TANDEM DIABETES CARE INC
Form 10-K
February 24, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2014

or

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

For the transition period from to

Commission File Number 001-36189

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

Delaware (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 x

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 x

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 x 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 x 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 x
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 x

As of June 30, 2014, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $180 million based on the closing price for the common stock of $16.26 on that date. Shares of common stock held by each executive officer, director, and their affiliated stockholders have been excluded from this calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of February 20, 2015, there were 23,714,990 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2015 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K. Except for the portions of the Proxy Statement specifically incorporated by reference in this Form 10-K, the Proxy Statement shall not be deemed to be filed as part hereof.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. 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 ne such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements.

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 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. You should read this Annual Report with the understanding that our actual future results may be materially different and worse from 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. We qualify all of our forward-looking statements by these cautionary 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 Stock Market, we undertake no obligation to update or review any forward-looking statement because of new information, future events or other factors. Readers are cautioned not to place undue reliance on forward-looking statements.

TRADEMARKS

As of December 31, 2014 our trademark portfolio contains eight pending U.S. trademark applications and six pending foreign trademark applications, as well as 14 trademark registrations, including four U.S. trademark registrations and 10 foreign trademark registrations.

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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. The foundation of our product portfolio is our proprietary technology platform and unique consumer-focused approach, which allows us to focus on both consumer and clinical needs to develop and commercialize products that address different segments of the insulin-dependent diabetes market. We began commercial sales of our flagship product, the t:slim Insulin Delivery System, or t:slim, in August 2012. In January 2015, we received clearance from the U.S. Food and Drug Administration, or FDA, to commercialize our next product, the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs. We intend to begin commercial sales of t:flex in the United States during the second quarter of 2015.

Our technology platform features our patented Micro-Delivery Technology, a miniaturized pumping mechanism which 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 both a rechargeable battery and t:connect, our data management application. Our innovative approach to product design and development is also consumer-focused and based on our extensive market research as we believe the user is the primary decision maker when purchasing an insulin pump. This research consists of more than 7,000 responses obtained in 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 to the intended users, allowing users to successfully operate our devices in their intended environment. Leveraging our technology platform and consumer-focused approach, we develop products to address unmet needs of people in the large and growing insulin-dependent diabetes market.

We developed our products to offer the specific features that people with insulin-dependent diabetes seek in a next-generation insulin pump. We designed our products to have the look and feel of a modern consumer electronic device, such as a smartphone. t:slim, our first commercial product, was the first insulin pump to feature a high resolution, color touchscreen. Our products also incorporate colors, language, icons and feedback that consumers find intuitive to use. t:slim is also the slimmest and smallest durable insulin pump currently on the market, and can easily and discreetly fit into a pocket, while still carrying a cartridge with 300 units of insulin. t:flex was designed to provide the benefits of t:slim while offering a cartridge with 480 units of insulin, giving it the largest capacity currently approved in the United States and providing enhanced flexibility to people with greater insulin needs. The touchscreen and intuitive software architecture of our products make them easy to use, learn and teach, and are designed to allow for software updates without requiring any hardware changes. We offer a broad range of accessories allowing users to customize their pump to their individual lifestyle and sense of style.

According to the Centers for Disease Control and Prevention, or CDC, in 2014 approximately 25 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, estimates 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.

The FDA cleared t:slim in November 2011, making it one of the first insulin pumps to be cleared under the FDA's Infusion Pump Improvement Initiative. This initiative is intended to foster the development of safer, more effective infusion pumps and support the safe use of these devices. We commenced commercial sales of t:slim in the United States in the third quarter of 2012. The FDA cleared t:flex in January 2015.

For the years ended December 31, 2014, 2013 and 2012, our sales were $49.7 million, $29.0 million and $2.5 million, respectively. For the years ended December 31, 2014, 2013 and 2012, our net loss was $79.5 million, $63.1 million and $33.0 million, respectively. Our accumulated deficit as of December 31, 2014 was $248.7 million. Since the launch of t:slim, we have shipped approximately 18,300 pumps as of December 31, 2014. Based on customer surveys, the average age of our existing customers that have purchased t:slim is 31 years old, with relatively equal distribution between men and women.

We believe we have an opportunity to rapidly increase sales by developing and commercializing new products that utilize our technology platform and consumer-focused approach, such as t:flex, by continuing to provide strong customer support, and by further expanding our sales and marketing infrastructure. We expanded our sales, clinical and marketing organization from approximately 100 people as of December 31, 2013 to approximately 160 people as of December 31, 2014. We believe this expansion will allow us to engage with more potential customers, their caregivers and healthcare providers on a more frequent basis to promote our products. In addition, by leveraging our sales and marketing infrastructure to demonstrate our product benefits, and the shortcomings of existing insulin therapies, we believe more people will choose t:slim or t:flex for their insulin pump therapy needs, allowing us to further penetrate and expand the market. As of December 31, 2014, approximately half of our customers reported that they had converted from multiple daily injection to t:slim for their insulin therapy. We also believe we are positioned to address consumers' needs in different segments of the large and growing insulin-dependent diabetes market with our products, and products in development. In particular, we see opportunities in the following areas:

increased insulin volume capacity targeted to people with greater insulin requirements, in particular those with type 2 diabetes;

integrated continuous glucose monitoring, or CGM, eliminating the need to carry an additional device;

reduced size and mobile connectivity to appeal to people who seek greater flexibility and discretion;

advancements in the automated delivery of insulin, and

multiple hormone delivery through a single system.

Our headquarters and our manufacturing facility are located in San Diego, California and we employed 437 full-time employees as of December 31, 2014.

The Market

Diabetes is a chronic, life-threatening disease for which there is no known cure. The disease is caused when the pancreas 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, or IDF, estimates that in 2014 approximately 387 million people had diabetes worldwide and that by 2035, this will increase to 592 million people worldwide. According to the Centers for Disease

Control, or CDC, in 2014 nearly 25 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, approximately 1.6 million people have 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, approximately 1.7 million people in the United States with type 2 diabetes require daily 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 the 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.

According to the American Association of Diabetes Educators, insulin pump therapy is considered the “gold standard” of care for people with insulin-dependent diabetes. It 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
	Does not tether the user to a device	Delivers insulin less accurately than insulin pumps
	Lower upfront and ongoing supply costs	
	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	Can be 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, 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. Close Concerns also estimates that in 2014, the U.S. insulin pump market was approximately $1.4 billion, representing an 11% growth in sales.

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 be even greater if not for the significant and fundamental perceived shortcomings of durable 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, as well as the reasons why the adoption rate of insulin pump therapy is not greater in light of its benefits when compared to MDI therapy. We have conducted extensive research consisting of more than 7,000 responses 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 and statistical analysis, we believe that the limited adoption of insulin pump therapy by people with insulin-dependent diabetes is 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 a pager, as they generally still feature small, low contrast 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.

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. 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 can be time-consuming, and must be performed multiple times per day. 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 pressure changes 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 respond to the concerns and unmet needs of traditional insulin pump users, but also to motivate eligible MDI users to adopt pump therapy.

Our Solution

We developed our proprietary technology platform using a consumer-focused approach by first utilizing extensive market research to ascertain what consumers want, and then designing products to meet those specific consumer demands, as we believe the user is the primary decision maker when purchasing an insulin pump. 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, which often does not involve seeking out specific consumer feedback in advance or applying the science of human factors to optimize the design of a product.

Our products, technology platform and consumer-focused approach are intended to address the unmet needs of traditional insulin pump users and the concerns that have discouraged pump-eligible MDI users from adopting pump therapy. Specifically, our solution addresses the shortcomings of traditional pumps identified through our market research. Our solution includes:

Contemporary style. Our approved products, t:slim and t:flex, as well as all of 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. In addition, we designed a broad range of accessories allowing users to customize their pump to their individual lifestyle and sense of style.

t:slim Insulin Delivery System (Actual Size)

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Compact size. t:slim is the slimmest and smallest durable insulin pump on the market while still offering a cartridge with 300 units of insulin. t:flex offers the same sleek pump form factor as t:slim, while utilizing a cartridge with 480 units of insulin, providing enhanced flexibility to people with greater insulin needs. With a narrow profile, similar to many smartphones, our products can easily and discreetly fit into a pocket. The size and shape were 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 addresses both the embarrassment and functionality concerns related to the size and inconvenience of carrying a traditional pump.

t:slim Insulin Delivery System (Actual Size)

Easy to learn and teach. Our technology platform allows for the use of a vivid touchscreen and easy-to-navigate software architecture, providing users simple access to the key functions of their pump directly from the Home Screen. Insulin pump users can quickly learn how to efficiently navigate their pump's 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. We also believe the ease with which our pump can be learned and taught will help attract current insulin pump users as well as people who may have been frustrated or intimidated by traditional pumps.

Easy-to -Navigate Pump Software Architecture

Intuitive to use. Similar to what is found in modern consumer electronic devices, the embedded software displayed on our vivid 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 with greater confidence and expand the set of functions that they regularly utilize. Users can also execute most tasks in fewer steps than traditional pumps. We believe these features allow users to more efficiently manage their diabetes without fear or frustration.

Quick Access to Pump History

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 typical and extreme operating conditions and is designed to last for at least the anticipated four-year life of the pump. Our technology also allows us to reduce the size of the device as compared to traditional pumps and is capable of delivering the smallest increment of insulin to users of any pump currently available.

t:slim pump Mechanism

Our technology platform also features a touch screen and a micro-USB connection that supports rapid recharging and connectivity to t:connect, both of which can be performed without disconnecting or interrupting insulin delivery.

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 that were raised by people with diabetes, their caregivers and healthcare providers throughout our market research and iterative human factors-based design process. We also believe our product platform provides us with the opportunity to address unmet needs in the insulin-dependent diabetes market, including integrated CGM solutions, further device miniaturization, advancements in automated insulin delivery and multiple hormone delivery capabilities.

Our Strategy

Our goal is to significantly expand and further penetrate the insulin-dependent diabetes market and become the leading provider of insulin pump therapy by focusing on both consumer and clinical needs. We intend to pursue the following business strategies:

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. We intend to leverage this platform to expand our product offerings to address different segments of the large and growing insulin-dependent diabetes market, including supporting advances in the automated delivery of insulin through our clinical research partnerships,

strategic agreements and commercial product development efforts.

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.

Promote awareness of our products to consumers, their caregivers and healthcare providers. Our products were specifically designed to address the shortcomings of currently available technologies that have limited the adoption of insulin pump therapy. We intend to broaden our direct-to-consumer marketing and promote the benefits of our products through our redesigned website and use of social media tools. We plan to leverage our sales force and 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.

Drive adoption of our products through our expanded sales and marketing infrastructure and multiple product offerings. We have been able to achieve commercial success since the launch of our first commercial product, t:slim. Our sales and marketing infrastructure is scalable, and we have invested and will continue to invest in the expansion of this infrastructure to increase our access to people with diabetes, their caregivers and healthcare providers. In addition, we have an opportunity to leverage this infrastructure by launching new product offerings, such as t:flex, to primarily the same healthcare providers, thereby increasing our efficiency. We believe that further investment in our sales and marketing infrastructure combined with the launch of additional product offerings utilizing the same infrastructure will drive continued adoption of our products and significantly increase our revenues.

Broaden third-party payor coverage for our products in the United States. We believe that third-party reimbursement is an important determinant in driving consumer adoption. 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. As our sales and marketing resources have been limited thus far, we have generally located our sales representatives in larger metropolitan areas and have concentrated our reimbursement efforts on third-party payors with large numbers of members residing in the same areas. We intend to intensify our efforts to encourage third-party payors to establish reimbursement for our products as we expand our sales and marketing infrastructure.

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. With our existing production lines, we have the capacity to significantly increase our manufacturing output. We have the capability to replicate these production lines within our current facility to further increase our manufacturing capacity and we currently intend to install additional equipment for the automated manufacturing of our disposable cartridges over the next six to eighteen months. Our production system is also adaptable to new products due to shared product design features. We intend to reduce our product costs and drive operational efficiencies by leveraging our scalable, flexible manufacturing infrastructure.

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 our 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 that facilitates ease of learning, teaching and use. The flexible software architecture may also allow for updates to the software without requiring any hardware changes.

Vivid color touchscreen. Our full color touchscreen allows users to access a streamlined, easy-to-use interface. 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 vivid color 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 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 life of the pump. Our battery also allows for precise and 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 t:slim, t:flex and supported blood glucose meters. Our platform empowers people with diabetes, as well as their caregivers and healthcare providers, to easily and quickly identify meaningful insights and trends, allowing them to fine-tune therapy and lifestyle choices for better control of their diabetes. Additionally, our platform enables rapid data uploads through a micro-USB connection, without interrupting insulin delivery.

Our Products

We have introduced to the market our flagship product, the t:slim Insulin Delivery System, and t:connect, its companion diabetes management application. t:flex was submitted to the FDA in November 2014 and was cleared for commercialization by the FDA in January 2015. We expect to commence commercial sales of t:flex in the second quarter of 2015. These products were cleared by the FDA under its Infusion Pump Improvement Initiative. 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

t:slim Insulin Delivery System

The t:slim Insulin Delivery System is comprised of the t:slim pump, its 300-unit disposable insulin cartridge and an infusion set. We commercially introduced t:slim in the United States in the third quarter of 2012.

Cartridge being Inserted into t:slim pump

Measuring 2.0 x 3.1 x 0.6 inches, t:slim is the slimmest and smallest durable insulin pump on the market. t:slim has a black aluminum case and chrome trim that give it the look and feel of a modern consumer electronic device, such as a smartphone. t:slim is also watertight, with an IPX7 rating, eliminating concerns about getting it wet. The device also features a micro-USB connection that supports rapid recharging and connectivity to t:connect, both of which can be performed without disconnecting or interrupting insulin delivery.

t:slim's vivid, full color touchscreen is made of high-grade, shatter-resistant glass and 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 to facilitate rapid access to the features people use most, such as delivering a bolus, viewing insulin on board, viewing insulin cartridge volume and monitoring current pump status and settings. The interface also includes an options menu that provides quick and intuitive navigation to key insulin management features, pump settings, cartridge loading and use history. t:slim also features 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.

t:slim enables the creation of six 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, carbohydrates to insulin ratio and target blood glucose levels.

The other key components of the t:slim Insulin Delivery System are the disposable cartridge and standard infusion set. The cartridge features our proprietary Micro-Delivery Technology and miniaturized pumping mechanism and has a capacity of 300 units of insulin that is typically replaced by a user every three days. We designed t:slim with a standard Luer Lock connector to accommodate flexibility in a user's infusion set choice, thereby enabling a variety of options in cannula materials, adhesive materials, insertion angles and insertion techniques.

We also designed t:slim to support a broad range of accessories allowing users to customize their device to their individual lifestyle and sense of style. We offer a full set of accessories to increase user flexibility and willingness to use and carry their insulin pump. These accessories include different color casings, belt clips, leather cases and convenient portable power adapters.

t:slim Accessories

t:flex Insulin Pump

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

t:flex Insulin Delivery System

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, 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 t:flex cartridge 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. We have also developed accessories for t:flex that are similar to our t:slim accessories.

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 another 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:connect Diabetes Management Application

We commercially introduced our complementary product, t:connect Diabetes Management Application, or t:connect, in the first quarter of 2013. t:connect is a PC- and Mac-compatible, cloud-based data management application that is compatible with t:slim and t:flex and provides users, their caregivers and their healthcare providers a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters. This application empowers people with diabetes, as well as their healthcare providers, to easily and quickly identify meaningful insights and trends, allowing them to refine therapy and lifestyle choices for better management of their diabetes. We also believe that t:connect can serve as a key component of mobile health applications that we may decide to develop in the future.

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 also can generate color-coded graphs and interactive, multi-dimensional reports that make it easy to identify therapy management trends, problems and successes. There are six different report options, including a dashboard, therapy timeline, blood glucose trends, activity summary, notes and logbook and pump settings. While our insulin pumps hold the data generated over a period of up to 90 days, once a user uploads to t:connect their therapy management information is retained for as long as they retain an account. t:connect maintains the highest standards of patient data privacy and is hosted on secure, Health Insurance Portability and Accountability Act of 1996, or HIPAA, compliant servers.

t:connect Diabetes Management Application

Products in Development

Our products in 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 targeted at different segments of the insulin-dependent diabetes market.

t:slim G4™ Insulin Pump with an Integrated CGM System

We have entered into a development and commercialization agreement with DexCom, Inc., or DexCom, which provides us a non-exclusive license to integrate our product platform with the DexCom G4 PLATINUM Continuous Glucose Monitor. t:slim G4 insulin pump with an integrated CGM System, or t:slim G4, which we have previously referenced as t:sensor, will incorporate the same pump technology and user interface as t:slim. It will provide 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 will be able to utilize the pump to take direct action with their insulin pump therapy. In addition, we intend to update t:connect in order to display the additional CGM data that is collected on the pump and for other functionality associated with t:slim G4.

CGM is a therapy used in conjunction with blood glucose testing, and will provide users with real-time access to their glucose levels as well as trend information. Close Concerns estimates that approximately 10% of people with type 1 diabetes use CGM. We believe that CGM utilization will be increased by offering an accurate CGM sensor in combination with an innovative and consumer-focused insulin pump, such as t:slim.

We submitted a pre-market approval, or PMA, application for t:slim G4 with the FDA in July 2014 and anticipate a 12 to 18 month review cycle. The application referenced the PMA-approved DexCom G4 PLATINUM and the 510(k)-cleared t:slim, and provided information regarding the safety and effectiveness of t:slim G4. The PMA application also included t:connect, which will allow users to view data retrieved from the t:slim G4 on the user's computer.

Odyssey Web-based Software Updates

Odyssey is the development name for our proprietary PC- and Mac-compatible web based system that is being developed to allow users to update their pump's software in their home environment, similar to a smartphone. We are positioned to offer this capability with our product's modern and convenient micro-USB connection. Subject to future regulatory approvals, we anticipate that Odyssey will allow users to update their pump software to continue to enhance their experience with our products.

We intend to submit a 510(k) submission for Odyssey in the fourth quarter of 2015.

t:sport Insulin Delivery System

The t:sport Insulin Delivery System, or t:sport, is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump by further reducing the size of the insulin pump and controlling its operation through a mobile device application. We are developing a compact insulin pump capable of communicating wirelessly with a mobile device, such as a smartphone, which will be used to program its operations instead of a touchscreen on the device. By leveraging our current technology platform, including our existing touchscreen, software and user interface, we believe we are uniquely positioned to offer customers a consistent interface between our product offerings and their mobile device, which will allow our pumps to continue to be easy to use by customers and easy to train by healthcare providers, while also further reducing the size and visibility of the pumps.

The FDA issued Radio Frequency Wireless Technology in Medical Devices Guidance in August 2013. At this time, there is not a predicate device for an insulin pump wirelessly controlled through a mobile device application.

Automated Insulin Delivery

The concept of an artificial pancreas 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 sophisticated 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 artificial pancreas solutions. Within our commercial t:slim product there is a blue-tooth low energy radio (BLE) that is not enabled. In July 2013, we submitted a Master File to the FDA, allowing researchers to use the 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.

We anticipate our first commercial artificial pancreas offering will be based on our proprietary technology platform and will partially automate insulin delivery based on CGM information. We believe partial automated insulin delivery can be achieved through predictive algorithms that aid a user in maintaining their targeted blood glucose level, thereby reducing the frequency and severity of hyperglycemic or hypoglycemic events and the associated short and long-term complications.

We believe our first commercial artificial pancreas offering will require PMA approval and that the submission will include data from one or more clinical studies. We anticipate filing an investigational device exemption, or IDE, with the FDA in 2015 for the clinical study involving a first generation product with the capability of partial automation of insulin delivery.

t:dual Infusion System

In January 2013, we announced a strategic relationship with Juvenile Diabetes Research Foundation (JDRF) to develop the t:dual Infusion System, or t:dual, which is being designed to be a first-of-its-kind, dual-chamber infusion pump for the management of diabetes. The collaboration agreement with JDRF is designed to accelerate the development of a fully automated artificial pancreas system that has the capability of delivering other hormone therapies in conjunction with insulin. We believe that our unique Micro-Delivery Technology is particularly well suited for providing two-hormone therapy in a compact and sleek design, and that our easy-to-use touchscreen and software architecture are customizable for the needs of dual-therapy regimens. However, U-100 insulin is currently the only hormone indicated for use in pumps by the FDA for the management of diabetes. We do not believe alternative hormones will be commercially available for use in pumps in the next several years.

Sales and Marketing

Our sales and marketing objectives are to:

- generate demand and acceptance for t:slim, t:flex and future products developed with our technology platform among people with insulin-dependent diabetes; and
- promote advocacy and support for healthcare providers.

As of December 31, 2014, we had a sales, clinical and marketing team of approximately 160 full-time employees. In 2014, we expanded our sales and, clinical organization from 36 to 60 territories. Each territory within our sales organization consists of a territory manager and a clinical diabetes specialist who as a team call on endocrinologists, primary care physicians, certified diabetes educators and potential customers. Based on historical sales force performance, we expect most of the new territory managers to reach their steady state level of sales performance

within nine to twelve months from their date of hire. Our sales team is augmented by individuals in our 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. As t:slim market penetration continues to build momentum, and as we launch new products into the market, including t:flex, we expect to further expand our sales and marketing infrastructure in the United States and may evaluate international commercialization opportunities.

In addition, as of December 31, 2014, we had executed agreements with more than 30 independent distributors. For the year ended December 31, 2014, Edgepark Medical Supplies, Inc., CCS Medical, Inc. and Byram Healthcare, all independent distributors, accounted for 16.0%, 11.6% and 10.9% of our sales, respectively. For the year ended December 31, 2013, Edgepark Medical Supplies, Inc. and CCS Medical, Inc., both independent distributors, accounted for 16.1% and 13.6% of our sales, respectively. 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.

We expect our sales will fluctuate on a quarterly basis in the future due to a variety of factors, including seasonality and the impact of the buying patterns of our distributors and other customers. We believe that our sales are subject to seasonal fluctuation due to the impact of annual deductible and coinsurance requirements associated with most medical insurance plans utilized by our individual customers and the individual customers of our distributors. For example, our sales for the first quarter of 2014 represented approximately 16% of our total sales for 2014 and overall 2014 sales were weighted heavily towards the second half of the year. We expect seasonality will have a similar impact on our sales in 2015.

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 for pump demonstrations to their patients; and

partnerships with third-party diabetes management systems for the display of t:slim 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 that were designed to meet different needs in the diabetes community. 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 video modules and consumer-focused newsletters to drive online awareness and expand web presence;

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.

In the first quarter of 2015, we launched t:simulator, a free mobile application intended to illustrate the t:slim user interface for customers exploring diabetes treatment options. The touchscreen on our technology platform uniquely positions our products for simulation on a mobile application and will also allow users to contact a company representative and access additional pump resources, such as product specifications, a glossary and safety and disclaimer information.

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 family 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. 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 t:slim and t:flex 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 certified diabetes educators who have been certified to train on our products and will conduct customer training on our behalf.

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. 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.

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 24-hour product replacement program through which our technical services team members can provide a customer with a replacement device within 24 hours to minimize the interruption to their therapy.

Insurance Verification. Our insurance verification team provides support to help customers, and potential customers, understand their insurance benefits. We work with the customer and their healthcare provider 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. A member of the 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.

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 t:slim and its associated supplies using existing Healthcare Common Procedure Coding System codes for which Medicare reimbursement is well established. Over the last ten years, Medicare reimbursement rates for insulin pumps and disposable cartridges have remained relatively unchanged. However, Medicare has recently begun to review 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. Medicare also initiated a competitive bidding process for insulin pumps in limited geographies. As a result, there is some uncertainty as to the future Medicare reimbursement rate for our current and future products.

We intend to bill t:flex and its associated supplies under the same Healthcare Common Procedure Coding System codes as t:slim. 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, which may slow the adoption of t:flex.

As of December 31, 2014, we had entered into commercial contracts with more than 70 national and regional third-party payors to establish reimbursement for t:slim, its disposable cartridges and other related supplies. We are also currently in the process of approaching these and other third-party payors to discuss reimbursement for t:flex. 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, 2014, approximately 20% 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, 2014, we had executed distributor agreements with more than 30 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.

Manufacturing and Quality Assurance

We currently manufacture our products at our headquarters in San Diego, California. By locating our manufacturing operations near our other business functions, we believe we have significantly enhanced our ability to monitor and manage our manufacturing, and to adjust manufacturing operations quickly in response to our business needs.

We currently utilize a semi-automated manufacturing process for our pump products and disposable cartridges. The pump production line requires approximately 12 manufacturing assemblers and limited support staff to run the line and reaches a maximum output of approximately 20,000 pumps per year on a single shift. Disposable cartridges are manufactured on a production line that requires 12 to 20 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 on improving 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 cartridges. In addition, we are in the process of further automating the manufacturing of our disposable cartridges.

The cartridge automation equipment was designed to operate at capacity. As such, the line was 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.

With our existing pump and cartridge production lines, we have the capacity to significantly increase our manufacturing output. We can replicate these production lines within our current facility to further increase our manufacturing capacity and we currently intend to install additional equipment for the automated manufacturing of our disposable cartridges over the next six to eighteen months. Due to shared product design features, our production system is easily adaptable to new products. We intend to reduce our product cost and drive operational efficiencies by leveraging this scalable, flexible 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 the 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. Recently, the inspection associated with the t:slim G4 PMA was completed.

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 in development.

We have entered into a development and commercialization agreement with DexCom, which provides us a non-exclusive license to integrate the DexCom G4 PLATINUM 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, which related to our submission of a PMA application for the t:slim G4, which we have previously referenced as t:sensor, to the FDA. The payments were recorded as research and development costs. We will make one additional $1.0 million payment upon the achievement of certain milestones. We have agreed to pay DexCom a royalty payment in the amount of $100 for each integrated system sold. Additionally, we will reimburse DexCom up to $1.0 million of its development costs and are responsible for our own development costs and expenses. Our agreement with DexCom runs until January 4, 2017, with automatic one-year renewals. Prior to the commercial launch of t:slim G4, either party may terminate the agreement without cause provided that the party requesting the termination must reimburse the other party for up to $1.0 million of previously incurred development expenses. Following the commercial launch of t:slim G4, 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 at any time, subject to limited ongoing obligations.

We have also entered into a research, development and commercialization agreement with JDRF to develop a dual drug infusion pump designed to deliver both insulin and a second hormone or drug. Under this agreement, JDRF will provide research funding of up to $3.0 million payable upon reaching certain performance-based milestones. Through December 31, 2014, we have received a total of $0.7 million from JDRF under this agreement. Under the terms of the agreement, we have agreed to pay JDRF a royalty calculated as a percentage of each dual drug infusion pump we sell until JDRF has received royalty payments equal to three times the amount of funding that we receive from JDRF under this agreement. Thereafter, no royalty payments will be due under the agreement. Either party may terminate the agreement without cause at any time upon 90 days prior notice, provided that if we terminate the agreement without cause prior to 2017, then we may be required to pay JDRF two times the amount we have received from JDRF prior to such termination, and if we terminate the agreement without cause after that date we may be required to pay JDRF three times the amount we have received from JDRF. Any intellectual property developed by either party in the performance of this agreement will be owned or exclusively licensed by us.

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, 2014, our patent portfolio consisted of approximately 32 issued U.S. patents and 48 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2031. We are also seeking patent protection for our proprietary technology in other countries throughout the world. We also have eight pending U.S. trademark applications and six pending foreign trademark applications, as well as 14 trademark registrations, including four U.S. trademark registrations and ten 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, 2014, we had paid the initial license fees in full and have not entered into any sublicense agreements.

Our development and commercialization agreement with DexCom provides us with a non-exclusive license to integrate the DexCom G4 PLATINUM into t:slim G4. For additional information, see “Research and Development.”

Competition

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products 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, Roche Diagnostics, a division of F. Hoffman-La Roche Ltd., and Insulet Corporation.

Many of our competitors are either publicly traded companies or divisions or subsidiaries of publicly traded companies with significantly more market share and resources than we have. Many of 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 currently offers a traditional insulin pump that is integrated with a CGM system and a recently approved threshold suspend feature.

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.

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 and t:connect received FDA clearance as Class II devices, and we anticipate t:flex will also be considered a Class II 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.

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.

We filed a PMA application with the FDA for t:slim G4 in July 2014 and anticipate a 12 to 18 month review cycle. The application provided new information on how t:slim G4 interfaces with the DexCom PLATINUM G4 sensors and transmitter, and with t:connect, as well as human factors testing completed on the CGM display screens.

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

the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;

patients do not enroll in clinical trials at the rate expected;

patients do not comply with trial protocols;

patient follow-up is not at the rate expected;

patients experience adverse side effects;

patients die during a clinical trial, even though their death may not be related to the products that are part of our trial;

institutional review boards and third-party clinical investigators may delay or reject the trial protocol;

third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;

we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;

third-party clinical investigators have significant financial interests related to us or our study that the FDA deems to make the study results unreliable, or the company or investigators fail to disclose such interests;

regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;

changes in governmental regulations or administrative actions;

the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and

the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

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

establishment registration and device listing;

QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations that prohibit the promotion of products for uncleared, unapproved or “off-label” uses, and impose other restrictions on labeling, advertising and promotion;

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

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

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

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

In January 2014, we implemented a voluntary recall of select lots of cartridges used with t:slim that may be at risk of leaking. A cartridge leak could potentially result in the delivery of too much or too little insulin, which could lead to unexpected high or low blood glucose levels. Too much insulin can result in severe low blood sugar, or hypoglycemia, and too little insulin can lead to severe high blood sugar, or hyperglycemia, both of which can lead to serious injury or death. We notified the FDA of the recall and promptly notified our customers and any of our independent distributors that may have received affected cartridges. The cause of the recall was identified during our internal product testing and related to a certain piece of equipment used to test cartridges after they are manufactured. We have modified our cartridge testing process to prevent this issue from occurring in the future and the FDA has determined that the recall is terminated.

Of the lots that were recalled, an aggregate of approximately 13,000 boxes were shipped to customers or distributors. We are replacing any affected cartridges at no additional charge. Through December 31, 2014, we have replaced approximately 6,000 boxes of affected cartridges. We are uncertain whether additional boxes of the affected lots will be returned in the future. In addition, we have removed additional material that was in our internal inventory at the time of the recall, including finished goods and work in process, that we determined was not sellable and have segregated it in a different location.

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

warning letters or untitled letters that require corrective action;

fines and civil penalties;

unanticipated expenditures;

delays in approving or refusal to approve future products;

FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;

suspension or withdrawal of FDA clearance or approval;

product recall or seizure;

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

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

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

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

Federal Anti-Kickback and Self-Referral Laws. The Federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The definition of “remuneration” has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at less than its fair market value. The 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 assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each 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 and Medicaid 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 and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. The PPACA also provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

We provide the initial training to patients necessary for appropriate use of our products either through our own diabetes educators or by contracting with outside diabetes educators that 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. In addition, because we may provide some coding and billing information to purchasers of our devices, and because we cannot guarantee that the government will regard any billing errors that may be made as inadvertent, the federal anti-kickback legislation may be applied to us. Noncompliance with the federal anti-kickback legislation could result in our exclusion from Medicare, Medicaid or other governmental programs, 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.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider and training arrangements may ultimately be found to be not in compliance 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 against companies under the Federal False Claims Act. 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 act of that person. 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 or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action. We believe that we currently are in compliance with the federal government's laws and regulations concerning the filing of reimbursement claims.

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 the 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 the applicable HIPAA regulations.

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, 2014, we had 437 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.

Available Information

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 Securities and Exchange Commission, or the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. 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 reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

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Item 1A. Risk Factors

An investment in our common stock involves risks. You should consider carefully 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, 2014, we had an accumulated deficit of $248.7 million. To date, we have financed our operations primarily through sales of equity securities, debt financing with Capital Royalty Partners and certain of its affiliates, and sales of our products. We have devoted substantially all of our resources to the research and development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

We began commercial sales of t:slim in the third quarter of 2012. Beginning in the first quarter of 2013, we have been able to manufacture and sell t:slim at a cost and in volumes sufficient to allow us to achieve a positive gross margin. For the year ended December 31, 2014 and 2013, our gross profit was $15.2 million and $6.2 million, respectively. However, although we have achieved a positive gross margin, we still operate at a substantial net loss and expect that we will continue to do so for the next several years. In addition, the launch of new products that we manufacture and sell at lower volumes may negatively impact our gross margin in the future.

To implement our business strategy we need to, among other things, grow our sales and marketing infrastructure to increase sales of our products, fund ongoing research and development activities, expand our manufacturing capabilities, and obtain regulatory clearance or approval to commercialize our products currently under development. We expect our expenses to increase significantly as we pursue these objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, especially given that we only recently expanded the size of our sales, clinical and marketing infrastructure and that we expect to begin sales of our next commercial product, t:flex, in the second quarter of 2015, which makes forecasting our sales more difficult. 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 t:slim to generate a significant portion of our revenue, and any factors that negatively impact sales of this product may adversely affect our business, financial condition and operating results.

Our primary revenue-generating commercial product is t:slim, which we introduced to the market in the third quarter of 2012. We expect to continue to derive a significant portion of our revenue from the sale of t:slim and pump-related supplies. Accordingly, our ability to generate revenue is highly dependent on our ability to market and sell t:slim.

Sales of t:slim may be negatively impacted by many factors, including:

problems arising from the expansion of our manufacturing capabilities, or destruction, loss, or temporary shutdown of our manufacturing facility;

changes in reimbursement rates or policies relating to t:slim or similar products or technologies by third-party payors;

our inability to enter into contracts with third-party payors on a timely basis and on acceptable terms;

claims that t:slim, or any component thereof, infringes on patent rights or other intellectual property rights of third parties;

the harm to our reputation or any other associated liability or perceived risks that may arise from our January 2014 recall of cartridges used with t:slim; and

adverse regulatory or legal actions relating to t:slim or similar products or technologies.

Because we currently rely on a single product to generate a significant portion of our revenue, any factors that negatively impact sales of this product, or result in sales of this product 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.

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 t:slim and t:flex achieving and maintaining market acceptance. We do not intend to begin commercial sales of t:flex until the second quarter of 2015. 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, as to 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 t:slim or t:flex, 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, insulin-prescribing healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;

lack of evidence supporting the safety, ease-of-use or other perceived benefits of our products over competitive products or other currently available insulin treatment methodologies;

perceived risks associated with the use of t:slim or t:flex or similar products or technologies generally;

the introduction of competitive products and the rate of acceptance of those products as compared to t:slim and t:flex;

discounts, rebates and other financial incentives that our competitors may offer for competitive products;

results of clinical studies relating to t:slim, t:flex or similar competitive products.

In addition, t:slim or t:flex may be perceived by people with insulin-dependent diabetes, their caregivers or healthcare providers to be more complicated, less reliable or less effective than traditional insulin therapies, including MDI, and people may be unwilling to change their current treatment regimens. These negative perceptions may be heightened following our January 2014 recall of cartridges used with t:slim.

Moreover, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend our products until there is sufficient evidence to convince them to alter the treatment methods they typically recommend, such as receiving recommendations from prominent healthcare providers or other key opinion leaders in the diabetes treatment community that our products are effective in providing insulin therapy. Additionally, payors may have more stringent requirements for reimbursement.

Further, 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, 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, it is possible that a consumer that is currently interested in purchasing t:slim will delay the purchase decision in anticipation of the future release of t:slim G4, or the release of a product with advanced features offered by one of our competitors.

If t:slim or t:flex 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 projections, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be materially and adversely affected.

Failure to secure or retain adequate coverage or reimbursement for t:slim, t:flex 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 the sale of t:slim in the United States, and we do not expect to begin commercial sales of t:flex in the United States until the second quarter of 2015. We expect to derive nearly all of our revenue during 2015 from sales of t:slim and t:flex insulin pumps and associated supplies, and expect to continue to do so until we are able to commercialize our other products that are currently under development. 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. Because we have not initiated commercial sales of t:flex, there remains considerable uncertainty regarding the coverage that third-party payors will offer for this new product, particularly for individuals with type 2 diabetes where coverage requirements may necessitate additional laboratory tests or other information to support a determination of medical necessity. 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.

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, as guidelines in setting their coverage and reimbursement policies. Medicare has recently begun to review 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, Medicare has also initiated a competitive bidding process for insulin pumps in limited geographies. 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.

We currently have contracts establishing reimbursement for t:slim with approximately 70 national and regional third-party payors in the United States. We are also currently in the process of approaching these and other third-party payors to discuss reimbursement for t:flex. While we anticipate adding coverage for t:flex under our current agreements and entering into additional contracts with third-party payors to provide reimbursement for both t:slim and t:flex, 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 addition, 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 t:slim or t:flex and our future products by third-party payors, or delays in processing approvals by those payors, could result in the loss of sales, which could have a material adverse effect on our business, financial condition and operating results.

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

profitable basis.

We 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 or technologies, or other activities of industry participants. We expect our products will compete directly with a number of traditional insulin pumps as well as other methods for the treatment of diabetes. In particular, we expect that the competitive landscape for t:flex will be similar to that of t:slim.

Many of our existing and potential 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, Roche Diagnostics, a division of F. Hoffman-La Roche Ltd., and Insulet Corporation. There are also newer companies entering the field.

Many of these more established competitors enjoy several competitive advantages over us, including:

greater financial and human resources for sales and marketing, and product development;

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, an established base of long-time 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 also 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, and 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 strategic objectives and forecasted budget, and our business, financial condition and operating results could be materially and adversely affected.

Competitive products or other technological breakthroughs for the monitoring, treatment or prevention of diabetes or technological developments 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, 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 t:slim or t:flex or render our products obsolete altogether, which would significantly reduce our sales. In addition, even the perception that technological or treatment advancements could occur in the future 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, the entry of multiple new products has led some of our competitors to employ pricing strategies, including the use of discounts, rebates 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 own 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 continual 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.

If we are unable to expand our sales, marketing and clinical infrastructure effectively and on a timely basis, we may fail to increase our sales to meet our forecasts.

Because we began commercialization of t:slim in the third quarter of 2012, we have only limited experience marketing and selling our products as well as training new customers on the use of t:slim. We currently intend to begin marketing and selling our t:flex product during the second quarter of 2015. The vast majority of our existing customers for t:slim are individuals with type 1 diabetes, and we have only limited experience in marketing and selling our products to customers with type 2 diabetes. As a result, we may face unexpected challenges as we begin marketing and selling t:flex. We expect to derive nearly all of our revenue from the sale of t:slim, t:flex and pump-related supplies unless and until we receive regulatory clearance or approval for other products currently in development. As a result, our financial condition and operating results are and will continue to be highly dependent on the ability of our sales representatives to adequately promote, market and sell t:slim and t:flex, 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.

A key element of our business strategy is the continued expansion of our sales, marketing and clinical infrastructure to drive adoption of our products, which includes our team of diabetes educators that trains new customers on the use of our products. We have rapidly increased the number of sales, marketing and clinical personnel employed by us since the initial commercial launch of t:slim. However, we have faced considerable challenges in growing our sales, marketing and clinical force over the past 12-18 months, 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 sales, marketing and clinical infrastructure and work to motivate and retain the individuals who make up those networks. In particular, newly hired sales representatives require training and take time to achieve full productivity, and the overall expansion of our sales force also disrupts the productivity of our existing sales representatives. In addition, unexpected turnover would have a negative impact on our ability to achieve our sales projections. Further, if a sales, marketing or clinical representative were 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, we may not be able to successfully train new customers on the use of t:slim or t:flex, which could delay new sales and harm our reputation. We expect that the management and future expansion of our sales, marketing and clinical personnel will continue to place significant burdens on our management team. If we are unable to retain and expand our sales, marketing and clinical capabilities in line with our strategic plans, we may not be able to effectively commercialize our existing or planned products, 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 own. 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, 2014, sales to approximately 36 independent distributors represented approximately 75% of our sales. While we expect that the percentage of our sales to independent distributors will decrease 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 on a direct basis. 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.

Some of our independent distributors account for a significant portion of our sales volume. For the year ended December 31, 2014, our 3 largest independent distributors comprised approximately 38% of our sales. If any of our key independent distributors were to cease to distribute our products, 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, the terms of the arrangements could cause our product margins to be lower than if we directly marketed and sold our products.

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. In addition, our pumps are designed and tested to remain effective for 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 as a result of the introduction of competitive products, changes in reimbursement policies, manufacturing problems, perceived safety or reliability issues with our or competitors' products, the failure to secure regulatory clearance or approvals, or for other reasons, our ability to attract and retain customers could be harmed. 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. 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 rapidly. However, each of these trends is uncertain and limited sources exist to 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. Moreover, even if our market research has allowed us to better understand the features 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 and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

We commenced operations in 2006, began commercializing t:slim in the third quarter of 2012 and significantly expanded our operations during 2014. We have not yet commenced any significant marketing activities or commercial sales of t:flex. Accordingly, we have a limited operating history upon which to evaluate our business and forecast our future sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization 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;

expand and improve the productivity of our sales 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;

manage expanding 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 commercialize proposed products and enhance our existing 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 and 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;

our failure to increase production of products to meet demand;

the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;

our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;

our ability to manufacture multiple products simultaneously within the same manufacturing facility and utilizing common manufacturing equipment;

difficulty identifying and qualifying alternative suppliers for components in a timely manner; 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. However, it is possible that we may not derive the anticipated improvements from these investments. If we fail to increase our production capacity efficiently while also maintaining quality requirements, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features and components with t:slim, 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, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

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

We rely on third-party suppliers to supply components of t:slim, t:flex 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. Increases in 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 most 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 products, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of products. As a result, our ability to purchase adequate quantities of our products may be limited. Additionally, our suppliers may encounter problems that limit their ability to manufacture 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.

We generally use a small number of suppliers for our products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. Moreover, due to the recent commercialization of our products and the limited amount of our sales to date, 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 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. It 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 result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm

our commercialization efforts and adversely affect our operating results.

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

Our principal offices are presently located in four buildings in San Diego, California. Substantially all of our operations are 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 or 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. In addition, 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.

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 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 consumers, their caregivers, healthcare providers or third-party payors who reimburse consumers for our products. The success of any proposed product offerings will depend on numerous factors, including our ability to:

identify the product features 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 proposed 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 developing products that incorporate features requested by consumers, 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 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 commercial launch, 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.

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, which we currently market in the United States, received pre-market clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA. t:flex, which we intend to begin marketing and selling in the United States during the second quarter of 2015, also has received 501(k) clearance. 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. 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. Moreover, if future results and experience indicate that our products cause 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 or 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, 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 or any future collaborators devote to our collaborators' or our future products. Disputes between our collaborators and us may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

For example, we have entered into a development and commercialization agreement with DexCom, which provides us a non-exclusive license to integrate the DexCom G4 PLATINUM Continuous Glucose Monitor with t:slim G4, which we have previously referred to as t:sensor, during the term of the agreement. This agreement currently runs until January 4, 2017, with automatic one-year renewals. The license granted covers the United States and other territories

may be added from time to time. Under certain circumstances, the agreement may be terminated by either party without cause or on short notice. Termination of this agreement could require us to redesign t:slim G4 and attempt to integrate an alternative CGM system into our insulin pump systems, which would require significant development and regulatory activities that might delay the launch and commercialization of t:slim G4 or, following its launch, might not be completed in time to prevent an interruption in the availability of the product to our customers.

If there are significant disruptions in our information technology systems, our business, financial condition and operating results could be adversely affected.

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, inventory management, product development tasks, research and development data, customer service and technical support functions. Our information technology systems 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, t:connect, our cloud-based data management application, is hosted by a third-party service provider whose security and information technology systems are subject to similar risks, and our t:slim and t:flex pumps and products currently in development contain software which could be subject to computer virus or hacker attacks or other failures.

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 and could result in decreased sales, increased overhead costs, and product shortages, all of which could have a material adverse effect on our reputation, 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 on our financial resources. For example, between December 31, 2013 and December 31, 2014 our employee base has increased more than 30% and we expect to continue to experience growth of our employee base during 2015. Failure to manage our growth effectively could cause us to misallocate management or financial resources, and result in losses or weaknesses in our infrastructure, which could materially adversely affect our business. Additionally, our anticipated growth 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. 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 the 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 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 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. 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

Our future capital needs are uncertain and we may need to raise additional funds in the future, and these funds may not be available on acceptable terms or at all.

At December 31, 2014, we had $69.3 million in cash, cash equivalents and short-term investments, which included $2.0 million of restricted cash. We believe that our cash on hand, cash available under our term loan agreement and proceeds from the exercise of warrants and options will be sufficient to satisfy our liquidity requirements for at least the next 12 months. However, the continued growth of our business, including the expansion of our sales and marketing infrastructure, research and development activities, and manufacturing capabilities, will significantly increase our expenses. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. As a result, we expect to seek additional funds in the future. Our future capital requirements will depend on many factors, including:

the revenue generated by sales of t:slim and t:flex, and any other future products that we may develop and commercialize;

the costs associated with maintaining and expanding our sales and marketing infrastructure;

the expenses we incur in maintaining our manufacturing facility and adding additional manufacturing equipment and capacity;

the cost associated with developing and commercializing our proposed products or technologies;

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;

anticipated or unanticipated capital expenditures; and

unanticipated general and administrative expenses.

As a result of these and other factors, we do not know the extent to which we may be required to raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, borrowings under credit lines or other sources. In particular, we have an effective shelf registration statement on file with the SEC, under which we may offer to sell equity securities. 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 expand our sales and marketing infrastructure, enhance our current products or develop new products, take advantage of future opportunities, or respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results.

Our operating results may fluctuate significantly from quarter to quarter.

We began commercial sales of t:slim in the third quarter of 2012. There has been and may continue to be meaningful variability in our operating results from quarter to quarter, as well as within each quarter. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

our ability to increase sales of t:slim and to commercialize and sell our future products, and the number of our products sold in each quarter;

acceptance of our products by people with insulin-dependent diabetes, their caregivers, healthcare providers and third-party payors;

the pricing of our products and competitive products, including the use of discounts, rebates or other financial incentives by our competitors;

the effect of third-party coverage and reimbursement policies;

our ability to establish and grow an effective sales and marketing 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 manufacture 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 recognition associated with our product sales pursuant to applicable accounting standards.

As a result of our limited operating history, and due to the complexities of the industry in which we operate, it will be difficult for us to forecast demand for our current or future products with any degree of certainty, which means it will be difficult for us to forecast our sales. In addition, we will be significantly increasing our operating expenses as we expand our business. Accordingly, we may experience substantial variability in our operating results from quarter to quarter, including anticipated or unanticipated quarterly losses. If our quarterly or annual operating results fall below the expectation of investors or securities analysts, the price of our common stock could decline substantially. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

As of December 31, 2014, we owed an aggregate principal amount of $30.0 million to Capital Royalty Partners and their related affiliates pursuant to term loan agreements under which we could borrow up to an additional $30.0 million under certain circumstances. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our 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, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital 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. In addition, in the event of our breach of the term loan agreements with Capital Royalty Partners, we may not be allowed to draw additional amounts under the agreements, and we may be required to repay any outstanding amounts earlier than anticipated.

Our term loan agreements contain restrictive and financial covenants that may limit our operating flexibility.

Our loan agreements with Capital Royalty Partners contain 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 therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lenders or terminate the applicable loan agreement. Our term loan agreements also contain 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 our agreements. Further, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under a given agreement.

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, 2014, our patent portfolio consisted of approximately 32 issued U.S. patents and 48 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2031. We are also seeking patent protection for our proprietary technology in other countries throughout the world. In addition, we also have eight pending U.S. trademark applications and six pending foreign trademark applications, as well as 14 trademark registrations, including four U.S. trademark registrations and ten foreign trademark registrations.

We have applied for patent protection relating to certain existing and proposed products and processes. Currently, eight of our issued U.S. patents as well as various pending U.S. and foreign patent applications relate to the structure and operation of our pumping mechanism and are therefore particularly important to the functionality of our products. 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 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 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 desire 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, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results.

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 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 be 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 the t:slim pump. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, including death, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain customers, any of which could have a material adverse effect on our business, financial condition and operating results.

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

Risks Related to our Legal and Regulatory Environment

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

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

product design and development;

pre-clinical and clinical testing and trials;

product safety;

establishment registration and product listing;

labeling and storage;

marketing, manufacturing, sales and distribution;

pre-market clearance or approval;

servicing and post-market surveillance;

advertising and promotion; and

recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through 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) clearance for t:connect and t:flex in February 2013 and January 2015, respectively. From time to time, we make modifications to these products that may require a new 510(k). We received 510(k) clearance for modifications to t:slim and its associated cartridge during 2014 and may pursue 510(k) clearance for additional modifications in the future. If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our forecasts. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

we may not be able 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

the manufacturing process or facilities we use may not 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 comply any such requirements, our international expansion and business could be significantly harmed.

Modifications to our products may require new 510(k) clearances or pre-market approvals, 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 previously 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 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 and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost-effective and timely manner.

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.

In January 2014, we implemented a voluntary recall of select lots of cartridges used with t:slim that may be at risk of leaking. A cartridge leak could potentially result in the delivery of too much or too little insulin, which could lead to unexpected high or low blood glucose levels. Too much insulin can result in severe low blood sugar, or hypoglycemia, and too little insulin can lead to severe high blood sugar, or hyperglycemia, both of which can lead to serious injury or death. We notified the FDA of the recall and also notified our customers and any of our independent distributors that may have received affected cartridges. We have also filed multiple MDRs with the FDA following the recall and we may file additional MDRs in the future as we collect additional information.

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 Law, 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;

the federal HIPAA of 1996, which created federal criminal laws 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. A person 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 the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of those prohibitions. Any violations 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, especially in light of the lack of applicable precedent and regulations. 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 off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of 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. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

Legislative or regulatory healthcare reforms may 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