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.

TABLE OF CONTENTS

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.

2

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)

8

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: