;

the cost of ongoing compliance with legal and regulatory requirements;

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 II, L.P. and its affiliate funds, or Capital Royalty Partners, as amended, 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, management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock. We may in the future seek additional capital from public or private offerings of our capital stock or we may elect to 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, 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 our existing indebtedness. 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. 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 financial and accounting impacts of the Technology Upgrade Program;

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 and reliability 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 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, which means it will be difficult for us to forecast our sales. For example, in the period leading up to the commercial launch of t:slim X2, we believe there were an increasing number of customers anticipating its availability who delayed their purchasing decisions until they could include t:slim X2 in their decision-making process.

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 as has occurred over the past several months. 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 have concluded that we do not have sufficient cash to fund our operations through December 31, 2017 and, as a result, the audit report and opinion of our independent registered public accounting firm includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern, which could have a material adverse impact on our business.

The audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. This explanatory paragraph arises from management's conclusion that our cash on hand and cash expected to be generated from operations will not be sufficient to fund our operations through December 31, 2017 without additional financing. Our financial statements included in this Annual Report have been prepared on a basis that assumes that we will continue as a going concern, and does not include any adjustments that may result from the outcome of this uncertainty.

Our ability to continue as a going concern is dependent upon a number of factors, including our ability to increase our sales and gross profits, our ability to generate positive cash flow from operations, and our ability to obtain the necessary financing to meet our obligations and repay our liabilities arising from obligations that become due in the ordinary course of business. Management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock. However, reports issued by independent registered public accounting firm's expressing substantial doubt about a company's ability to continue as a going concern are generally viewed unfavorably by current and prospective investors, as well as by analysts and creditors. As a result, this report may make it more difficult for us to raise the additional financing necessary to continue to operate our business. In addition, this report may make it more difficult for us to sell our products and meet our sales forecasts, which may further impede our ability to raise additional financing.

If we cannot generate sufficient revenues from the sale of our products or secure additional financing on acceptable terms, we may be forced to significantly alter our business strategy, substantially curtail our current operations, or cease operations altogether. We may also be unable to satisfy covenants in our existing indebtedness if we are unable to secure additional equity financing.

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, 2016, we had \$81.1 million aggregate borrowings outstanding under the Term Loan Agreement with Capital Royalty Partners. Our ability to make scheduled payments or to 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, sell or 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 explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in the report of our independent registered public accounting firm, and general concerns among potential investors and creditors about our financial well-being 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 required payments of principal, premium, if any, and interest on our indebtedness, 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. The audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. This explanatory paragraph in our auditor's report constitutes a potential event of default under the Term Loan Agreement. As a result, on March 7, 2017, we entered into Waiver and Amendment No. 4 to Term Loan Agreement, or the Fourth Amendment, which includes a limited waiver of a potential event of default that could have resulted from the inclusion of the explanatory paragraph in our auditor's report. The Fourth Amendment also imposes additional restrictive and financial covenants on us, which may increase our risk of triggering defaults under the Term Loan Agreement. In particular, the Fourth Amendment provides that we must complete a financing in which our gross proceeds from the sale of equity securities is at least \$30.0 million no later than January 15, 2018.

In the event of a future default triggered by any violations of the covenants in the Term Loan Agreement, including the new covenants in the Fourth Amendment, we will need to obtain additional waivers from Capital Royalty Partners to avoid being in default. If we are unable to obtain additional waivers of those events of default, or amendments 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, including if we fail to complete a \$30.0 million equity financing by January 15, 2018, 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, 2016, our patent portfolio consisted of approximately 50 issued U.S. patents and 50 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2035. We also have and are seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we have one pending U.S. trademark application as well as 23 trademark registrations, including 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 against potential product liability claims could prevent or limit our commercialization of current products or products currently under development.

Risks Related to our Legal and Regulatory Environment

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

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

product design and development;

pre-clinical and clinical testing and trials;

product safety;

establishment registration and product listing;

labeling and storage;

marketing, manufacturing, sales and
distribution;

pre-market clearance or approval;

servicing and post-market surveillance;

advertising and promotion; and

recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. We received approval of our PMA for t:slim G4 in September 2015. 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 modifications to t:slim X2 and t:flex in the future. In addition, in July 2016, we received 510(k) clearance for the first use of our Tandem Device Updater. 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, 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 or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and operating results.

Further, we may evaluate international expansion opportunities in the future. 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. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. 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 of any products that we distribute would divert managerial and financial resources, which could impair our ability to produce our products in a cost-effective and timely manner, 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, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement;

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;

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

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.

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. 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, 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, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. 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 medical devices, and make it more difficult and costly for us to obtain regulatory clearance or approval of our products.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. 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 contain or reduce the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our proposed products would have a material adverse effect on our business, financial condition and operating results.

Federal and state governments in the United States have enacted legislation to overhaul the nation's healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA substantially changes 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. Among other things, the PPACA:

establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;

implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and

creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. Most recently, on August 2, 2011, President Barack Obama signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which commenced in 2013. The uncertainties regarding the ultimate features of the PPACA and other healthcare reform initiatives and their enactment and implementation may have an adverse effect on our customers' purchasing decisions regarding our products. In the coming years, 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, or the PPACA, may have on our business and operations, and any of these impacts may have an 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.

Beginning in 2013 through the end of 2015, the PPACA imposed, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States. Congress suspended this tax on December 18, 2015 for two years, for sales of devices during the period January 1, 2016 through December 31, 2017. We do not believe that our products were subject to this tax (prior to its suspension) 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. The future of the medical device tax (and the PPACA generally) is uncertain. If the tax is not repealed and the two-year suspension of the tax is not extended beyond 2017, 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.

Risks Related to our Common Stock

Because of their significant stock ownership, certain of our executive officers, directors and principal stockholders will be able to exert control over our company and our significant corporate decisions.

Based on an aggregate of 31,095,598 shares of our common stock outstanding as of December 31, 2016, our executive officers and directors, and their affiliates owned, in the aggregate, approximately 39% of the voting power of our outstanding common stock. These persons, acting together, will have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets.

The interests of the aforementioned stockholders might not coincide with the interests of the other holders of our capital stock. This concentration of ownership may reduce the value of our common stock by, among other things:

delaying, deferring or preventing a change of control of our company;

impeding a merger, consolidation, takeover or other business combination involving our company; or

causing us to enter into transactions or agreements that are not in the best interests of all stockholders.

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

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

authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;

provide for the adoption of a staggered board of directors whereby the board is divided into three classes each of which has a different three-year term;

provide that the number of directors shall be fixed by the board;

prohibit our stockholders from filling board vacancies;

provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;

prohibit stockholders from calling special stockholder meetings;

prohibit stockholders from acting by written consent without holding a meeting of stockholders;

require the vote of at least two-thirds of the outstanding shares to approve amendments to the certificate of incorporation or bylaws; and

require advance written notice of stockholder proposals and director nominations.

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

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

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

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

As of December 31, 2016, we had federal net operating loss, or NOL, carryforwards of approximately \$283.5 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, 2013, the offering that we conducted in March of 2015, either separately or together with any future equity financing, 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.

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 the Term Loan Agreement, 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. Investors may not receive a gain on their investment when they sell their shares of our common stock and may lose the entire amount of 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, including tantalum, tin, gold and tungsten. The number of suppliers who provide conflict-free minerals may be limited. 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. Within our supply chain, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the due diligence procedures that we implement, which may harm our reputation. We continue to investigate the use of conflict materials, if any, within our supply chain.

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 intend 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 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 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.

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,” 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” under the JOBS Act, 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. We could be an “emerging growth company” for up to five years from our November 2013 initial public offering. 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 on the NASDAQ Global Market 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 quarterly financial and operating results, including the financial and accounting impacts of the Technology Upgrade Program;

our actual or perceived need for additional capital to fund our operations;

perceptions about the market acceptance of our products and the recognition of our brand;

perceptions about our financial stability relative to our competitors and our ability to sustain our business operations long term;

the reaction of investors to our conclusion that if we do not successfully raise additional capital there is substantial doubt about our ability to continue as a going concern;

overall performance of the equity markets;

introduction of proposed products, or announcements of significant contracts, licenses or acquisitions, 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.

Future sales, or the perception of future sales, of shares of our common stock could materially reduce the market price of our common stock.

Sales of our common stock, or the perception in the market that the holders of a large number of our shares intend to sell such shares, could reduce the market price of our common stock, which would impair our ability to raise future capital through the sale of additional equity securities. We had outstanding 31,095,598 shares of common stock as of December 31, 2016, of which approximately 11,985,636 shares are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act. In addition, as of December 31, 2016, we had outstanding options to purchase 8,228,387 shares of common stock and warrants to purchase 990,031 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. As of December 31, 2016, there was also 562,282 shares and 78,459 shares of our common stock reserved for future grant or issuance under our 2013 Stock Incentive Plan, and our 2013 Employee Stock Purchas Plan, or our ESPP, respectively.

Certain holders of shares of common stock have the right, subject to various conditions and limitations, to include their shares in registration statements relating to our securities. In addition, these holders are entitled to piggyback registration rights with respect to the registration under the Securities Act of shares of our common stock. Shares of

common stock registered under these registration statements can be freely sold in the public market. In the event registration rights are exercised and a large number of shares of common stock are sold in the public market, those sales could reduce the trading price of our common stock.

In the future, we may issue additional securities if we need to raise more capital. In particular, management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

As of December 31, 2016, we leased an aggregate of approximately 108,000 square feet of manufacturing, laboratory and office space in San Diego, California under an operating lease, which is scheduled to expire in June 2019. Substantially all of our operations are currently conducted at this facility, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions.

On June 30, 2016, we entered into a lease agreement for 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. The Barnes

Canyon Lease is scheduled to expire in November 2023. We 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. We intend to transition substantially all of our manufacturing operations into the Barnes Canyon building during 2017.

We believe that the facilities that we presently occupy together with the additional facilities that we expect to occupy under the Barnes Canyon Lease will be sufficient to support our current operations and that suitable additional facilities would be available to us should our operations require it.

Item 3. Legal Proceedings.

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

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock began trading on the NASDAQ Global Market on November 14, 2013 under the symbol "TNDM." Prior to such time, there was no public market for our common stock. The following table sets forth 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, 2016:		
First Quarter	\$11.80	\$6.59
Second Quarter	\$11.30	\$6.48
Third Quarter	\$8.81	\$6.04
Fourth Quarter	\$8.10	\$1.60
Year Ended December 31, 2015:		
First Quarter	\$14.27	\$11.50
Second Quarter	\$14.19	\$10.54
Third Quarter	\$13.48	\$8.52
Fourth Quarter	\$12.48	\$7.26

The last sale price for our common stock as reported by the NASDAQ Global Market on March 6, 2017 was \$2.40 per share.

Holders of Record

As of March 6, 2017, there were approximately 72 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 restricts 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 2016 or 2015.

Performance Measurement Comparison

The following graph shows a comparison from November 14, 2013 (the date our common stock commenced trading on The NASDAQ Global Market) through December 31, 2016 of the cumulative total return for our common stock, compared against the NASDAQ Composite Index and NASDAQ Medical Equipment Index. The graph assumes an initial investment of \$100 on November 14, 2013. The comparisons in the graph are not intended to forecast or be indicative of possible future performance of our common stock.

The preceding graph and related information shall not be deemed “soliciting material,” shall not be deemed “filed” with the SEC, shall not be subject to the liabilities of Section 18 of the Exchange Act, and shall not be incorporated by reference in any of our filings under the Securities Act or the Exchange Act whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

Item 6. Selected Financial Data.

The selected financial data presented below under the heading “Statements of Operations Data” for the years ended December 31, 2016, 2015 and 2014 and the selected financial data presented below under the heading “Balance Sheet Data” as of December 31, 2016 and 2015 have been derived from our audited financial statements included elsewhere in this Annual Report. The selected statement of operations data for the years ended December 31, 2013 and 2012 and the balance sheet data as of December 31, 2014, 2013 and 2012 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:

(in thousands, except per share data)	Year Ended December 31,				
	2016	2015	2014	2013	2012
Sales	\$84,248	\$72,850	\$49,722	\$29,007	\$2,475
Cost of sales	60,656	46,270	34,474	22,840	3,823
Gross profit (loss)	23,592	26,580	15,248	6,167	(1,348)
Operating expenses:					
Selling, general and administrative	82,834	78,621	75,121	44,522	22,691
Research and development	18,809	16,963	15,791	11,079	9,009
Total operating expenses	101,643	95,584	90,912	55,601	31,700
Operating loss	(78,051)	(69,004)	(75,664)	(49,434)	(33,048)
Total other income (expense), net:	(5,411)	(3,404)	(3,789)	(13,705)	33
Net loss before taxes	\$(83,462)	\$(72,408)	\$(79,453)	\$(63,139)	\$(33,015)
Provision for income tax (benefit) expense	(15)	10	71	—	—
Net loss	\$(83,447)	\$(72,418)	\$(79,524)	\$(63,139)	\$(33,015)
Net loss per share, basic and diluted:	\$(2.73)	\$(2.50)	\$(3.42)	\$(21.46)	\$(175.88)
Weighted average shares used to compute basic and diluted net loss per share:	30,570	28,923	23,272	2,942	188

Balance Sheet Data:

(in thousands)	As of December 31,				
	2016	2015	2014	2013	2012
Cash and cash equivalents	\$44,678	\$43,088	\$31,176	\$124,385	\$17,163
Short-term investments	\$8,860	\$28,018	\$36,106	\$5,095	\$—
Working capital	\$60,616	\$80,464	\$72,657	\$134,390	\$10,762
Property and equipment, net	\$18,409	\$15,526	\$12,581	\$9,886	\$8,989
Total assets	\$112,392	\$124,725	\$106,464	\$162,215	\$39,817
Notes payable	\$78,960	\$29,275	\$29,440	\$29,397	\$4,203
Convertible preferred stock	\$—	\$—	\$—	\$—	\$124,638

Total stockholders' equity (deficit) \$(5,927) \$63,468 \$54,572 \$115,537 \$(106,052)

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 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 that our competitive advantage is rooted in our unique consumer-focused approach and proprietary technology platform. This allows us to deliver innovative hardware and software solutions to meet the various needs and preferences of people with diabetes and their healthcare providers. We manufacture and sell insulin pump products in the United States that are designed to address large and differentiated segments of the insulin-dependent diabetes market. Our insulin pump products include:

- the t:slim X2 Insulin Delivery System, or t:slim X2, our next-generation flagship product,
- the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs, and
- the t:slim G4 Insulin Delivery System, or t:slim G4, the first continuous glucose monitoring, or CGM, enabled pump with touchscreen simplicity.

From the launch of our first product in August 2012, through December 2016, we have shipped more than 50,000 pumps. For the past three consecutive years, our company and our products have been ranked #1 by insulin pump users in the United States for customer support, product features and ease of training in an independent survey by dQ&A, a leading diabetes research firm.

We began commercial sales of our first insulin pump product, 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. t:slim, t:slim X2 and t:flex 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 faster than the industry has been able to in the past. Its first cleared use by the U.S. Food and Drug Administration, or FDA, was to update t:slim Pumps purchased before April 2015 to the latest software. In the first quarter of 2017, we filed a regulatory submission with the FDA to permit t:slim X2 customers to update their pumps' software using the Tandem Device Updater to allow integration with the DexCom G5 Mobile CGM system. Subject to FDA approval, we intend to offer this update to t:slim X2 customers free of charge. 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, 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, which seeks to optimize our devices, allowing users to successfully operate our devices in their intended environment.

We developed our products to provide the specific features that people with insulin-dependent diabetes seek in a next-generation insulin pump. Our proprietary pumping technology allows us to design the slimmest and smallest durable insulin pumps on the market, without sacrificing insulin capacity. Our insulin pump platform features our patented Micro-Delivery technology, and a miniaturized pumping mechanism that draws insulin from a flexible bag within the pump's cartridge, rather than relying on a syringe and plunger mechanism. It also features an easy-to-navigate software architecture, a vivid color touchscreen and a micro-USB connection that supports a rechargeable battery, software updates through the Tandem Device Updater, and uploads to t:connect Diabetes Management Application, or t:connect. t:connect is our custom cloud-based data management application that provides customers and healthcare providers a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters. Our next generation pump, t:slim X2, also features an advanced Bluetooth radio capable of communicating with multiple compatible devices.

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 technology platform and consumer-focused approach, and by providing strong customer support. 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.

Products under Development

Our products under development support our strategy to focus on both consumer and clinical needs. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionality that will allow us to target people in different segments of the insulin-dependent diabetes market. Our current products under development include:

- t:slim X2 with G5 integration, which will feature the display of DexCom G5 CGM sensor information directly on the pump Home Screen;
- t:slim X2 with PLGS, our first generation AID system is expected to include a predictive low glucose suspend, or PLGS, algorithm;
- t:slim X2 with TypeZero, our second generation AID system is expected to integrate t:slim X2 with technology that we licensed from TypeZero; and
- t:sport Insulin Delivery System will 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.

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 over 50,000 insulin pumps since the initiation of our commercial efforts in 2012. Pump shipments are broken down by product and by fiscal quarter as follows:

70

Pump Units Shipped for Each of the Three Months Ended in Respective Years ⁽¹⁾

Total	March 31	June 30	September 30	December 31	Total
2012	N/A	9	204	844	1,057
2013	852	1,363	1,851	2,406	6,472
2014	1,723	2,235	2,935	3,929	10,822
2015	2,487	3,331	3,431	6,234	15,483
2016 ⁽²⁾	4,042	4,582	3,896	4,418	16,938

t:slim	March 31	June 30	September 30	December 31	Total
2012	N/A	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	2,957	2,390	1,658	9,492
2016	1,255	1,498	1,965	76	4,794

t:slim X2	March 31	June 30	September 30	December 31	Total
2016	N/A	N/A	N/A	3,699	3,699

t:flex	March 31	June 30	September 30	December 31	Total
2015	N/A	374	555	569	1,498
2016	371	493	389	354	1,607

t:slim G4	March 31	June 30	September 30	December 31	Total
2015	N/A	N/A	486	4,007	4,493
2016	2,416	2,591	1,542	289 ⁽³⁾	6,838

(1) This table does not reflect returns or exchanges of pump products that occur in the ordinary course of business.

(2) This table does not reflect the impact of 1,413 trade-ins made under the Technology Upgrade Program (discussed below) related to our commercial launch of t:slim X2.

(3) The decrease in t:slim G4 shipments coincided with our commercial launch of t:slim X2.

Technology Upgrade Program

In the third quarter of 2016, we launched a Technology Upgrade Program that provides eligible t:slim and t:slim G4 customers a path towards ownership of t:slim X2 by providing customers the right to exchange their t:slim or t:slim G4 for t:slim X2, under a variable pricing structure. The Technology Upgrade Program expires on September 30, 2017.

Due to the high degree of accounting complexity, the Technology Upgrade Program has created, and will continue to create, unpredictable financial results under United States generally accepted accounting principles, or GAAP, for the duration of the program. The accounting treatment for this program requires the deferral of up to 100% of sales and cost of sales for shipments of eligible pumps beginning in the third quarter of 2016. We have determined that, from an accounting perspective, the opportunity for a customer to trade a t:slim or t:slim G4 in exchange for a t:slim X2 represents either a right of return or a guarantee at the time of the initial product purchase. Because we have not offered an upgrade program in the past, we do not have sufficient history with similar upgrade programs to estimate the number of customers that will participate. As a result, sales and cost of sales for all eligible t:slim and t:slim G4 shipments are subject to deferral. The amount of sales and cost of sales deferred varies based on a number of factors, including the model of pump involved and the timing of the initial sales relative to the availability of certain future products.

We expect to recognize the deferred amount of sales and cost of sales at the earlier of when the obligations under the Technology Upgrade Program are satisfied or when the program expires. If a customer elects to participate in the Technology Upgrade Program, we will recognize upgrade fees that we receive, if any, and the associated costs at the time of fulfilling the given obligation. At this time, we are not able to estimate when we will recognize deferred sales or cost of sales as a result of the Technology Upgrade Program, nor are we able to estimate the amount of upgrade fees or associated costs for a customer's election to participate in the Technology Upgrade Program. In general, the deferrals required by the Technology Upgrade Program may have the effect of initially decreasing our GAAP sales even where the number of our pump shipments increases.

Historical Financial Results

For the years ended December 31, 2016, 2015 and 2014, our sales were \$84.2 million, \$72.9 million and \$49.7 million, respectively. For the year ended December 31, 2016, we recorded net sales deferrals of \$4.3 million and recognized net additional \$0.3 million in cost of sales as a result of the Technology Upgrade Program. For the years ended December 31, 2016, 2015 and 2014, our net loss was \$83.4 million, \$72.4 million and \$79.5 million, respectively. Our accumulated deficit as of December 31, 2016 was \$404.6 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 fluctuate on a quarterly or annual basis, particularly in the periods surrounding anticipated and actual regulatory approvals, and initial stages of commercialization of our new products and those of our competitors. These fluctuations have been, and may continue to be, more pronounced since the commencement of the Technology Upgrade Program.

Prior to 2016, we experienced sequential growth of sales in each quarter from the first quarter to the fourth quarter, and sequential sales from the fourth quarter to the following first quarter decreased. In 2016, we did not experience our historical sales growth in the second half of the year compared to the first half of the year. We believe that the timing of the commercial launch of t:slim X2, as well as the launch and regulatory approval of competitive products, impacted our quarterly pump shipments during the six months ended December 31, 2016. In particular, in the period leading up to the commercial launch of t:slim X2, we believe there was an increasing number of potential customers who delayed their purchasing decision until they could include t:slim X2 in their decision-making process. In addition, pump shipments were impacted by a decision by UnitedHealthcare that restricted a majority of their members from accessing our pumps.

We expect our financial results will fluctuate on a quarterly or annual basis in the future due to a variety of factors, including the impact of:

- market acceptance of our products, and the timing of the sale of our products;

- seasonality associated with summer vacations, annual deductibles and coinsurance requirements associated with most medical insurance plans utilized by our individual customers and the individual 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;

- reimbursement decisions by third-party payors;

- the size and timing of any changes to our infrastructure;

- anticipated and actual regulatory approvals of new products; and

- our Technology Upgrade Program and its related financial and accounting impact.

In particular, in 2017, we expect the combined effect of the timing of our launch of DexCom G5 sensor integration with t:slim X2, the increasing productivity of our existing sales force, and our expectation that customers will largely return to their historical decision making patterns will once again result in our sales being heavily weighted towards the second half of the year.

On the date our financial statements for the year ended December 31, 2016 were issued, we did not have sufficient cash to fund our operations through December 31, 2017 without additional financing, and therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements were issued. As a result, the audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern.

Third Party Reimbursement

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. Access to adequate coverage and reimbursement for our current and future products by third-party payors is essential to the acceptance of our products by customers. 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. For example, 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 believe this decision has 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.

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 our recently-approved 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. 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.

Additional Financing

From inception through December 31, 2016, we have primarily financed our operations through sales of equity securities, and, to a lesser extent, debt financings. The continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers, additional research and development activities, and the transition to our new manufacturing facility, will continue to increase our expenses and capital needs. We expect we will be required to raise additional capital through equity and debt financings in order to satisfy covenants in our existing indebtedness and fund our operations until we achieve a level of sales and gross profits adequate to support our cost structure. In particular, management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock. We expect our ability to raise additional financing may be negatively impacted by a number of factors, including our recent financial results, recent changes in our stock price, our conclusion that there is substantial doubt about our ability to continue as a going concern, the competitive environment in our industry, and accounting complexities brought about by our Technology Upgrade Program.

Term Loan Agreement

We previously entered into an Amended and Restated Term Loan Agreement with Capital Royalty Partners II, L.P. and its affiliate funds, or Capital Royalty Partners, which was subsequently amended by Consent and Amendment Agreement, dated June 20, 2014, Omnibus Amendment Agreement No. 2, dated February 23, 2015, and two additional amendments as further discussed below, which we refer to as the Term Loan Agreement. In the first quarter of 2016, we entered into Amendment No. 3 to 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, 2016, we had \$81.1 million aggregate borrowings outstanding under the Term Loan Agreement.

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

Subsequent Event

On March 7, 2017, we entered into Waiver and Amendment No. 4 to Term Loan Agreement, or the Fourth Amendment. The Fourth Amendment includes a limited waiver of a potential event of default that could have resulted from the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in the audit report of our independent registered public accounting firm included in our financial statements for the year ended December 31, 2016.

For additional information about the Fourth Amendment, see the section entitled “Indebtedness” below.

Components of Results of Operations

Sales

We offer products for people with insulin-dependent diabetes. We commenced commercial sales of t:slim in the United States in the third quarter of 2012. We launched our second insulin pump product, t:flex, in the second quarter of 2015, and launched our third insulin pump product, t:slim G4, in the third quarter of 2015. In October 2016, we began shipping t:slim X2, our next generation flagship product, at which time we discontinued sales of t:slim. Our products currently include these insulin pumps, 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 our sales will fluctuate on a quarterly basis in the future due to a variety of factors, including the impact of:

- market acceptance of our products, and the timing of the sale of our products;
- annual deductibles and coinsurance requirements associated with most medical insurance plans utilized by our individual customers and the individual customers of our distributors, as well as some limited seasonality associated with summer vacations;
- the buying patterns of our distributors and other customers;
- the timing of the commercialization of new products by us or our competitors;
- reimbursement decisions by third-party payors;
- the size and timing of any changes to our infrastructure;
- anticipated and actual regulatory approvals of new products; and

our Technology Upgrade Program and its related financial and accounting impact.

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, whether our own or 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 facility in San Diego, California. Infusion sets and pump accessories are manufactured by third-party suppliers. Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs, reserves for expected warranty costs, and scrap and inventory excess and obsolescence. Manufacturing overhead expenses include expenses relating to quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management. We anticipate that our cost of sales will continue to increase as our products continue to 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. However, we do expect our overall gross margin to fluctuate in future quarterly periods as a result of numerous factors besides those associated with production volumes. Specifically, in 2017, we are increasing our manufacturing capacity by relocating our manufacturing operations and related functions to a new facility over a period of several quarters, which may add duplicative and incremental cost in the short-term and pressure our overall

gross margin for the duration of the transition. Additionally, we will continue to be impacted by the financial and accounting impact of the Technology Upgrade Program, which requires us to defer a portion of our sales and cost of sales. 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, costs or output.

Selling, General and Administrative

Our selling, general and administrative, or SG&A, expenses primarily consist of salary, cash-based incentive compensation, fringe benefits and non-cash stock-based compensation for our executive, financial, marketing, sales, clinical, customer care, technical services, insurance verification, regulatory affairs and administrative functions. In particular, our sales and clinical organization consisted of 72 territories as of December 31, 2016. 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, we expect our SG&A expenses, including the cost of our customer care infrastructure, to increase as our customer base grows. Our SG&A expenses may also increase due to costs associated with additional compliance and regulatory reporting requirements.

Research and Development

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

Other Income and Expense

Our other income and expense primarily consists of interest expense and amortization of debt discount and issuance costs associated with the Term Loan Agreement. At December 31, 2016, there was \$81.1 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 increase in 2017 as a result of additional borrowings under the Term Loan Agreement as compared to 2016 (see the section below entitled “Indebtedness”).

Results of Operations

	Year Ended December 31,		
(in thousands, except percentages)	2016	2015	2014

Edgar Filing: TANDEM DIABETES CARE INC - Form 10-K

Sales	\$84,248	\$72,850	\$49,722
Cost of sales	60,656	46,270	34,474
Gross profit	23,592	26,580	15,248
Gross margin	28 %	36 %	31 %
Operating expenses:			
Selling, general and administrative	82,834	78,621	75,121
Research and development	18,809	16,963	15,791
Total operating expenses	101,643	95,584	90,912
Operating loss	(78,051)	(69,004)	(75,664)
Other income (expense), net:			
Interest and other income	(5,351)	337	112
Interest and other expense	(60)	(3,741)	(3,901)
Total other expense, net	(5,411)	(3,404)	(3,789)
Net loss before taxes	\$(83,462)	\$(72,408)	\$(79,453)
Provision for income taxes (benefit)	(15)	10	71
Net loss	\$(83,447)	\$(72,418)	\$(79,524)

Comparison of Years Ended December 31, 2016 and 2015

Sales. For the year ended December 31, 2016, sales were \$84.2 million, net of \$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 \$62.4 million and \$60.8 million, respectively, for the years ended December 31, 2016 and 2015. Sales of pump-related supplies were \$21.4 million and \$11.9 million, respectively, for the years ended December 31, 2016 and 2015. 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.

Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor. Sales to distributors accounted for 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.

During 2016, in conjunction with the Technology Upgrade Program, we recorded net sales deferrals of \$4.3 million, net deferrals of \$0.8 million in cost of sales and recognized \$1.1 million of incremental cost of sales for the upgrade of 1,413 pumps to t:slim X2. 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, tradeshow 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.

Edgar Filing: TANDEM DIABETES CARE INC - Form 10-K

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. We borrowed \$30.0 million under the agreement in January 2013, an additional \$15 million in January 2016, and the remaining \$35.0 million in December 2016. Other income for both periods presented was not significant.

Comparison of Years Ended December 31, 2015 and 2014

Sales. For the years ended December 31, 2015 and 2014, sales were \$72.9 million and \$49.7 million, respectively. Sales of insulin pumps were \$60.8 million and \$42.7 million, respectively, for the years ended December 31, 2015 and 2014. Pump sales accounted for 83% and 86% of sales, respectively, for the years ended December 31, 2015 and 2014, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in either year.

The growth in sales was primarily driven by a 43% increase in pump shipments from 10,822 in 2014 to 15,483 in 2015. This included shipments of 1,498 t:flex Pumps and 4,493 t:slim G4 Pumps during 2015 compared to none in 2014. Sales of t:flex Pumps and t:slim G4 Pumps began in May 2015 and September 2015, respectively.

Sales to distributors accounted for 77% and 75% of our total sales for the years ended December 31, 2015 and 2014, respectively.

Cost of Sales and Gross Profit. Our cost of sales in 2015 was \$46.3 million, resulting in gross profit of \$26.6 million, compared to \$34.5 million cost of sales and gross profit of \$15.2 million in 2014. The gross margin in 2015 was 36%, compared to 31% in 2014. The improvement in the gross margin was primarily a result of manufacturing efficiencies associated with an increase in production volume and improvement in our manufacturing processes. Our pump manufacturing overhead spending decreased 8% while our pump units produced increased 22% in 2015 compared to 2014, and our cartridge manufacturing overhead spending increased 28% while our cartridge units produced increased 78% in 2015 compared to 2014.

Selling, General and Administrative Expenses. SG&A expenses increased 5% to \$78.6 million in 2015 from \$75.1 million in 2014. The SG&A expenses increased at a slower rate as compared to our sales growth, as well as compared to our SG&A expense increase in 2014.

Employee-related expenses increased \$3.9 million during 2015 compared to 2014, including an increase of \$5.3 million in salaries, sales commission and bonus expenses offset by a decrease of \$1.4 million in stock-based compensation. The increase in employee-related expenses was offset by a decrease of \$0.3 million in travel expenses, supplies, and outside services as compared to the same period in 2014.

Research and Development Expenses. R&D expenses increased 7% to \$17.0 million in 2015 from \$15.8 million in 2014. The increase in R&D expenses in 2015 consisted primarily of an increase of \$1.0 million in employee-related expenses. Included in R&D expenses were \$1.0 million milestone payments made to DexCom, under the development and commercialization agreement, in each of the years ended December 31, 2015 and 2014.

Other Income (Expense). Other expense in 2015 was \$3.4 million, compared to \$3.8 million in 2014. Other expense in 2015 and 2014 primarily consisted of interest expense as a result of the Term Loan Agreement.

Liquidity and Capital Resources

At December 31, 2016, we had \$55.5 million in cash and cash equivalents and short-term investments, which included \$2.0 million of restricted cash. During 2016, we borrowed \$15.0 million in January and \$35.0 million in December under the Term Loan Agreement. At the date our financial statements for the year ended December 31, 2016 were issued, we did not have sufficient cash to fund our operation through December 31, 2017, without additional financing and, therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements were issued. As a result, the audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016 includes a paragraph that states that conditions existed that could raise substantial doubt about our ability to continue as a going concern. The financial information throughout this Annual Report and the financial statements included elsewhere in this Annual Report have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. This financial information and these financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock. However, we expect our ability to raise additional financing may be negatively impacted by a number of factors, including our recent financial results, recent changes in our stock price, our conclusion that there is substantial doubt about our ability to continue as a going concern, the competitive environment in our industry, and accounting complexities brought about by our Technology Upgrade Program. There can be no assurances that we will be able to complete any financing on acceptable terms or at all. If we are unable to complete the financing, we may be required to significantly alter our business strategy, substantially curtail our current operations, or cease operations altogether.

We expect that, in addition to the outcome of any additional financing activities, 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 management decisions. We may also use additional cash for the manufacture of t:slim X2 to fulfill our obligations under the Technology Upgrade Program, which will be partially offset by any fees we collect under the program.

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.

We have utilized, and may continue to utilize, debt arrangements with debt providers and financial institutions to finance our operations. Factors such as debt service obligations, interest rates, repayment terms, available cash and projected operating results will impact our decision to continue to utilize debt arrangements as a source of cash.

Historically, our principal sources of cash have included private placements and public offerings of equity securities, debt arrangements, and cash generated from operations. 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, 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.

The following table shows a summary of our cash flows for the years ended December 31, 2016, 2015 and 2014:

(in thousands)	Year Ended December 31,		
	2016	2015	2014
Net cash provided by (used in):			
Operating activities	\$(61,186)	\$(58,764)	\$(61,378)
Investing activities	10,461	2,421	(35,470)
Financing activities	52,315	68,255	3,639
Total	\$1,590	\$11,912	\$(93,209)

Operating activities. Net cash used in operating activities was \$61.2 million for the year ended December 31, 2016, compared to \$58.8 million and \$61.4 million for the same periods in 2015 and 2014, respectively.

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 an increase in inventory to meet higher production volumes, including those associated with new products, and an increase in prepaid expenses.

The decrease in net cash used in operating activities for 2015 compared to 2014 was primarily associated with an improvement in operating margin, offset by changes in working capital. The change in working capital was primarily due to an increase in accounts receivable and increase in inventory to meet higher production volumes, including those associated with new products, offset by increase in accounts payable, employee-related liabilities and other current liabilities.

Investing activities. Net cash provided by investing activities was \$10.5 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. Net cash provided by investing activities was \$2.4 million for the year ended December 31, 2015, which was primarily related to proceeds from sales and maturities of short-term investments of \$88.5 million offset by the net purchase of \$80.2 million in short-term investments and \$5.8 million in purchases of property and equipment. Net cash used in investing activities was \$35.5 million for the year ended December 31, 2014, which was primarily related to the net purchase of \$67.1 million in short-term investments and \$4.4 million in purchases of property and equipment, offset by proceeds from sales and maturities of short-term investments of \$36.2 million.

Financing activities. 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 indebtedness 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 ESPP. Net cash provided by financing activities was \$68.3 million for the year ended December 31, 2015, which was primarily due to net proceeds from a public offering of our common stock in the amount of \$64.9 million and \$3.4 million in proceeds from the exercise of outstanding stock options and warrants, as well as proceeds from employee contributions for the purchase of our common stock through our ESPP. The net cash provided by financing activities was \$3.6 million for the year ended December 31, 2014, which was primarily related to \$3.7 million in net proceeds from the exercise of outstanding stock options and warrants, as well as proceeds from employee contributions for the purchase of our common stock through our ESPP.

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;

our ability to complete any additional equity 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;

costs associated with the Technology Upgrade Program;

improvements in our manufacturing capacity and efficiency;

new 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;

facilities expansion needs, including the funding of tenant improvements at our Barnes Canyon location; 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. We expect we will need to raise additional funds in the future. Management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock. We may in the future seek additional capital from public or private offerings of our capital stock or we may elect to borrow additional amounts under new credit lines or from other sources. If we issue equity securities, our existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders. If we issue debt securities or obtain additional credit facilities, we may incur debt service obligations, we may become subject to restrictions limiting our ability to operate our business and we may be required to encumber all or a portion of our assets. There can be no assurance that we will be able to raise any such capital on terms acceptable to us, if at all.

Indebtedness

Capital Royalty Partners Term Loan Agreement

At December 31, 2015, we had \$30.2 million aggregate borrowings outstanding under the Term Loan Agreement. In January 2016, we entered into the Third Amendment, which allowed us 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, 2016, we had \$81.1 million aggregate borrowings outstanding under the Term Loan Agreement.

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% of the 11.5% per annum in cash and 2.0% of the 11.5% per annum 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 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, \$0.9 million and \$0.2 million were added to the principal of the loan for the years ended December 31, 2016 and 2015, respectively, which we refer to as PIK Loans.

The loan is collateralized by all of our assets. The Term Loan Agreement also imposes various affirmative and negative covenants on us. The principal financial covenants require that we attain minimum annual revenues of \$65.0 million in 2016, \$80.0 million in 2017 and \$95.0 million each year thereafter until the end of the term of the loan.

The audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016, includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. This explanatory paragraph included in the report of our independent registered public accounting firm constitutes a potential event of default under the Term Loan Agreement.

As a result, on March 7, 2017, we entered into the Fourth Amendment, which includes 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 1,937,890 shares of our common stock at an exercise price equal to \$2.35 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 includes a covenant requiring us to complete a financing in which our gross proceeds from the sale of equity securities is at least \$30.0 million, no later than January 15, 2018.

Furthermore, in connection with the Third Amendment, we previously agreed to pay, on the earlier of (i) the maturity date of the Term Loan Agreement, which is March 31, 2020, (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 (as defined in the Term Loan Agreement) issued in relation to the Third Amendment, which we refer to as the Back End Financing Fee. Pursuant to the Fourth Amendment, we have 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 \$81.1 million as of December 31, 2016. 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.

Contractual Obligations & Commitments

The following table summarizes our long-term contractual obligations as of December 31, 2016:

(in thousands)	Total	Payments Due by Period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligation relating to our facility ⁽¹⁾	\$ 11,355	\$ 3,198	\$ 5,529	\$ 1,986	\$ 642
Capital Royalty Partners term loans, including interest ⁽²⁾	115,145	8,182	16,868	90,095	-
Firm purchase commitments ⁽³⁾	28,768	24,205	4,563	-	-
Total contractual obligations	\$ 155,268	\$ 35,585	\$ 26,960	\$ 92,081	\$ 642

(1) The Barnes Canyon Lease allows 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. Any amounts funded by the landlord from the TI Allowance will be 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, or the TI Rent, paid concurrently with the base rent. TI Rent is not included in the table above. No TI Rent was due as of December 31, 2016. Assuming the full TI Allowance is drawn on April 1, 2017, TI Rent would be \$0.5 million for the year ended December 31, 2017, \$0.7 million for each of the years ended December 31, 2018 through 2021, and \$1.3 million for the years ended December 31, 2022 and thereafter.

(2) The amounts indicated include principal, interest and other payments due under the Term Loan Agreement. These amounts assume that we will continue to elect 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. These amounts also assume that the principal, as well as the accrued 3.0% 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.

Trade-In Rights

The trade-in rights under our Technology Upgrade Program are accounted for as guarantees or rights to return based on specific factors and circumstances, including the period of time the trade-in rights are exercisable, the likelihood that the trade-in rights will be exercised, and the amount of the specified-price trade-in value.

We have determined that trade-in rights for t:slim G4 Pump customers are guarantees. We account for the guarantees under applicable accounting standards, which requires a guarantor to recognize, at the inception of a guarantee, a liability for the estimated fair value of the obligation undertaken in issuing certain guarantees. Subsequently, the initial liability recognized for the guarantee is generally reduced as we are released from the risk under the guarantee, which is when the trade-in right is exercised or the right expires. The guarantee is accounted for as an element of a multiple element arrangement. The estimated fair value of the guarantees are based on various economic and customer behavioral assumptions, including the probability of a trade-in, 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. At December 31, 2016, \$1.2 million was recorded as a guarantee liability in other current liabilities on our balance sheet.

We have determined that t:slim Pump trade-in rights are in-substance rights to return products. Such rights to return are accounted for pursuant to the right of return accounting guidance. As we do not have sufficient history to reasonably estimate returns associated with trade-in rights, all eligible t:slim Pump sales between July 1, 2016 and December 31, 2016 were recorded as deferred revenue until such time as the trade-in right is exercised or the right expires. At December 31, 2016, \$3.2 million was recorded as a trade-in rights reserve in deferred revenue on our balance sheet.

Revenue Recognition for Arrangements with Multiple Deliverables

We consider the deliverables in our product offering as separate units of accounting and recognize 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. 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, 2016 and 2015, \$1.6 million and \$1.1 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 \$0.3 million at December 31, 2016 and 2015, 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, 2016 and 2015, the warranty reserve was \$5.7 million and \$3.5 million, respectively.

Off-Balance Sheet Arrangements

As of December 31, 2016, 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.

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, 2016, 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, 2016 and 2015 and for each of the three years in the period ended December 31, 2016, and the Report of the Independent Registered Public Accounting Firm are included in this report as listed in the index.

INDEX TO FINANCIAL STATEMENTS

<u>Report of Independent Registered Public Accounting Firm</u>	87
<u>Balance Sheets as of December 31, 2016 and 2015</u>	88
<u>Statements of Operations and Comprehensive Loss for the Years ended December 31, 2016, 2015, and 2014</u>	89
<u>Statements of Stockholders' Equity (Deficit) for the Years ended December 31, 2016, 2015 and 2014</u>	90
<u>Statements of Cash Flows for the Years ended December 31, 2016, 2015, and 2014</u>	91
<u>Notes to Financial Statements</u>	92

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of Tandem Diabetes Care, Inc.

We have audited the accompanying balance sheets of Tandem Diabetes Care, Inc. as of December 31, 2016 and 2015, and the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Tandem Diabetes Care, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and has a net capital deficiency, and does not have sufficient cash to fund its operations through December 31, 2017. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The 2016 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

San Diego, California

March 8, 2017

TANDEM DIABETES CARE, INC.

BALANCE SHEETS

(In thousands except par values)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$44,678	\$43,088
Restricted cash	2,000	2,000
Short-term investments	8,860	28,018
Accounts receivable, net	11,172	14,055
Inventory, net	21,195	17,543
Prepaid and other current assets	4,187	2,280
Total current assets	92,092	106,984
Property and equipment, net	18,409	15,526
Patents, net	1,784	2,110
Other long-term assets	107	105
Total assets	\$112,392	\$124,725
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$7,513	\$5,234
Accrued expense	1,629	2,121
Employee-related liabilities	10,183	11,761
Deferred revenue	5,208	1,822
Other current liabilities	6,943	5,582
Total current liabilities	31,476	26,520
Notes payable—long-term	78,960	29,275
Deferred rent—long-term	2,609	2,743
Other long-term liabilities	5,274	2,719
Total liabilities	118,319	61,257
Commitments and contingencies (Note 10)		
Stockholders' equity (deficit):		
Common stock, \$0.001 par value; 100,000 shares authorized as of December 31, 2016 and 2015, respectively, 31,096 and 30,255 shares issued and outstanding at December 31, 2016 and 2015, respectively.	31	30
Additional paid-in capital	398,623	384,551
Accumulated other comprehensive income (loss)	(1)	20
Accumulated deficit	(404,580)	(321,133)
Total stockholders' equity (deficit)	(5,927)	63,468
Total liabilities and stockholders' equity (deficit)	\$112,392	\$124,725

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

TANDEM DIABETES CARE, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except per share data)

	Year Ended December 31,		
	2016	2015	2014
Sales	\$84,248	\$72,850	\$49,722
Cost of sales	60,656	46,270	34,474
Gross profit	23,592	26,580	15,248
Operating expenses:			
Selling, general and administrative	82,834	78,621	75,121
Research and development	18,809	16,963	15,791
Total operating expenses	101,643	95,584	90,912
Operating loss	(78,051)	(69,004)	(75,664)
Other income (expense), net			
Interest and other income	296	337	112
Interest and other expense	(5,707)	(3,741)	(3,901)
Total other expense, net	(5,411)	(3,404)	(3,789)
Loss before taxes	(83,462)	(72,408)	(79,453)
Provision for income tax (benefit) expense	(15)	10	71
Net loss	\$(83,447)	\$(72,418)	\$(79,524)
Other comprehensive loss:			
Unrealized gain (loss) on short-term investments	\$(21)	\$12	\$8
Comprehensive loss	\$(83,468)	\$(72,406)	\$(79,516)
Net loss per share, basic and diluted	\$(2.73)	\$(2.50)	\$(3.42)
Weighted average shares used to compute basic and diluted net loss per			
share	30,570	28,923	23,272

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

TANDEM DIABETES CARE, INC.

STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except per share data)

	Common Shares	Stock Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2013	22,926	\$ 23	\$ 284,705	\$ —	\$ (169,191)	\$ 115,537
Exercise of common stock warrants	334	1	137	—	—	138
Exercise of stock options	144	—	325	—	—	325
Issuance of common stock for Employee Stock Purchase Plan	251	—	3,168	—	—	3,168
Stock-based compensation	—	—	14,920	—	—	14,920
Unrealized gain on short-term investments	—	—	—	8	—	8
Net loss	—	—	—	—	(79,524)	(79,524)
Balance at December 31, 2014	23,655	\$ 24	\$ 303,255	\$ 8	\$ (248,715)	\$ 54,572
Exercise of common stock warrants	17	—	122	—	—	122
Exercise of stock options	243	—	337	—	—	337
Issuance of common stock in public offering, net of underwriter's discount and offering costs	6,038	6	64,856	—	—	64,862
Issuance of common stock for Employee Stock Purchase Plan	302	—	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	30,255	\$ 30	\$ 384,551	\$ 20	\$ (321,133)	\$ 63,468
Exercise of stock options	149	—	170	—	—	170
Issuance of common stock for Employee Stock Purchase Plan	692	1	2,150	—	—	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	31,096	\$ 31	\$ 398,623	\$ (1)	\$ (404,580)	\$ (5,927)

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

TANDEM DIABETES CARE, INC.

STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Operating activities			
Net loss	\$(83,447)	\$(72,418)	\$(79,524)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	5,489	4,829	4,389
Interest expense related to amortization of debt discount and debt issuance costs	274	138	219
Payment in kind interest accrual of notes payable	927	153	—
Provision for allowance for doubtful accounts	632	70	188
Provision for inventory reserve	3,343	404	163
Amortization of (discount) premium on short-term investments	(85)	4	(53)
Stock-based compensation expense	11,660	13,096	14,995
Other	(78)	(76)	41
Changes in operating assets and liabilities:			
Accounts receivable, net	2,251	(6,473)	(2,541)
Inventory	(6,904)	(6,084)	(1,820)
Prepaid and other current assets	(2,466)	(395)	(82)
Other long-term assets	(2)	131	(150)
Accounts payable	3,234	3,355	(1,225)
Accrued expenses	(497)	(734)	973
Employee-related liabilities	(1,578)	2,039	3,846
Deferred revenue	4,610	981	429
Other current liabilities	573	1,924	(1,575)
Deferred rent	1	(631)	(461)
Other long-term liabilities	890	923	810
Net cash used in operating activities	(61,173)	(58,764)	(61,378)
Investing activities			
Purchase of short-term investments	(30,622)	(80,191)	(67,101)
Proceeds from sales and maturities of short-term investments	50,000	88,450	36,210
Purchase of property and equipment	(8,930)	(5,764)	(4,406)
Purchase of patents	-	(74)	(173)
Net cash provided by (used in) investing activities	10,448	2,421	(35,470)
Financing activities			
Issuance of notes payable, net of issuance costs	49,994	—	29,925
Restricted cash in connection with notes payable and corporate credit card	—	—	50
Principal payments on notes payable	—	—	(30,000)
Proceeds from public offering, net of offering costs	—	64,862	—
Proceeds from issuance of common stock	2,321	3,393	3,664
Net cash provided by financing activities	52,315	68,255	3,639
Net increase (decrease) in cash and cash equivalents	1,590	11,912	(93,209)
Cash and cash equivalents at beginning of period	43,088	31,176	124,385
Cash and cash equivalents at end of period	\$44,678	\$43,088	\$31,176
Supplemental disclosures of cash flow information			

Edgar Filing: TANDEM DIABETES CARE INC - Form 10-K

Interest paid	\$4,401	\$3,345	\$3,369
Income taxes paid	\$23	\$9	\$71
Supplemental schedule of noncash investing and financing activities			
Lease incentive - lessor-paid tenant improvements	\$—	\$933	\$1,604
Property and equipment included in accounts payable & other current liabilities	\$501	\$1,457	\$789
Patent included in accrued expense	\$—	\$—	\$74

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

TANDEM DIABETES CARE, INC.

NOTES TO 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. During 2016, the Company’s pump products included:

the t:slim Insulin Delivery System, or t:slim,
the t:flex Insulin Delivery System, or t:flex,
the t:slim G4 Insulin Delivery System, or t:slim G4, and
the t:slim X2 Insulin Delivery System, or t:slim X2.

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 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 announced and launched a Technology Upgrade Program that provides eligible t:slim and t:slim G4 customers a path to obtain t:slim X2. Participating customers have the right to exchange their original t:slim and t:slim G4 for a t:slim X2, under a variable pricing structure. The Technology Upgrade Program expires on September 30, 2017.

In October 2016, the Company began shipping t:slim X2. As a result, the Company discontinued new shipments of t:slim, though the Company will continue to provide ongoing service and support to existing t:slim Pump customers.

For the year ended December 31, 2016, the Company has adopted FASB Accounting Standard Codification (“ASC”) Topic 205-40, Presentation of Financial Statements – Going Concern, which requires that management evaluate whether there are relevant conditions and events that, in the aggregate, raise substantial doubt about the entity’s ability to continue as a going concern and to meet its obligations as they become due within one year after the date that the financial statements are issued.

The Company has incurred operating losses since its inception and as reflected in the accompanying financial statements, the Company has an accumulated deficit of \$404.6 million as of December 31, 2016, which includes a net loss of \$83.4 million for the year ended December 31, 2016. Additionally, the Company used \$61.2 million in cash for operations in the year ended December 31, 2016, which exceeded cash and cash equivalents and short-term investments of \$53.5 million at December 31, 2016. The Company concluded that, at the date its financial statements for the year ended December 31, 2016 were issued, it did not have sufficient cash to fund its operations through December 31, 2017 without additional financing and, therefore, there was substantial doubt about its ability to continue as a going concern within one year after the date the financial statements were issued.

As a result, the audit report contained in the accompanying financial statements includes an explanatory paragraph that describes conditions that raise substantial doubt about the Company’s ability to continue as a going concern. This explanatory paragraph constitutes a potential event of default under the Company’s existing term loan agreement (as amended by Consent and Amendment Agreement, dated June 20, 2014, Omnibus Amendment Agreement No. 2, dated February 23, 2015, Amendment No. 3 to Term Loan Agreement, dated January 8, 2016, and Waiver and Amendment No. 4 to Term Loan Agreement, dated March 7, 2017, the “Term Loan Agreement”) with Capital Royalty Partners II, L.P. and its affiliate funds (“Capital Royalty Partners”). Accordingly, on March 7, 2017, the Company entered into an amendment to the terms of the Term Loan Agreement (the “Fourth Amendment”) that included a limited waiver of the potential event of default that could have occurred due to the inclusion of the explanatory paragraph in the audit report. (See Note 5 “Term Loan Agreement” and Note 12 “Subsequent Event.”)

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 believes that it will be necessary to raise additional funding in the form of an equity financing from the sale of common stock. The Company may in the future seek additional capital from public or private offerings of its capital stock or it may elect to borrow additional amounts under new credit lines or from other sources. If the Company issues equity or debt securities to raise additional funds, its existing stockholders may experience dilution, it may incur significant financing costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of its existing stockholders. 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 raise significant additional capital, of which there can be no assurance. If the Company cannot generate sufficient revenues from the sale of its products or secure additional financing on acceptable terms, it may be forced to significantly alter its business strategy, substantially curtail its current operations, or cease operations altogether.

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.

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' equity (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. At December 31, 2016 and 2015, the Company had no investments that were classified as held-to-maturity. 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

Restricted cash as of December 31, 2016 and 2015 was comprised of a \$2.0 million 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,	
	2016	2015
Edgepark Medical Supplies, Inc.	15.2%	16.4%
Byram Healthcare	14.7%	21.8%

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

	December 31,		
	2016	2015	2014
Edgepark Medical Supplies, Inc.	18.7%	17.8%	16.0%
Byram Healthcare	14.0%	17.2%	10.9%
Solara Medical Supplies, Inc.	10.7%	N/A	N/A
CCS Medical	N/A	N/A	11.6%

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 and foreign exchange forward contracts that are not designated as hedges 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 Company offers to certain eligible customers trade-in rights which are determined to be guarantees. The Company records a liability for the estimated fair value of the guarantee at its inception. If actual results differ significantly from these estimates, the Company's results of operations could be materially affected. For further details regarding our guarantees, see the following section "Revenue Recognition" within Note 2 and Note 4, "Fair Value Measurements."

Inventories

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, at December 31, 2016 and 2015. 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, 2016.

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, 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 trade-in rights associated with the Company's Technology Upgrade Program are accounted for as guarantees or rights to return based on specific factors and circumstances, including the period of time the trade-in rights are exercisable, the likelihood that the trade-in rights will be exercised, and the amount of the specified-price trade-in value.

The Company has determined that trade-in rights for t:slim G4 Pump customers are guarantees. The Company accounts for the guarantees under applicable accounting standards, which require a guarantor to recognize, at the inception of a guarantee, a liability for the estimated fair value of the obligation undertaken in issuing certain guarantees. Subsequently, the initial liability recognized for the guarantee is reduced as the Company is released from the risk under the guarantee, which is when the trade-in right is exercised or the right expires. The guarantee is accounted for as an element of a multiple element arrangement. The estimated fair value of the guarantees are based on various economic and customer behavioral assumptions, including the probability of a trade-in, 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 Pump. At December 31, 2016, \$1.2 million was recorded as a guarantee liability in other current liabilities on the accompanying balance sheet.

The Company has determined that t:slim Pump trade-in rights are in-substance rights to return products. Such rights to return are accounted for pursuant to the right of return accounting guidance. As the Company does not have sufficient history to reasonably estimate returns associated with trade-in rights, all eligible t:slim Pump sales between July 1, 2016 and December 31, 2016 were recorded as deferred revenue until the trade-in right is exercised or the right expires. At December 31, 2016, \$3.2 million was 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, 2016 and 2015, \$1.6 million and \$1.1 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 sheet for product return allowance was \$0.2 million and \$0.3 million at December 31, 2016 and 2015, 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, 2016 and December 31, 2015, the warranty reserve was \$5.7 million and \$3.5 million, respectively. The following table provides a reconciliation of the change in estimated warranty liabilities for the years ended December 31, 2016 and 2015:

(in thousands)	December 31,	
	2016	2015
Balance at beginning of the year	\$3,547	\$1,974
Provision for warranties issued during the period	8,830	1,948
Settlements made during the period	(8,739)	(4,373)
Increases in warranty estimates	2,052	3,998
Balance at end of the year	\$5,690	\$3,547
Current portion	\$2,302	\$1,050
Non-current portion	\$3,388	2,497
Total	\$5,690	\$3,547

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.

Advertising Costs

The Company expenses advertising costs as they are incurred. For the years ended December 31, 2016, 2015 and 2014, advertising costs were \$0.9 million, \$1.0 million, and \$1.5 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 net loss per share is calculated by dividing the net loss by the sum of the weighted-average number of dilutive common share equivalents outstanding for the period determined using the treasury stock method. 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 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, 2016	2015	2014
Warrants for common stock	-	990	1,007
Common stock options	1,511	2,015	2,233
ESPP	18	4	4
	1,529	3,009	3,244

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 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 is in the process of assessing 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 will adopt this standard beginning in the first quarter of 2017. The Company has excess tax benefits for which a benefit could not previously be recognized of approximately \$656,000.

Upon adoption, the balance of the unrecognized excess tax benefits will be reversed with the impact recorded to (accumulated deficit) retained earnings, 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, 2016, the Company does not expect any impact to the financial statements as a result of this adoption in the first quarter of 2017.

In February 2016, FASB issued final guidance for lease accounting. The new guidance requires lessees to put most leases on their balance sheet but to recognize expenses on their income statement in a manner similar to today's accounting. The new guidance also eliminates today's real estate-specific provisions for all entities. The standard is effective for public business entities for annual periods beginning after December 15, 2018, and interim periods within those years. Early adoption is permitted for all entities. The Company is in the process of assessing the impact of the adoption of the standard on its financial statements.

In April 2015, FASB issued new guidance, which amended requirements that require debt issuance costs, related to a recognized debt liability, to be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, effective for the Company beginning January 1, 2016 and applied retroactively for all consolidated balance sheets presented. The Company applied the amended presentation requirements in the first quarter 2016, which resulted in the reclassification of \$0.4 million of debt issuance costs in the Company's balance sheet from other long-term assets to long-term notes payable at December 31, 2015.

In August 2014, FASB issued an accounting standards update, which requires management of public and private companies to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued (or available to be issued when applicable) and, if so, to disclose that fact. Management is required to make this evaluation for both annual and interim reporting periods, if applicable. Management is also required to evaluate and disclose whether its plans alleviate that doubt. The standard is effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. The Company adopted this standard as of December 31, 2016 and has included the expanded discussion on going concern above (see Note 1 "The Company").

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 currently expects to adopt the new revenue standards in its first quarter of 2018 utilizing the modified retrospective method. The Company has begun assessing the impact of the adoption of the new revenue standards on its financial statements, and will not know whether there will be any impact of adoption until its assessment is completed sometime later in 2017.

3. Financial Statement Information

Short-term investments

The Company invests in investment securities, principally debt instruments of financial institutions and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at December 31, 2016 and 2015 (in thousands):

Maturity

At December 31, 2016 (in years)