UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 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	**20-4327508**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
11045 Roselle Street San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 366-6900
Registrant's telephone number, including area code

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

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

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer, "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Annual Report, other than statements of historical fact, are forward-looking statements. You can identify forward-looking statements by the use of words such as "may," "will," "could," "anticipate," "expect," "intend," "believe," "continue" or the negative of 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.

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 • Does not tether the user to a device • Lower upfront and ongoing supply costs • Lower risk of technological malfunction	• Requires injections up to seven times per day • Delivers insulin less accurately than insulin pumps • Results in greater variability in blood glucose levels or less accurate glycemic control • Requires more planning around and restrictions regarding meals and exercise
Insulin Pump	• Eliminates individual insulin injections • Delivers insulin more accurately and precisely than injections • Often improves HbA1c, a common measure of blood glucose levels over time • Fewer large swings in blood glucose levels • Provides greater flexibility with meals, exercise and daily schedules • Can improve quality of life • Reduces severe low blood glucose episodes • Eliminates unpredictable effects of intermediate or long-acting insulin • Allows exercise without having to eat large amounts of carbohydrates, as insulin delivery can be adjusted	• Requires intensive education on insulin pump therapy and management • Wearing a pump can be bothersome • Can be more costly • Risk of diabetic ketoacidosis if the catheter comes out and insulin infusion is interrupted

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:

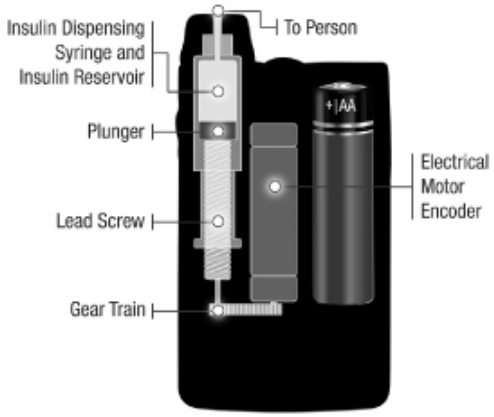
Antiquated style. While consumer electronic devices have rapidly evolved in form and function over the past decade, traditional pumps have not achieved similar advances. Our market research has shown that consumers believe traditional pumps resemble a pager, as they generally still feature small, low 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)

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

t:slim Insulin Delivery System (Actual Size)

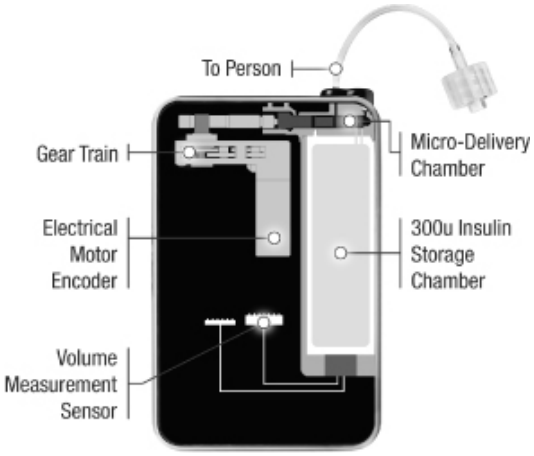
Easy to learn and teach. Our technology platform allows for the use of a vivid touchscreen and easy-to-navigate software architecture, providing users simple access to the key functions of their pump directly from the Home Screen. Insulin pump users can quickly learn how to efficiently navigate their pump's software, thereby enabling healthcare providers to spend less time teaching a person how to use the pump and more time improving management of their diabetes. We believe these features also allow healthcare providers to more efficiently train people to use our pump and have a higher degree of confidence that users can successfully operate our pump, including its more advanced features. We also believe the ease with which our pump can be learned and taught will help attract current insulin pump users as well as people who may have been frustrated or intimidated by traditional pumps.

Easy-to -Navigate Pump Software Architecture

Intuitive to use. Similar to what is found in modern consumer electronic devices, the embedded software displayed on our vivid touchscreen features intuitive and commonly interpreted colors, language, icons and feedback. Our software also features numerous shortcuts, including a simple way to return to the Home Screen and view critical information for therapy management. These features were designed to enable users to operate their pump with greater confidence and expand the set of functions that they regularly utilize. Users can also execute most tasks in fewer steps than traditional pumps. We believe these features allow users to more efficiently manage their diabetes without fear or frustration.

Quick Access to Pump History

Next generation technology platform. Our Micro-Delivery Technology is unique compared to traditional pumps. Its miniaturized pumping mechanism draws insulin from a flexible bag within the pump's cartridge rather than relying on a mechanical syringe and plunger mechanism. The pump is specifically designed to help prevent the unintentional delivery of insulin from the reservoir by limiting the volume of insulin that can be delivered to a person at any one time and to reduce fear associated with using a pump. Our technology was tested under typical and extreme operating conditions and is designed to last for at least the anticipated four-year life of the pump. Our technology also allows us to reduce the size of the device as compared to traditional pumps and is capable of delivering the smallest increment of insulin to users of any pump currently available.



t:slim pump Mechanism

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

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

Our Strategy

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

Advance our platform of innovative, consumer-focused products to address the unmet needs of people in the insulin-dependent diabetes market. We believe that our proprietary technology platform allows us to provide the most sophisticated and intuitive insulin pump therapy products on the market. We intend to leverage this platform to expand our product offerings to address different segments of the large and growing insulin-dependent diabetes market, including supporting advances in the automated delivery of insulin through our clinical research partnerships, strategic agreements and commercial product development efforts.

Invest in our consumer-focused approach. We believe that our consumer-focused approach to product design, marketing and customer care is a key differentiator. Our extensive market research involving people with diabetes, their caregivers and healthcare providers has driven the design and development of our current products and customer care model. This approach allows us to add the product features most requested by people with insulin-dependent diabetes, thereby affording the consumer the opportunity to more efficiently manage their diabetes. We will continue to apply the science of human factors throughout the design, development and continuous improvement of our products to optimize our products for intended users. We will continue to invest in our consumer-focused approach throughout our business.

Promote awareness of our products to consumers, their caregivers and healthcare providers. Our products were specifically designed to address the shortcomings of currently available technologies that have limited the adoption of insulin pump therapy. We intend to broaden our direct-to-consumer marketing and promote the benefits of our products through our redesigned website and use of social media tools. We plan to leverage our sales force and clinical specialists to cultivate relationships with diabetes clinics, insulin-prescribing healthcare professionals and other key opinion leaders. By promoting awareness of our products, we believe that we will attract users of other pump therapies and MDI to our products.

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

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

Leverage our manufacturing operations to achieve cost and production efficiencies. We manufacture our products at our headquarters in San Diego, California. We utilize a semi-automated manufacturing process for our pump products and disposable cartridges. With our existing production lines, we have the capacity to significantly increase our manufacturing output. We have the capability to replicate these production lines within our current facility to further increase our manufacturing capacity and we currently intend to install additional equipment for the automated manufacturing of our disposable cartridges over the next six to eighteen months. Our production system is also adaptable to new products due to shared product design features. We intend to reduce our product costs and drive operational efficiencies by leveraging our scalable, flexible manufacturing infrastructure.

Our Technology Platform

Utilizing our unique consumer-focused approach, which is based on our extensive market research and the science of human factors, we have developed an innovative technology platform that is fundamental to the design of our existing products and provides the foundation for development of our future products. The key elements of our platform are:

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

Easy-to-navigate embedded software architecture. Our technology platform was developed using an iterative human factors design process that results in the intuitive software architecture which features commonly interpreted colors, language, icons and feedback. This allows the user to easily navigate the system and perform necessary functions in fewer steps than traditional pumps, including a one-touch method to return to the Home Screen that facilitates ease of learning, teaching and use. The flexible software architecture may also allow for updates to the software without requiring any hardware changes.

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

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

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

Our Products

We have introduced to the market our flagship product, the t:slim Insulin Delivery System, and t:connect, its companion diabetes management application. t:flex was submitted to the FDA in November 2014 and was cleared for commercialization by the FDA in January 2015. We expect to commence commercial sales of t:flex in the second quarter of 2015. These products were cleared by the FDA under its Infusion Pump Improvement Initiative. We believe our unique products address the significant and fundamental shortcomings of traditional pumps and will allow people to manage their diabetes more efficiently.

Commercial Products

t:slim Insulin Delivery System

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

Cartridge being Inserted into t:slim pump

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

t:slim's vivid, full color touchscreen is made of high-grade, shatter-resistant glass and provides users the ability to enter numbers and access features directly, rather than scrolling through a list of numbers and screens. We designed the streamlined, user-friendly interface to facilitate rapid access to the features people use most, such as delivering a bolus, viewing insulin on board, viewing insulin cartridge volume and monitoring current pump status and settings. The interface also includes an options menu that provides quick and intuitive navigation to key insulin management features, pump settings, cartridge loading and use history. t:slim also features a Home Screen button that immediately returns the user to the Home Screen where important administrative features are displayed, including the current battery charge level, a time and date display and an LED indicator for alerts, alarms and reminders.

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

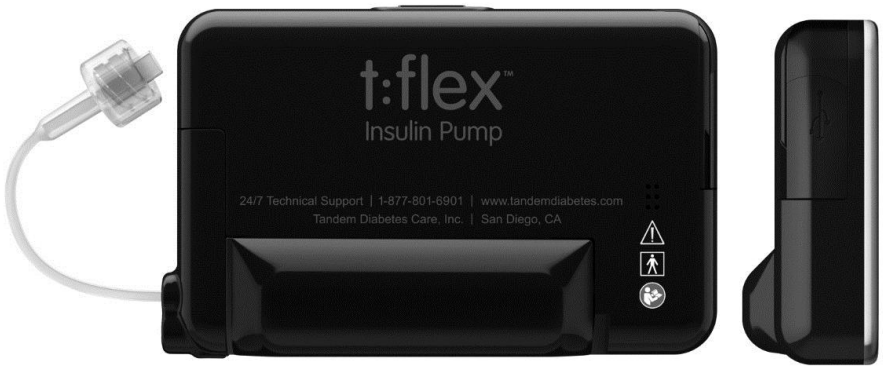
The other key components of the t:slim Insulin Delivery System are the disposable cartridge and standard infusion set. The cartridge features our proprietary Micro-Delivery Technology and miniaturized pumping mechanism and has a capacity of 300 units of insulin that is typically replaced by a user every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

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

t:slim Accessories

t:flex Insulin Pump

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



t:flex Insulin Delivery System

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

In our market research, two-thirds of endocrinologists cited limited volume capacity as the number one barrier to pump adoption for their patients with type 2 diabetes who use daily rapid acting insulin. We believe that offering a 480-unit cartridge addresses the typical insulin needs of a person with type 2 diabetes who is insulin-dependent. Our research has also shown that the appearance and bulky size of traditional pumps is another deterrent to pump adoption for people with greater insulin needs. We believe the combination of t:flex's larger insulin reservoir, combined with the other features and benefits offered by our technology platform, provides us with an opportunity to expand the current insulin pump market to address the unmet needs of individuals with greater insulin requirements.

t:connect Diabetes Management Application

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

We developed t:connect to be intuitive, with the same consumer-focused approach utilized in the development of our insulin pumps. It features built-in smart logic that manages duplicate blood glucose readings from a user's pump and blood glucose meter to ensure report accuracy. t:connect also can generate color-coded graphs and interactive, multi-dimensional reports that make it easy to identify therapy management trends, problems and successes. There are six different report options, including a dashboard, therapy timeline, blood glucose trends, activity summary, notes and logbook and pump settings. While our insulin pumps hold the data generated over a period of up to 90 days, once a user uploads to t:connect their therapy management information is retained for as long as they retain an account. t:connect maintains the highest standards of patient data privacy and is hosted on secure, Health Insurance Portability and Accountability Act of 1996, or HIPAA, compliant servers.

t:connect Diabetes Management Application

Products in Development

Our products in development support our strategy to focus on both consumer and clinical needs. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products targeted at different segments of the insulin-dependent diabetes market.

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

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

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

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

Odyssey Web-based Software Updates

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

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

t:sport Insulin Delivery System

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

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

Automated Insulin Delivery

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

We have supported leading researchers at facilities such as the University of Virginia, Boston University, Massachusetts General Hospital and Stanford University by providing pump hardware and software to advance development of artificial pancreas solutions. Within our commercial t:slim product there is a blue-tooth low energy radio (BLE) that is not enabled. In July 2013, we submitted a Master File to the FDA, allowing researchers to use the t:slim technology with the BLE enabled. This device provides researchers wireless use of our device with their selected algorithm and CGM for single hormone or dual hormone clinical studies.

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

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

t:dual Infusion System

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

Sales and Marketing

Our sales and marketing objectives are to:

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

As of December 31, 2014, we had a sales, clinical and marketing team of approximately 160 full-time employees. In 2014, we expanded our sales and, clinical organization from 36 to 60 territories. Each territory within our sales organization consists of a territory manager and a clinical diabetes specialist who as a team call on endocrinologists, primary care physicians, certified diabetes educators and potential customers. Based on historical sales force performance, we expect most of the new territory managers to reach their steady state level of sales performance within nine to twelve months from their date of hire. Our sales team is augmented by individuals in our customer sales support organization who follow up on leads generated through promotional activities and educate people on the benefits of our proprietary technology and products. As t:slim market penetration continues to build momentum, and as we launch new products into the market, including t:flex, we expect to further expand our sales and marketing infrastructure in the United States and may evaluate international commercialization opportunities.

In addition, as of December 31, 2014, we had executed agreements with more than 30 independent distributors. For the year ended December 31, 2014, Edgepark Medical Supplies, Inc., CCS Medical, Inc. and Byram Healthcare, all independent distributors, accounted for 16.0%, 11.6% and 10.9% of our sales, respectively. For the year ended December 31, 2013, Edgepark Medical Supplies, Inc. and CCS Medical, Inc., both independent distributors, accounted for 16.1% and 13.6% of our sales, respectively. None of our independent distributors has been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements generally have one-year initial terms with automatic one-year renewal terms, and are terminable in connection with a party’s material breach.

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

Healthcare provider focused initiatives. Healthcare providers are a critical resource in helping patients understand and select their diabetes therapy options. Each of our territories is supported by a clinical diabetes specialist who is a certified diabetes educator and holds either a registered nurse or registered dietician license. Our clinical diabetes specialists support and educate healthcare providers on our products and proprietary technology, certify healthcare providers to train people to use our products and support our customers with initial training following the purchase of our products.

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

- presentations and product demonstrations at local, regional, and national tradeshows, including American Diabetes Association Scientific Sessions and the American Association of Diabetes Educators Annual Meeting;

- our Demonstration Unit Program, through which we provide healthcare professionals with our products for pump demonstrations to their patients; and

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

Consumer-focused initiatives. We sell our products directly to consumers through referrals from healthcare providers and through leads generated through our promotional activities. Our direct-to-consumer marketing efforts focus on positioning our products as innovative, consumer-focused insulin pumps with a unique Micro-Delivery Technology, slim touchscreen design and an intuitive user interface that were designed to meet different needs in the diabetes community. Some of our recent consumer-focused marketing initiatives include:

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

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

- corporate sponsorships of organizations focused on people with diabetes, including JDRF, TCOYD, Diabetes Hands Foundation, Students with Diabetes, College Diabetes Network, Diabetes Scholars; and

- community diabetes fundraising and awareness events.

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

Branding. We developed our comprehensive branding strategy to engage consumers and communicate our identity as a modern and progressive company that works “in tandem” with the diabetes community, healthcare providers, our employees and business partners. We strive to embody this through our product offerings, marketing efforts and interactions throughout our business. Our product names are family branded using a “t:” to create uniformity and help consumers quickly identify our products. Our “touch simplicity” marketing campaign highlights the slim touchscreen design and easy-to-navigate software. Our other product packaging, website, advertising and promotional materials are a reflection of our consumer-focused approach and modern style. We value having clear, friendly and helpful communications throughout our business.

Training and Customer Care

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

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

By offering an intuitive user interface, we believe healthcare providers will be able to train people to use our products more efficiently than traditional pumps, and will have a higher degree of confidence in their patients ability to operate it, including the more advanced features. In addition, the intuitive nature of t:slim and t:flex likely will allow healthcare providers to spend less time teaching a person how to use their pump and more time helping to improve the management of their diabetes. This ease of training may also help users feel less intimidated and fearful of pump therapy, leading to increased adoption and market expansion.

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

Technical Services. We believe that a difficult-to-use pump will result in users making more frequent calls to the pump manufacturer or their healthcare provider for support in using the device. This can be frustrating for the customer and costly for the pump manufacturer as well as for the healthcare provider. We expect the intuitive nature of our products to result in fewer calls from users requesting support from our technical services team or their healthcare provider.

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

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

Following communication of a person’s estimated financial responsibility, final confirmation of their desire to purchase the device and method of fulfillment, the customer’s order is typically shipped to their home. The initial order generally contains their insulin pump as well as a 90-day supply of infusion sets and cartridges. A member of the team then contacts the customer prior to the end of their 90-day supply to re-verify their insurance benefits and assist in reordering supplies.

Third-Party Reimbursement

Customer orders are typically fulfilled by billing third-party payors on behalf of our customers, or by utilizing our network of distributors who then bill third-party payors on our customers’ behalf. Our fulfillment and reimbursement systems are fully integrated such that our products are shipped only after receipt of a valid physician’s order and verification of current health insurance information.

We are accredited by the Community Health Accreditation Program and are an approved Medicare provider. We currently bill t:slim and its associated supplies using existing Healthcare Common Procedure Coding System codes for which Medicare reimbursement is well established. Over the last ten years, Medicare reimbursement rates for insulin pumps and disposable cartridges have remained relatively unchanged. However, Medicare has recently begun to review its reimbursement practices for diabetes-related products. Medicare implemented a competitive bidding process for blood glucose strip reimbursement, which resulted in a significant reduction in the reimbursement rate for those products. Medicare also initiated a competitive bidding process for insulin pumps in limited geographies. As a result, there is some uncertainty as to the future Medicare reimbursement rate for our current and future products.

We intend to bill t:flex and its associated supplies under the same Healthcare Common Procedure Coding System codes as t:slim. However, pump eligibility criteria for people with type 2 diabetes can be different and often requires additional documentation and laboratory testing to gain in-network insurance reimbursement benefits, which may slow the adoption of t:flex.

As of December 31, 2014, we had entered into commercial contracts with more than 70 national and regional third-party payors to establish reimbursement for t:slim, its disposable cartridges and other related supplies. We are also currently in the process of approaching these and other third-party payors to discuss reimbursement for t:flex. We employ a team of managed care managers who are responsible for negotiating and securing contracts with third-party payors throughout the United States. For the year ended December 31, 2014, approximately 20% of our sales were generated through our direct third-party payor contracts.

If we are not contracted with a person's third-party payor and in-network status cannot be otherwise obtained, then to the extent possible we utilize distribution channels so our customers' orders can be serviced. As of December 31, 2014, we had executed distributor agreements with more than 30 distributors. In some cases, but not all, this network of distributors allows us to access people who are covered by commercial payors with whom we are not contracted, at in-network rates that are generally more affordable for our customers.

Manufacturing and Quality Assurance

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

We currently utilize a semi-automated manufacturing process for our pump products and disposable cartridges. The pump production line requires approximately 12 manufacturing assemblers and limited support staff to run the line and reaches a maximum output of approximately 20,000 pumps per year on a single shift. Disposable cartridges are manufactured on a production line that requires 12 to 20 manufacturing operators and limited support staff and reaches a maximum output of approximately 1,000,000 cartridges per year on a single shift. We are actively working on improving the efficiency of our disposable cartridge manufacturing process. For instance, we are currently working towards manufacturing t:flex cartridges primarily using the same semi-automated manufacturing equipment used in the manufacture of t:slim cartridges. In addition, we are in the process of further automating the manufacturing of our disposable cartridges.

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

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

Outside suppliers are the source for most of the components and some sub-assemblies in the production of our insulin pumps. Any sole and single source supplier is managed through our supplier management program that is focused on reducing supply chain risk. Key aspects of this program include managing component inventory in house and at the supplier, contractual requirements for last time buy opportunities and second sourcing approaches for specific suppliers. Typically, our outside vendors produce the components to our specifications and in many instances to our designs. Our suppliers are audited periodically by our quality department to ensure conformity with the specifications, policies and procedures for our devices. Members of our quality department also inspect our devices at various steps during the manufacturing cycle to facilitate compliance with our devices' stringent specifications.

We have received certification from BSI Group, a Notified Body to the International Standards Organization, or ISO, of our quality system. This ISO 13485 certification includes design control requirements. Certain processes utilized in the manufacturing and testing of our devices have been verified and validated as required by the FDA and other regulatory bodies. As a medical device manufacturer, our manufacturing facility and the facilities of our sterilization and other critical suppliers are subject to periodic inspection by the FDA and certain corresponding state agencies. Recently, the inspection associated with the t:slim G4 PMA was completed.

Research and Development

Our research and development team includes employees who specialize in software engineering, mechanical engineering, electrical engineering, fluid dynamics and graphical user interface design, many of whom have considerable experience in diabetes-related products. Our research and development team focuses on the continuous improvement and support of current product offerings, as well as our products in development.

We have entered into a development and commercialization agreement with DexCom, which provides us a non-exclusive license to integrate the DexCom G4 PLATINUM with t:slim G4 during the term of the agreement. The license covers the United States, and such other territories as may be added from time to time. We paid DexCom $1.0 million at the commencement of the collaboration, and a $1.0 million milestone payment in July 2014, which related to our submission of a PMA application for the t:slim G4, which we have previously referenced as t:sensor, to the FDA. The payments were recorded as research and development costs. We will make one additional $1.0 million payment upon the achievement of certain milestones. We have agreed to pay DexCom a royalty payment in the amount of $100 for each integrated system sold. Additionally, we will reimburse DexCom up to $1.0 million of its development costs and are responsible for our own development costs and expenses. Our agreement with DexCom runs until January 4, 2017, with automatic one-year renewals. Prior to the commercial launch of t:slim G4, either party may terminate the agreement without cause provided that the party requesting the termination must reimburse the other party for up to $1.0 million of previously incurred development expenses. Following the commercial launch of t:slim G4, either party may terminate the agreement without cause upon 18 months prior notice. In addition, in the event of a change of control of either party, the other party may unilaterally elect to terminate the agreement at any time, subject to limited ongoing obligations.

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

Intellectual Property

We have made protection of our intellectual property a strategic priority. We rely on a combination of copyright, patent, trademark, trade secret and other intellectual property laws, non-disclosure agreements and other measures to protect our proprietary rights.

As of December 31, 2014, our patent portfolio consisted of approximately 32 issued U.S. patents and 48 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2031. We are also seeking patent protection for our proprietary technology in other countries throughout the world. We also have eight pending U.S. trademark applications and six pending foreign trademark applications, as well as 14 trademark registrations, including four U.S. trademark registrations and ten foreign trademark registrations.

In July 2012, we entered into an agreement with Smiths Medical pursuant to which we were granted, through certain assignments and certain non-exclusive and exclusive, worldwide, fully paid-up, royalty-free licenses, certain rights to patents and patent applications related to ambulatory infusion pumps and related software and accessories for the treatment of diabetes. We agreed to pay $5.0 million in license fees and to share equally any associated sublicense revenues we may receive. As of December 31, 2014, we had paid the initial license fees in full and have not entered into any sublicense agreements.

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

Competition

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. We compete with a number of companies that manufacture insulin delivery devices, such as Medtronic MiniMed, a division of Medtronic, Inc., Animas Corporation, a division of Johnson & Johnson, Roche Diagnostics, a division of F. Hoffman-La Roche Ltd., and Insulet Corporation.

Many of our competitors are either publicly traded companies or divisions or subsidiaries of publicly traded companies with significantly more market share and resources than we have. Many of these companies have several competitive advantages over us, including greater financial resources for sales and marketing and product development, established relationships with healthcare providers and third-party payors and larger and more established distribution networks. In some instances, our competitors also offer products that include features that we do not currently offer. For instance, Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set, and Medtronic currently offers a traditional insulin pump that is integrated with a CGM system and a recently approved threshold suspend feature.

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

Government Regulation

Our products are medical devices subject to extensive regulation by the FDA, corresponding state regulatory authorities and, if we commence international sales, other regulatory bodies in other countries. The Federal Food, Drug and Cosmetic Act, or FDCA, and the FDA's implementing regulations govern:

- product design and development;
- pre-clinical and clinical testing;
- establishment registration and product listing;
- product manufacturing;
- labeling and storage;
- pre-market clearance or approval; advertising and promotion;
- product sales and distribution;
- recalls and field safety corrective actions; and
- servicing and post-market surveillance.

FDA's Pre-Market Clearance and Approval Requirements. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a pre-market notification under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA through the PMA process. Both the 510(k) clearance and PMA processes can be expensive, lengthy and require payment of significant user fees, unless an exemption is available.

The FDA classifies medical devices into one of three classes. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are subject to general controls such as labeling, pre-market notification and adherence to the FDA's Quality System Regulation, or QSR, which cover manufacturers' methods and documentation of the design, testing, production, control quality assurance, labeling, packaging, sterilization, storage and shipping of products. Class II devices are subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling, as well as general controls. Some Class I and Class II devices are exempted by regulation from the 510(k) clearance requirement, and the requirement of compliance with substantially all of the QSR. t:slim and t:connect received FDA clearance as Class II devices, and we anticipate t:flex will also be considered a Class II device. A PMA application is required for devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or those that are "not substantially equivalent" either to a device previously cleared through the 510(k) process or to a "preamendment" Class III device in commercial distribution before May 28, 1976 when PMA applications were not required.

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

We obtained 510(k) clearance for t:connect in February 2013 and for t:flex in January 2015.

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

A PMA application must be supported by valid scientific evidence that typically includes extensive technical, pre-clinical, clinical, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the device. A PMA application also must include a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA. In addition, the FDA generally will conduct a pre-approval inspection of the manufacturing facility to evaluate compliance with QSR, which requires manufacturers to implement and follow design, testing, control, documentation and other quality assurance procedures.

FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- systems may not be safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If an FDA evaluation of a PMA application is favorable, the FDA will issue either an approval letter, or approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of a device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel.

Clinical trials are typically required to support a PMA application and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and eligible for abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites. The FDA's approval of an IDE allows clinical testing to go forward, but it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria. All clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's regulations for institutional review board approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to the products that are part of our trial;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to us or our study that the FDA deems to make the study results unreliable, or the company or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

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

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

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

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

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

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

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

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

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

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

- warning letters or untitled letters that require corrective action;

- fines and civil penalties;

- unanticipated expenditures;

- delays in approving or refusal to approve future products;

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

- suspension or withdrawal of FDA clearance or approval;

- product recall or seizure;

- interruption of production;

- operating restrictions;

- injunctions; and

- criminal prosecution.

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

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

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

Federal Anti-Kickback and Self-Referral Laws. The Federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The definition of "remuneration" has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at less than its fair market value. The Department of Health and Human Services, or HHS, has issued regulations, commonly known as safe harbors, that set forth certain provisions which, if fully met, will assure healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the HHS Office of Inspector General.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to five years, fines of up to $25,000 per violation and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare and Medicaid programs. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or PPACA, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. The PPACA also provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

We provide the initial training to patients necessary for appropriate use of our products either through our own diabetes educators or by contracting with outside diabetes educators that have completed a Tandem pump training course. Outside diabetes educators are reimbursed for their services at fair market value. Although we believe that these arrangements do not violate the law, regulatory authorities may determine otherwise, especially as enforcement of this law historically has been a high priority for the federal government. In addition, because we may provide some coding and billing information to purchasers of our devices, and because we cannot guarantee that the government will regard any billing errors that may be made as inadvertent, the federal anti-kickback legislation may be applied to us. Noncompliance with the federal anti-kickback legislation could result in our exclusion from Medicare, Medicaid or other governmental programs, restrictions on our ability to operate in certain jurisdictions, and civil and criminal penalties.

Federal law also includes a provision commonly known as the "Stark Law," which prohibits a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these arrangements may not expressly meet the requirements for applicable exceptions from the law.

Additionally, as some of these laws are still evolving, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers with respect to patient training. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider and training arrangements may ultimately be found to be not in compliance with applicable federal law.

Federal False Claims Act. The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits against companies under the Federal False Claims Act. Penalties include fines ranging from $5,500 to $11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action. We believe that we currently are in compliance with the federal government's laws and regulations concerning the filing of reimbursement claims.

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

State Fraud and Abuse Provisions. Many states have also adopted some form of anti-kickback and anti-referral laws and a false claims act. We believe that we are in conformance to such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Health Insurance Portability and Accountability Act of 1996. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government sponsored programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines or imprisonment. We believe we are in substantial compliance with the applicable HIPAA regulations.

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

International Regulation

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

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

Employees

As of December 31, 2014, we had 437 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

Available Information

Our website address is *www.tandemdiabetes.com*. We post links to our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, and any amendments to those reports filed or furnished pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. All such filings are available through our website free of charge. However, the information contained on or accessed through our website does not constitute part of this Annual Report, and references to our website address in this Annual Report are inactive textual references only.

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

Item 1A. Risk Factors

An investment in our common stock involves risks. You should consider carefully the risks described below, together with all of the other information included in this Annual Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results and prospects. Certain statements below are forward-looking statements. For additional information, see "Cautionary Note Regarding Forward-Looking Statements."

Risks Relating to Our Business and our Industry

We have incurred significant operating losses since inception and cannot assure you that we will achieve profitability.

Since our inception in January 2006 we have incurred a significant net loss. As of December 31, 2014, we had an accumulated deficit of $248.7 million. To date, we have financed our operations primarily through sales of equity securities, debt financing with Capital Royalty Partners and certain of its affiliates, and sales of our products. We have devoted substantially all of our resources to the research and development of our products, the commercial launch of our products, the development of a sales and marketing team and the assembly of a management team to manage our business.

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

To implement our business strategy we need to, among other things, grow our sales and marketing infrastructure to increase sales of our products, fund ongoing research and development activities, expand our manufacturing capabilities, and obtain regulatory clearance or approval to commercialize our products currently under development. We expect our expenses to increase significantly as we pursue these objectives. The extent of our future operating losses and the timing of profitability are highly uncertain, especially given that we only recently expanded the size of our sales, clinical and marketing infrastructure and that we expect to begin sales of our next commercial product, t:flex, in the second quarter of 2015, which makes forecasting our sales more difficult. Any additional operating losses will have an adverse effect on our stockholders' equity, and we cannot assure you that we will ever be able to achieve or sustain profitability.

We currently rely on sales of t:slim to generate a significant portion of our revenue, and any factors that negatively impact sales of this product may adversely affect our business, financial condition and operating results.

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

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

- problems arising from the expansion of our manufacturing capabilities, or destruction, loss, or temporary shutdown of our manufacturing facility;
- changes in reimbursement rates or policies relating to t:slim or similar products or technologies by third-party payors;
- our inability to enter into contracts with third-party payors on a timely basis and on acceptable terms;
- claims that t:slim, or any component thereof, infringes on patent rights or other intellectual property rights of third parties;
- the harm to our reputation or any other associated liability or perceived risks that may arise from our January 2014 recall of cartridges used with t:slim; and
- adverse regulatory or legal actions relating to t:slim or similar products or technologies.

Because we currently rely on a single product to generate a significant portion of our revenue, any factors that negatively impact sales of this product, or result in sales of this product increasing at a lower rate than expected, could adversely affect our business, financial condition and operating results and negatively impact our ability to successfully launch future products currently under development.

The failure of our products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.

Our current business strategy is highly dependent on t:slim and t:flex achieving and maintaining market acceptance. We do not intend to begin commercial sales of t:flex until the second quarter of 2015. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that it is an attractive alternative to competitive products for the treatment of diabetes, including traditional insulin pump products and MDI therapies, as well as alternative insulin treatment methodologies. Market acceptance and adoption of our products depends on educating people with diabetes, as well as their caregivers and healthcare providers, as to the distinct features, ease-of-use, positive lifestyle impact, and other perceived benefits of our products as compared to competitive products. If we are not successful in convincing existing and potential customers of the benefits of our products, or if we are not able to achieve the support of caregivers and healthcare providers for t:slim or t:flex, our sales may decline or we may fail to increase our sales in line with our forecasts.

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

- the failure of our products to achieve wide acceptance among people with insulin-dependent diabetes, their caregivers, insulin-prescribing healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;
- lack of evidence supporting the safety, ease-of-use or other perceived benefits of our products over competitive products or other currently available insulin treatment methodologies;
- perceived risks associated with the use of t:slim or t:flex or similar products or technologies generally;
- the introduction of competitive products and the rate of acceptance of those products as compared to t:slim and t:flex;
- discounts, rebates and other financial incentives that our competitors may offer for competitive products;
- results of clinical studies relating to t:slim, t:flex or similar competitive products.

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

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

Further, even if we are able to convince people with insulin-dependent diabetes, their caregivers or healthcare providers that our products compare favorably to the products and treatment alternatives offered by our competitors, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements, or the perception that advancements could occur, in our products or the products offered by our competitors. For example, it is possible that a consumer that is currently interested in purchasing t:slim will delay the purchase decision in anticipation of the future release of t:slim G4, or the release of a product with advanced features offered by one of our competitors.

If t:slim or t:flex do not achieve and maintain widespread market acceptance, we may fail to achieve sales at or above our projected amounts. If our sales do not meet our projections, we may fail to meet our strategic objectives, and our business, financial condition and operating results could be materially and adversely affected.

Failure to secure or retain adequate coverage or reimbursement for t:slim, t:flex and our potential future products by third-party payors could adversely affect our business, financial condition and operating results.

We have derived nearly all of our revenue from the sale of t:slim in the United States, and we do not expect to begin commercial sales of t:flex in the United States until the second quarter of 2015. We expect to derive nearly all of our revenue during 2015 from sales of t:slim and t:flex insulin pumps and associated supplies, and expect to continue to do so until we are able to commercialize our other products that are currently under development. A substantial portion of the purchase price of an insulin pump is typically paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Future sales of our current and future products will be limited unless our customers can rely on third-party payors to pay for all or part of the associated purchase cost. Because we have not initiated commercial sales of t:flex, there remains considerable uncertainty regarding the coverage that third-party payors will offer for this new product, particularly for individuals with type 2 diabetes where coverage requirements may necessitate additional laboratory tests or other information to support a determination of medical necessity. Access to adequate coverage and reimbursement for our current and future products by third-party payors is essential to the acceptance of our products by customers.

Many third-party payors use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the U.S. Medicare program, as guidelines in setting their coverage and reimbursement policies. Medicare has recently begun to review its reimbursement practices for diabetes-related products. Medicare implemented a competitive bidding process for blood glucose strip reimbursement, which resulted in a significant reduction in the reimbursement rate for those products. More recently, Medicare has also initiated a competitive bidding process for insulin pumps in limited geographies. As a result, there is uncertainty as to the future Medicare reimbursement rate for our products. In addition, those third-party payors that do not follow the CMS guidelines may adopt different coverage and reimbursement policies for our current and future products. It is possible that some third-party payors will not offer any coverage for our current or future products.

We currently have contracts establishing reimbursement for t:slim with approximately 70 national and regional third-party payors in the United States. We are also currently in the process of approaching these and other third-party payors to discuss reimbursement for t:flex. While we anticipate adding coverage for t:flex under our current agreements and entering into additional contracts with third-party payors to provide reimbursement for both t:slim and t:flex, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis. In addition, contracts with third-party payors generally can be modified or terminated by the third-party payor without cause and with little or no notice to us. Moreover, compliance with the administrative procedures or requirements of third-party payors may result in delays in processing approvals by those third-party payors for customers to obtain coverage for our products. Failure to secure or retain adequate coverage or reimbursement for t:slim or t:flex and our future products by third-party payors, or delays in processing approvals by those payors, could result in the loss of sales, which could have a material adverse effect on our business, financial condition and operating results.

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

We operate in a very competitive industry and if we fail to compete successfully against our existing or potential competitors, many of whom have greater resources than us, our sales and operating results may be negatively affected.

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or technologies, or other activities of industry participants. We expect our products will compete directly with a number of traditional insulin pumps as well as other methods for the treatment of diabetes. In particular, we expect that the competitive landscape for t:flex will be similar to that of t:slim.

Many of our existing and potential competitors are major medical device companies that are either publicly traded companies or divisions or subsidiaries of publicly traded companies. For instance, Medtronic MiniMed, a division of Medtronic, Inc., has been the market leader for many years and has the majority share of the traditional insulin pump market in the United States. Other significant insulin pump suppliers in the United States include Animas Corporation, a division of Johnson & Johnson, Roche Diagnostics, a division of F. Hoffman-La Roche Ltd., and Insulet Corporation. There are also newer companies entering the field.

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

- greater financial and human resources for sales and marketing, and product development;
- established relationships with healthcare providers and third-party payors;

- established reputation and name recognition among healthcare providers and other key opinion leaders in the diabetes industry;
- in some cases, an established base of long-time customers;
- products supported by long-term clinical data;
- larger and more established distribution networks;
- greater ability to cross-sell products or provide incentives to healthcare providers to use their products; and
- more experience in conducting research and development, manufacturing, clinical trials, and obtaining regulatory approval or clearance.

In some instances, our competitors also offer products that include features that we do not currently offer. For instance, Medtronic currently offers a traditional insulin pump that is integrated with a CGM system with a threshold suspend feature, and Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set. For these and other reasons, we may not be able to compete successfully against our current or potential future competitors. As a result, we may fail to meet our strategic objectives and forecasted budget, and our business, financial condition and operating results could be materially and adversely affected.

Competitive products or other technological breakthroughs for the monitoring, treatment or prevention of diabetes or technological developments may render our products obsolete or less desirable.

Our ability to achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the treatment of diabetes that offer distinct features, are easy-to-use, receive adequate coverage and reimbursement from third-party payors, and are more appealing than available alternatives. Our primary competitors, as well as a number of other companies, medical researchers and pharmaceutical companies are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any technological breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for t:slim or t:flex or render our products obsolete altogether, which would significantly reduce our sales. In addition, even the perception that technological or treatment advancements could occur in the future could cause consumers to delay the purchase of our products.

Because the insulin-dependent diabetes market is large and growing, we anticipate that companies will continue to dedicate significant resources to developing competitive products. The frequent introduction by competitors of products that are or claim to be superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competitive products. In addition, the entry of multiple new products has led some of our competitors to employ pricing strategies, including the use of discounts, rebates or other financial incentives that could adversely affect sales of our products. If a competitor develops a product that competes with or is perceived to be superior to our own products, or if competitors continue to utilize strategies that place downward pressure on pricing within our industry, our sales may decline, our operating margins could be reduced and we may fail to meet our projections, which would materially and adversely affect our business, financial condition and operating results.

Moreover, we have designed our products to resemble modern consumer electronic devices to address certain embarrassment and functionality concerns consumers have raised with respect to traditional pumps. The consumer electronics industry is itself highly competitive, and characterized by continual new product introductions, rapid developments in technology, and subjective and changing consumer preferences. If, in the future, consumers cease to view our products as contemporary or convenient as compared to then-existing consumer electronics technology, our products may become less desirable.

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

Because we began commercialization of t:slim in the third quarter of 2012, we have only limited experience marketing and selling our products as well as training new customers on the use of t:slim. We currently intend to begin marketing and selling our t:flex product during the second quarter of 2015. The vast majority of our existing customers for t:slim are individuals with type 1 diabetes, and we have only limited experience in marketing and selling our products to customers with type 2 diabetes. As a result, we may face unexpected challenges as we begin marketing and selling t:flex. We expect to derive nearly all of our revenue from the sale of t:slim, t:flex and pump-related supplies unless and until we receive regulatory clearance or approval for other products currently in development. As a result, our financial condition and operating results are and will continue to be highly dependent on the ability of our sales representatives to adequately promote, market and sell t:slim and t:flex, and the ability of our diabetes educators to train new customers on the use of our products. If our sales and marketing representatives or diabetes educators fail to achieve their objectives, our sales could decrease or may not increase at levels that are in line with our forecasts.

A key element of our business strategy is the continued expansion of our sales, marketing and clinical infrastructure to drive adoption of our products, which includes our team of diabetes educators that trains new customers on the use of our products. We have rapidly increased the number of sales, marketing and clinical personnel employed by us since the initial commercial launch of t:slim. However, we have faced considerable challenges in growing our sales, marketing and clinical force over the past 12-18 months, including with respect to recruiting, training and assimilation of new territories and accounts. We expect to continue to face significant challenges as we manage and grow our sales, marketing and clinical infrastructure and work to motivate and retain the individuals who make up those networks. In particular, newly hired sales representatives require training and take time to achieve full productivity, and the overall expansion of our sales force also disrupts the productivity of our existing sales representatives. In addition, unexpected turnover would have a negative impact on our ability to achieve our sales projections. Further, if a sales, marketing or clinical representative were to depart and be retained by one of our competitors, we may fail to prevent him or her from helping competitors solicit business from our existing customers, which could adversely affect our sales. Similarly, if we are not able to recruit and retain a network of diabetes educators, we may not be able to successfully train new customers on the use of t:slim or t:flex, which could delay new sales and harm our reputation. We expect that the management and future expansion of our sales, marketing and clinical personnel will continue to place significant burdens on our management team. If we are unable to retain and expand our sales, marketing and clinical capabilities in line with our strategic plans, we may not be able to effectively commercialize our existing or planned products, or enhance the strength of our brand, either of which could result in the failure of our sales to increase in line with our projections or could even cause sales to decline.

Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with our own. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

For the year ended December 31, 2014, sales to approximately 36 independent distributors represented approximately 75% of our sales. While we expect that the percentage of our sales to independent distributors will decrease over time as we enter into contracts with additional third-party payors, we believe that a meaningful percentage of our sales will continue to be to independent distributors for the foreseeable future and it is possible that the percentage of our sales to independent distributors could even increase in the near term. For example, our dependence upon independent distributors could increase if third-party payors decide to contract with independent distributors directly in lieu of contracting with us to supply our products to their members on a direct basis. None of our independent distributors has been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements generally have one-year initial terms with automatic one-year renewal terms, and are terminable in connection with a party’s material breach.

Some of our independent distributors account for a significant portion of our sales volume. For the year ended December 31, 2014, our 3 largest independent distributors comprised approximately 38% of our sales. If any of our key independent distributors were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent distributors to perform sales, marketing, or distribution services, the terms of the arrangements could cause our product margins to be lower than if we directly marketed and sold our products.

Our ability to maintain and grow our revenue depends in part on retaining a high percentage of our customer base.

A key to maintaining and growing our revenue is the retention of a high percentage of our customers due to the potentially significant revenue generated from ongoing purchases of disposable insulin cartridges. In addition, our pumps are designed and tested to remain effective for four years and a satisfied customer may consider purchasing another product from us when the time comes to replace the pump. We have developed retention programs aimed at customers, their caregivers and healthcare providers, which include training specific to our products, ongoing support by sales and clinical employees and 24/7 technical support and customer service. If demand for our products fluctuates as a result of the introduction of competitive products, changes in reimbursement policies, manufacturing problems, perceived safety or reliability issues with our or competitors' products, the failure to secure regulatory clearance or approvals, or for other reasons, our ability to attract and retain customers could be harmed. The failure to retain a high percentage of our customers would negatively impact our revenue growth and may have a material adverse effect on our business, financial condition and operating results.

If important assumptions about the potential market for our products are inaccurate, or if we have failed to understand what people with insulin-dependent diabetes are seeking in an insulin pump, our business and operating results may be adversely affected.

Our business strategy was developed based on a number of important assumptions about the diabetes industry in general, and the insulin-dependent diabetes market in particular, any one or more of which may prove to be inaccurate. For example, we believe that the benefits of insulin pump therapy as compared to other common insulin treatment alternatives will continue to drive growth in the market for insulin pump therapy. In addition, we believe the incidence of diabetes in the United States and worldwide is increasing rapidly. However, each of these trends is uncertain and limited sources exist to obtain reliable market data. The actual incidence of diabetes, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. In addition, our strategy of focusing exclusively on the insulin-dependent diabetes market may limit our ability to increase sales or achieve profitability.

Another key element of our business strategy is utilizing market research to understand what people with diabetes are seeking to improve their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed our current products and are pursuing the development of new products. However, our market research is based on interviews, focus groups and online surveys involving people with insulin-dependent diabetes, their caregivers and healthcare providers that represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we received may not be reflective of the broader market and may not provide us accurate insight into the desires of people with insulin-dependent diabetes. In addition, understanding the meaning and significance of the responses received during our market research necessarily requires that analysis be conducted and conclusions be drawn. We may not be able perform an analysis that yields meaningful results, or the conclusions we draw from the analysis could be misleading. Moreover, even if our market research has allowed us to better understand the features consumers are seeking in an insulin pump to improve management of their diabetes therapy, there can be no assurance that consumers will actually purchase our products or that our competitors will not develop products with similar features.

We have a limited operating history and may face difficulties encountered by companies early in their commercialization in competitive and rapidly evolving markets.

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

- implement and execute our business strategy;
- expand and improve the productivity of our sales and marketing infrastructure to grow sales of our existing and proposed products;
- increase awareness of our brand and build loyalty among people with insulin-dependent diabetes, their caregivers and healthcare providers;
- manage expanding operations, including complying with a broad range of legal requirements within a highly regulated industry;

- expand our manufacturing capabilities, including increasing production of current products efficiently while maintaining quality standards and adapting our manufacturing facilities to the production of new products;
- respond effectively to competitive pressures and developments;
- enhance our existing products and develop proposed products;
- obtain and maintain regulatory clearance or approval to commercialize proposed products and enhance our existing products;
- perform clinical trials with respect to our existing products and proposed products; and
- attract, retain and motivate qualified personnel in various areas of our business.

Due to our limited operating history, we may not have the institutional knowledge or experience to be able to effectively address these and other risks that may face our business. In addition, we may not be able to develop insights into trends that could emerge and negatively affect our business and may fail to respond effectively to those trends. As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

Manufacturing risks may adversely affect our ability to manufacture products and could negatively impact our sales and operating margins.

Our business strategy depends on our ability to manufacture our current and proposed products in sufficient quantities and on a timely basis so as to meet consumer demand, while adhering to product quality standards, complying with regulatory requirements and managing manufacturing costs. We are subject to numerous risks relating to our manufacturing capabilities, including:

- quality or reliability defects in product components that we source from third-party suppliers;
- our inability to secure product components in a timely manner, in sufficient quantities and on commercially reasonable terms;
- our failure to increase production of products to meet demand;
- the challenge of implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our inability to modify production lines to enable us to efficiently produce future products or implement changes in current products in response to regulatory requirements;
- our ability to manufacture multiple products simultaneously within the same manufacturing facility and utilizing common manufacturing equipment;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facility.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes. As demand for our products increases, and as the number of our commercial products expands, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. Over the past year we have implemented several new pieces of equipment that are intended to improve our manufacturing capacity and efficiency. However, it is possible that we may not derive the anticipated improvements from these investments. If we fail to increase our production capacity efficiently while also maintaining quality requirements, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features and components with t:slim, manufacturing of these products may require the modification of our production lines, the hiring of specialized employees, the identification of new suppliers for specific components, or the development of new manufacturing technologies. It may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

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

We rely on third-party suppliers to supply components of t:slim, t:flex and of our potential future products, including our disposable cartridges. For example, we rely on plastic injection molding companies to provide plastic molded components, electronic manufacturing suppliers to provide electronic assemblies, and machining companies to provide machined mechanical components. We also purchase all of our infusion sets and pump accessories from third-party suppliers. For our business strategy to be successful, our suppliers must be able to provide us with components in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Increases in our product sales, whether forecasted or unanticipated, could strain the ability of our suppliers to deliver an increasingly large supply of components in a manner that meets these various requirements.

We do not have long-term supply agreements with most of our suppliers and, in many cases, we make our purchases on a purchase order basis. Under most of our supply agreements, we have no obligation to buy any given quantity of products, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of products. As a result, our ability to purchase adequate quantities of our products may be limited. Additionally, our suppliers may encounter problems that limit their ability to manufacture products for us, including financial difficulties or damage to their manufacturing equipment or facilities. If we fail to obtain sufficient quantities of high quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed and our business could suffer.

We generally use a small number of suppliers for our products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. Moreover, due to the recent commercialization of our products and the limited amount of our sales to date, we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us. We have in the past been, and we may in the future be, required to make significant “last time” purchases of component inventory that is being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA, or other regulatory agencies, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. It could also require us to cease using the components, seek alternative components or technologies and modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm our commercialization efforts and adversely affect our operating results.

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

Our principal offices are presently located in four buildings in San Diego, California. Substantially all of our operations are conducted at this location, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions. In addition, substantially all of our inventory of component supplies and finished goods is held at this location. We take precautions to safeguard our facilities, including acquiring insurance, employing back-up generators, adopting health and safety protocols and utilizing off-site storage of computer data. However, vandalism, terrorism or a natural or other disaster, such as an earthquake, fire or flood, could damage or destroy our manufacturing equipment or our inventory of component supplies or finished goods, cause substantial delays in our operations, result in the loss of key information, and cause us to incur additional expenses. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

If we do not enhance our product offerings through our research and development efforts, we may fail to effectively compete or become profitable.

In order to increase our sales and market share in the insulin-dependent diabetes market, we must enhance and broaden our product offerings in response to the evolving demands of people with insulin-dependent diabetes and healthcare providers, as well as competitive pressures and technologies. We may not be successful in developing, obtaining regulatory approval for, or marketing our proposed products when anticipated, or at all. In addition, notwithstanding our market research efforts, our future products may not be accepted by consumers, their caregivers, healthcare providers or third-party payors who reimburse consumers for our products. The success of any proposed product offerings will depend on numerous factors, including our ability to:

- identify the product features that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in an insulin pump and successfully incorporate those features into our products;
- develop and introduce proposed products in sufficient quantities and in a timely manner;
- offer products at a price that is competitive with other products then available;
- work with third-party payors to obtain reimbursement for our products;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of proposed products; and
- obtain the necessary regulatory approvals for proposed products.

If we fail to generate demand by developing products that incorporate features requested by consumers, their caregivers or healthcare providers, or if we do not obtain regulatory clearance or approval for proposed products in time to meet market demand, we may fail to generate sales sufficient to achieve or maintain profitability. We have in the past experienced, and we may in the future experience, delays in various phases of product development and commercial launch, including during research and development, manufacturing, limited release testing, marketing and customer education efforts. Any delays in our anticipated regulatory submissions or approvals, or subsequent product launches, may significantly impede our ability to successfully compete in our markets. In particular, such delays could cause customers to delay or forego purchases of our products, or to purchase our competitors' products. Even if we are able to successfully develop proposed products when anticipated, these products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by changing consumer preferences or the introduction by our competitors of products embodying new technologies or features.

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

t:slim, which we currently market in the United States, received pre-market clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA. t:flex, which we intend to begin marketing and selling in the United States during the second quarter of 2015, also has received 501(k) clearance. The 510(k) clearance process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes and does not always require long-term clinical studies. As a result, we currently lack the breadth of published long-term clinical data supporting the safety and efficacy of our products and the benefits they offer that might have been generated in connection with other approval processes. For these reasons, people with insulin-dependent diabetes and healthcare providers may be slower to adopt or recommend our products, we may not have comparative data that our competitors have or are generating, third-party payors may not be willing to provide coverage or reimbursement for our products and we may be subject to greater regulatory and product liability risks. These and other factors could slow the adoption of our products and result in our sales being lower than anticipated. In addition, future studies or clinical experience may indicate that treatment with our products is not superior to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, significant legal liability or harm to our business reputation.

Any alleged illness or injury associated with any of our products or product recall may negatively impact our financial results and business prospects depending on the scope, degree of publicity, reaction of our customers, healthcare professionals, and collaborators, competitive reaction, and consumer attitudes overall. Even if such an allegation or product liability claim lacks merit, cannot be substantiated, is unsuccessful or is not fully pursued, the negative publicity surrounding any assertion that our products caused illness, injury or death could adversely affect our reputation with customers, healthcare professionals, and existing and potential collaborators, and could adversely affect our operating results and cause a decline in our stock price.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products and to pursue new markets, or we may amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between our collaborators and us may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

For example, we have entered into a development and commercialization agreement with DexCom, which provides us a non-exclusive license to integrate the DexCom G4 PLATINUM Continuous Glucose Monitor with t:slim G4, which we have previously referred to as t:sensor, during the term of the agreement. This agreement currently runs until January 4, 2017, with automatic one-year renewals. The license granted covers the United States and other territories may be added from time to time. Under certain circumstances, the agreement may be terminated by either party without cause or on short notice. Termination of this agreement could require us to redesign t:slim G4 and attempt to integrate an alternative CGM system into our insulin pump systems, which would require significant development and regulatory activities that might delay the launch and commercialization of t:slim G4 or, following its launch, might not be completed in time to prevent an interruption in the availability of the product to our customers.

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

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, inventory management, product development tasks, research and development data, customer service and technical support functions. Our information technology systems are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures. In addition, t:connect, our cloud-based data management application, is hosted by a third-party service provider whose security and information technology systems are subject to similar risks, and our t:slim and t:flex pumps and products currently in development contain software which could be subject to computer virus or hacker attacks or other failures.

The failure of our or our service providers' information technology systems or our pumps' software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation or adversely affect our software products and could result in decreased sales, increased overhead costs, and product shortages, all of which could have a material adverse effect on our reputation, business, financial condition and operating results.

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

Our rapid growth has placed, and we expect that it will continue to place, a significant strain on our management team and on our financial resources. For example, between December 31, 2013 and December 31, 2014 our employee base has increased more than 30% and we expect to continue to experience growth of our employee base during 2015. Failure to manage our growth effectively could cause us to misallocate management or financial resources, and result in losses or weaknesses in our infrastructure, which could materially adversely affect our business. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our business objectives.

We depend on the knowledge and skills of our senior management and other key employees, and if we are unable to retain and motivate them or recruit additional qualified personnel, our business may suffer.

We have benefited substantially from the leadership and performance of our senior management, as well as certain key employees. For example, our chief executive officer, as well as other key members of management, have experience successfully scaling an early stage medical device company to achieve profitability. Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. Competition for senior management and key employees in our industry is intense and we cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. The loss of the services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements. Each member of senior management as well as our key employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated patient privacy rules under the HIPAA. These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. If we, or any of our service providers, are found to be in violation of the promulgated patient privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to our Financial Results and Need for Financing

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

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

- the revenue generated by sales of t:slim and t:flex, and any other future products that we may develop and commercialize;
- the costs associated with maintaining and expanding our sales and marketing infrastructure;
- the expenses we incur in maintaining our manufacturing facility and adding additional manufacturing equipment and capacity;
- the cost associated with developing and commercializing our proposed products or technologies;
- the cost of obtaining and maintaining regulatory clearance or approval for our current or future products;
- the cost of ongoing compliance with legal and regulatory requirements;
- expenses we incur in connection with potential litigation or governmental investigations;
- anticipated or unanticipated capital expenditures; and
- unanticipated general and administrative expenses.

As a result of these and other factors, we do not know the extent to which we may be required to raise additional capital. We may in the future seek additional capital from public or private offerings of our capital stock, borrowings under credit lines or other sources. In particular, we have an effective shelf registration statement on file with the SEC, under which we may offer to sell equity securities. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

If we are unable to raise additional capital, we may not be able to expand our sales and marketing infrastructure, enhance our current products or develop new products, take advantage of future opportunities, or respond to competitive pressures, changes in supplier relationships, or unanticipated changes in customer demand. Any of these events could adversely affect our ability to achieve our strategic objectives, which could have a material adverse effect on our business, financial condition and operating results.

Our operating results may fluctuate significantly from quarter to quarter.

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

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

- acceptance of our products by people with insulin-dependent diabetes, their caregivers, healthcare providers and third-party payors;
- the pricing of our products and competitive products, including the use of discounts, rebates or other financial incentives by our competitors;
- the effect of third-party coverage and reimbursement policies;
- our ability to establish and grow an effective sales and marketing infrastructure;
- the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans;
- interruption in the manufacturing or distribution of our products;
- our ability to manufacture products that meet quality and reliability requirements;
- seasonality and other factors affecting the timing of purchases of our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- results of clinical research and trials on our existing and future products;
- the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements;
- regulatory clearance or approvals affecting our products or those of our competitors; and
- the timing of revenue recognition associated with our product sales pursuant to applicable accounting standards.

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

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

As of December 31, 2014, we owed an aggregate principal amount of $30.0 million to Capital Royalty Partners and their related affiliates pursuant to term loan agreements under which we could borrow up to an additional $30.0 million under certain circumstances. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. In addition, in the event of our breach of the term loan agreements with Capital Royalty Partners, we may not be allowed to draw additional amounts under the agreements, and we may be required to repay any outstanding amounts earlier than anticipated.

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

Our loan agreements with Capital Royalty Partners contain certain restrictive covenants that limit our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lenders or terminate the applicable loan agreement. Our term loan agreements also contain certain financial covenants, including minimum revenue and cash balance requirements, and financial reporting requirements. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under our agreements. Further, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under a given agreement.

Risks Related to our Intellectual Property and Potential Litigation

Our ability to protect our intellectual property and proprietary technology is uncertain.

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of December 31, 2014, our patent portfolio consisted of approximately 32 issued U.S. patents and 48 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2031. We are also seeking patent protection for our proprietary technology in other countries throughout the world. In addition, we also have eight pending U.S. trademark applications and six pending foreign trademark applications, as well as 14 trademark registrations, including four U.S. trademark registrations and ten foreign trademark registrations.

We have applied for patent protection relating to certain existing and proposed products and processes. Currently, eight of our issued U.S. patents as well as various pending U.S. and foreign patent applications relate to the structure and operation of our pumping mechanism and are therefore particularly important to the functionality of our products. If we fail to file a patent application timely in any jurisdiction, we may be precluded from doing so at a later date. Further, we cannot assure you that any of our patent applications will be approved in a timely manner or at all. The rights granted to us under our patents, and the rights we are seeking to have granted in our pending patent applications, may not be meaningful or provide us with any commercial advantage. In addition, those rights could be opposed, contested or circumvented by our competitors, or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Even if we are successful in receiving patent protection for certain products and processes, our competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing on our intellectual property rights. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available.

We rely on our trademarks and trade names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved in a timely manner or at all. Third parties also may oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information.

If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult and time consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management’s attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results.

The medical device industry is characterized by patent litigation, and from time to time we may be subject to litigation that could be costly, result in the diversion of management's time and efforts, or require us to pay damages.

Our success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

From time to time we receive communications from third parties alleging our infringement of their intellectual property rights. Any intellectual property dispute or litigation could force us to do one or more of the following:

- stop selling our products or using technology that contains the allegedly infringing intellectual property;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing;
- redesign those products that contain the allegedly infringing intellectual property; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

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

We may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including those that are our direct competitors or could potentially be our direct competitors. In some cases, those employees joined our company recently. We may be subject to claims that we, or our employees, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we successfully defend against these claims, litigation could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. We cannot guarantee that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize proposed products, which could have an adverse effect on our business, financial condition and operating results.

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the design, manufacture, testing and sale of medical devices. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition, injury or death to customers. The risk of one or more product liability claims or lawsuits may be even greater following our January 2014 voluntary recall of cartridges used with the t:slim pump. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, including death, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain customers, any of which could have a material adverse effect on our business, financial condition and operating results.

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

Risks Related to our Legal and Regulatory Environment

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

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

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance or approval;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, or at all for our proposed products.

We initially received pre-market clearance for t:slim under Section 510(k) of the FDCA in November 2011. We obtained 510(k) clearance for t:connect and t:flex in February 2013 and January 2015, respectively. From time to time, we make modifications to these products that may require a new 510(k). We received 510(k) clearance for modifications to t:slim and its associated cartridge during 2014 and may pursue 510(k) clearance for additional modifications in the future. If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our forecasts. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process.

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

- we may not be able to demonstrate that our products are safe and effective for their intended users;
- the data from our clinical trials may be insufficient to support clearance or approval; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared or approved products on a timely basis.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some customers from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and operating results.

Further, we may evaluate international expansion opportunities in the future. If we expand our operations outside of the United States, we will become subject to various additional regulatory and legal requirements under the applicable laws and regulations of the international markets we enter. These additional regulatory requirements may involve significant costs and expenditures and, if we are not able comply any such requirements, our international expansion and business could be significantly harmed.

Modifications to our products may require new 510(k) clearances or pre-market approvals, or may require us to cease marketing or recall the modified products until clearances are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary for changes that we have made to our products. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared or approved products for which we previously concluded that new clearances or approvals were not necessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Further, the FDA's ongoing review of the 510(k) program may make it more difficult for us to modify our previously cleared products, either by imposing stricter requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or by applying more onerous review criteria to such submissions.

If we or our third-party suppliers fail to comply with the FDA's good manufacturing practice regulations, this could impair our ability to market our products in a cost-effective and timely manner.

We and our third-party suppliers are required to comply with the FDA's Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may impose inspections or audits at any time. If we or our suppliers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us. Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results.

A recall of our products, or the discovery of serious safety issues with our products, could have a significant negative impact on us.

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us, one of our distributors or any of our other third-party suppliers could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any products that we distribute would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost-effective and timely manner.

Further, under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results.

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

Any adverse event involving any products that we distribute could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our failure to comply with U.S. federal and state fraud and abuse laws, including anti-kickback laws and other U.S. federal and state anti-referral laws, could have a material, adverse impact on our business.

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

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

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

- the federal HIPAA of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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

- foreign and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, or, collectively, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty under the PPACA without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of those prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results.

To enforce compliance with the federal laws, the U.S. Department of Justice, or DOJ, has recently increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from our core business. Additionally, if a healthcare company settles an investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any of these challenges could have a material adverse effect on our reputation, business, financial condition and operating results. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

We may be liable if we engage in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of the off-label use of our products. Healthcare providers may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could result in substantial damage awards against us and harm our reputation.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our products.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the Federal and state governments in the United States continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. This legislation and regulation may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

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

Federal and state governments in the United States have enacted legislation to overhaul the nation's healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industries. Among other things, the PPACA:

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

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

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

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. Most recently, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year which commenced in 2013. The uncertainties regarding the ultimate features of the PPACA and other healthcare reform initiatives and their enactment and implementation may have an adverse effect on our customers' purchasing decisions regarding our products. In the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. Cost control initiatives could decrease the price that we receive for our products. At this time, we cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they, or the PPACA, may have on our business and operations, and any of these impacts may be adverse on our operating results and financial condition.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

The PPACA imposes, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States beginning in 2013. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to $20 billion over the next decade. We do not believe that our current products are currently subject to this tax based on the retail exemption under applicable Treasury Regulations. However, the availability of this exemption is subject to interpretation by the IRS, and the IRS may disagree with our analysis. In addition, future products that we manufacture, produce or import may be subject to this tax. The financial impact this tax may have on our business is unclear and there can be no assurance that our business will not be materially adversely affected by it.

Risks Related to our Common Stock

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

Based on an aggregate of 23,654,745 shares of our common stock outstanding as of December 31, 2014, our executive officers and directors, and their affiliates owned, in the aggregate, over 50% of the voting power of our outstanding common stock. These persons, acting together, will have the ability to significantly influence or determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets.

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

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

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

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

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

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

- authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;
- provide for the adoption of a staggered board of directors whereby the board is divided into three classes each of which has a different three-year term;
- provide that the number of directors shall be fixed by the board;
- prohibit our stockholders from filling board vacancies;
- provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;
- prohibit stockholders from calling special stockholder meetings;
- prohibit stockholders from acting by written consent without holding a meeting of stockholders;
- require the vote of at least two-thirds of the outstanding shares to approve amendments to the certificate of incorporation or bylaws; and
- require advance written notice of stockholder proposals and director nominations.

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

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

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

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

As of December 31, 2014, we have federal net operating loss, or NOL, carryforwards of approximately $177.2 million. In general, if there is an “ownership change” with respect to our company, as defined under Section 382 of the Internal Revenue Code of 1986, as amended, which we refer to as the Code, the utilization of our NOL carryforwards may be subject to substantial limitations imposed by the Code, and similar state provisions. In general, an ownership change occurs whenever there is a shift in ownership of our company by more than 50% by one or more 5% stockholders over a specified time period. We updated our Section 382/383 analysis, from January 1, 2012 through December 31, 2013, regarding the limitation of the net operating losses and research and development credits. Based upon the analysis, we determined that no ownership changes occurred during that period. However, previous analysis determined that ownership changes have occurred in years prior to 2012, but will not have a material impact on the future utilization of such carryforwards. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. Accordingly, if we earn net taxable income, our ability to use net operating loss carryforwards to offset U.S. federal taxable income may become subject to limitations, which could potentially result in increases in our future tax liabilities.

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, pursuant to the term loan agreements with Capital Royalty Partners, we are precluded from paying any cash dividends. Accordingly, you may have to sell some or all of your shares of our common stock in order to generate cash flow from your investment. You may not receive a gain on your investment when you sell shares and you may lose the entire amount of the investment.

The requirements of being a public company will increase our costs and may strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of The NASDAQ Stock Market and other applicable securities rules and regulations. Compliance with these rules and regulations has increased our legal and financial compliance costs, make some activities more difficult, time-consuming or costly, and increase demand on our systems and resources.

The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Recent legislation permits "emerging growth companies" to implement many of these requirements over a longer period and up to five years from the end of our last fiscal year. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses.

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

New regulations related to "conflict minerals" may cause us to incur additional expenses and could limit the supply and increase the cost of certain metals used in manufacturing our products.

On August 22, 2012, the SEC adopted a new rule requiring disclosures by public companies of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured. The rule requires companies to perform due diligence, disclose and annually report to the SEC whether or not such minerals originate from the Democratic Republic of Congo or an adjoining country. The rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals used in the manufacture of our products, including tantalum, tin, gold and tungsten. The number of suppliers who provide conflict-free minerals may be limited. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities. Within our supply chain, we may not be able to sufficiently verify the origins of the relevant minerals used in our products through the due diligence procedures that we implement, which may harm our reputation. We are currently investigating the use of conflict materials, if any, within our supply chain.

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

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

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

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

Pursuant to the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting for so long as we are an "emerging growth company."

Under existing SEC rules and regulations, we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis and management will be required to assess the effectiveness of our controls annually. However, under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 until we are no longer an "emerging growth company." We could be an "emerging growth company" for up to five years from our November 2013 initial public offering.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act after we no longer qualify as an "emerging growth company," may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are required to disclose changes made in our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years from our November 2013 initial public offering. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

The price of our common stock might fluctuate significantly.

Prior to our initial public offering in November 2013, there was no public market for our common stock. The trading price of our common stock is likely to be volatile for the foreseeable future. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- actual or anticipated fluctuations in our quarterly financial and operating results;
- our actual or perceived need for additional capital to fund our operations;
- perceptions about the market acceptance of our products and the recognition of our brand;
- overall performance of the equity markets;
- introduction of proposed products, or announcements of significant contracts, licenses or acquisitions, by us or our competitors;
- legislative, political or regulatory developments;
- issuance of securities analysts' reports or recommendations;
- additions or departures of key personnel;

- threatened or actual litigation and government investigations;
- sale of shares of our common stock by us or members of our management; and
- general economic conditions.

These and other factors might cause the market price of our common stock to fluctuate substantially, which may negatively affect the liquidity of our common stock. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce our share price.

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

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

Sales of our common stock, or the perception in the market that the holders of a large number of our shares intend to sell such shares, could reduce the market price of our common stock which would impair our ability to raise future capital through the sale of additional equity securities. We had outstanding 23,654,745 shares of common stock as of December 31, 2014, of which approximately 12,125,412 shares are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act of 1933, as amended, or the Securities Act. In addition, as of December 31, 2014, we had outstanding options to purchase 5,011,063 shares of common stock and warrants to purchase 1,006,577 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. As of December 31, 2014, there are also an aggregate of 2,519,848 shares of our common stock reserved for future grant or issuance under our 2013 Equity Incentive Plan and Employee Stock Purchase Plan.

Certain holders of shares of common stock have the right, subject to various conditions and limitations, to include their shares in registration statements relating to our securities. In addition, these holders are entitled to piggyback registration rights with respect to the registration under the Securities Act of shares of our common stock. Shares of common stock sold under these registration statements can be freely sold in the public market. In the event registration rights are exercised and a large number of shares of common stock are sold in the public market, those sales could reduce the trading price of our common stock.

In the future, we also may issue our securities if we need to raise additional capital. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

As of December 31, 2014, we leased an aggregate of approximately 107,000 square feet of manufacturing, laboratory and office space in San Diego, California under an operating lease, which is scheduled to expire in June 2019. Substantially all of our operations are conducted at this facility, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions.

We believe that the facilities that we presently occupy of approximately 90,000 square feet, together with the additional facilities of approximately 17,000 square feet, that we expect to occupy in 2015, are sufficient to support our current operations, and that suitable additional facilities would be available to us should our operations require it.

Item 3. Legal Proceedings.

From time to time we may be involved in various disputes and litigation matters that arise in the ordinary course of business. We are currently not a party to any material legal proceedings.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock began trading on The NASDAQ Global Market on November 14, 2013 under the symbol "TNDM." Prior to such time, there was no public market for our common stock. The following table sets forth the high and low sales prices per share of our common stock as reported on The NASDAQ Global Market for the period indicated.

	Price Range	
	High	Low
Year Ended December 31, 2013:		
Fourth Quarter (commencing November 14, 2013)	$ 27.00	$ 18.61
Year Ended December 31, 2014:		
First Quarter	$ 30.25	$ 20.65
Second Quarter	$ 22.64	$ 13.50
Third Quarter	$ 17.63	$ 12.36
Fourth Quarter	$ 17.98	$ 10.75

The last sale price for our common stock as reported by The NASDAQ Global Market on February 20, 2015 was $13.54 per share.

Holders of Record

As of February 20, 2015, there were approximately 77 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Securities Authorized for Issuance under Equity Compensation Plans

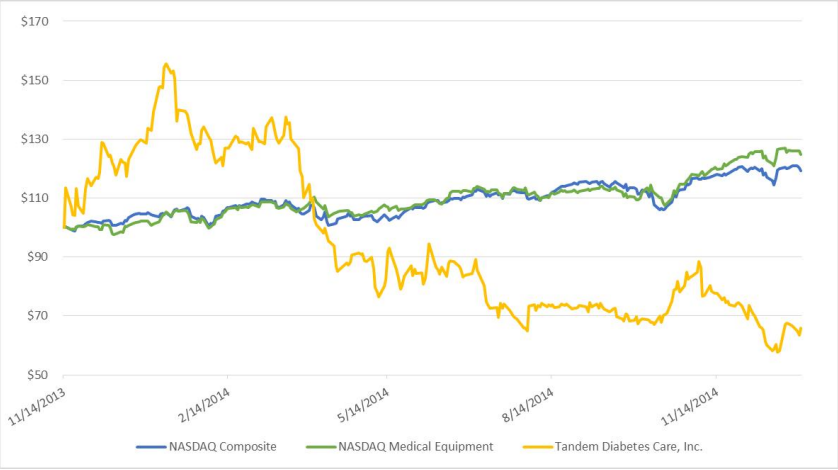
Information about our equity compensation plans is incorporated herein by reference to Part III, Item 12.

Repurchases of Equity Securities

There were no repurchases of equity securities in 2014.

Performance Measurement Comparison

The following graph shows a comparison from November 14, 2013 (the date our common stock commenced trading on The NASDAQ Global Market) through December 31, 2014 of the cumulative total return for our common stock, compared against the NASDAQ Composite Index and NASDAQ Medical Equipment Index. The graph assumes an initial investment of $100 on November 14, 2013. The comparisons in the graph are not intended to forecast or be indicative of possible future performance of our common stock.



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

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-191601) which was declared effective by the SEC on November 13, 2013. On November 14, 2013, additional shares of our common stock were registered through a Registration Statement on Form S-1 (File No. 333-192324) filed pursuant to Rule 462(b) under the Securities Act. On November 19, 2013, a total of 8,000,000 shares of common stock were sold on our behalf at the initial public offering price of $15.00 per share, for aggregate gross offering proceeds of $120.0 million, managed by Merrill Lynch, Pierce, Fenner & Smith Incorporated and Piper Jaffray & Co. In addition, on November 19, 2013, in connection with the exercise of the underwriters' over-allotment option, 1,200,000 additional shares of common stock were sold on our behalf at the initial public offering price of $15.00 per share, for aggregate gross offering proceeds of $18.0 million. We paid to the underwriters underwriting discounts totaling approximately $9.7 million in connection with the offering. In addition, we incurred additional costs of approximately $3.3 million in connection with the offering, which when added to the underwriting discounts paid by us, amounts to total costs of approximately $13.0 million. As a result, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were approximately $125.0 million.

The net proceeds from the offering were initially invested in money market funds and highly-liquid, highly-rated securities. We also estimate that we have since used approximately $67.5 million to expand and support our sales and marketing infrastructure, approximately $19.0 million to fund research and development activities, and approximately $34.5 million to expand and support our manufacturing capabilities. The remaining $4.0 million offering proceeds were used for interest payments.

Item 6. Selected Financial Data

The selected financial data presented below under the heading "Statements of Operations Data" for the years ended December 31, 2014, 2013 and 2012 and the selected financial data presented below under the heading "Balance Sheet Data" as of December 31, 2014 and 2013 have been derived from our audited financial statements included elsewhere in this Annual Report. The selected statement of operations data for the years ended December 31, 2011 and the balance sheet data as of December 31, 2012 and 2011 are derived from our audited financial statements not included in this Annual Report. The selected financial data presented below should be read in conjunction with the information included under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 and the financial statements and the related notes in Part II, Item 8. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

Statements of Operations Data:

	Year Ended December 31,			
(in thousands, except per share data)	**2014**	**2013**	**2012**	**2011**
Sales	$ 49,722	$ 29,007	$ 2,475	$ —
Cost of sales	34,474	22,840	3,823	—
Gross profit (loss)	15,248	6,167	(1,348)	—
Operating expenses:				
Selling, general and administrative	75,121	44,522	22,691	15,951
Research and development	15,791	11,079	9,009	8,261
Total operating expenses	90,912	55,601	31,700	24,212
Operating loss	(75,664)	$ (49,434)	$ (33,048)	$ (24,212)
Total other income (expense), net	(3,789)	(13,705)	33	(1,298)
Net loss before taxes	$ (79,453)	$ (63,139)	$ (33,015)	$ (25,510)
Provision for income taxes	71			
Net loss	$ (79,524)	$ (63,139)	$ (33,015)	$ (25,510)
Net loss per share, basic and diluted:	$ (3.42)	$ (21.46)	$ (175.88)	$ (149.87)
Weighted average shares used to compute basic and diluted net loss per share:	23,272	2,942	188	170

Balance Sheet Data:

	As of December 31,			
(in thousands)	**2014**	**2013**	**2012**	**2011**
Cash and cash equivalents	$ 31,176	$ 124,385	$ 17,163	$ 8,657
Short-term investments	$ 36,106	$ 5,095	$ —	$ —
Working capital	$ 72,657	$ 134,390	$ 10,762	$ (6,876)
Property and equipment, net	$ 12,581	$ 9,886	$ 8,989	$ 4,171
Total assets	$ 106,464	$ 162,215	$ 39,817	$ 13,978
Notes payable	$ 29,440	$ 29,397	$ 4,203	$ 12,857
Convertible preferred stock	$ —	$ —	$ 124,638	$ 67,930
Total stockholders' equity (deficit)	$ 54,572	$ 115,537	$ (106,052)	$ (71,295)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis together with "Selected Financial Data" in Part II, Item 6 and our financial statements and related notes in Part II, Item 8. The following discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Risk Factors" in Part I, Item 1A.

Certain statements contained in this Annual Report on Form 10-K, including statements regarding the development, growth and expansion of our business, our intent, belief or current expectations, primarily with respect to our future operating performance, and the products we expect to offer and other statements regarding matters that are not historical facts, are "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, and are subject to the "safe harbor" created by these sections. Future filings with the SEC, future press releases and future oral or written statements made by us or with our approval, which are not statements of historical fact, may also contain forward-looking statements. Because such statements include risks and uncertainties, many of which are beyond our control, actual results may differ materially from those expressed or implied by such forward-looking statements. Some of the factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements can be found under the caption "Risk Factors" and elsewhere in this Annual Report. Readers are cautioned not to place undue reliance on forward-looking statements. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.

Overview

We are a medical device company with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. We designed and commercialized our flagship product, the t:slim Insulin Delivery System, or t:slim, based on our proprietary technology platform and unique consumer-focused approach. 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 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 embedded 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. 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 different segments of the large and growing insulin-dependent diabetes market.

The FDA cleared t:slim in November 2011 and we commenced commercial sales of t:slim in the United States in the third quarter of 2012. In January 2015, we received FDA clearance to commercialize t:flex. We intend to begin commercial sales of t:flex in the United States during the second quarter of 2015. We consider the number of units shipped per quarter to be an important metric for managing our business. Since the launch of t:slim, we have shipped approximately 18,300 pumps as of December 31, 2014, broken down by quarter as follows:

	Units Shipped for Each of the Three Month Periods		
	2014	2013	2012
March 31	1,723	852	N/A
June 30	2,235	1,363	9
September 30	2,935	1,851	204
December 31	3,929	2,406	844
Total	10,822	6,472	1,057

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.

We have derived nearly all of our revenue from the sale of t:slim and associated supplies in the United States and expect to continue to do so until we are able to commercialize t:flex and our other products that are currently under development. During the third quarter of 2014, we submitted a PMA application to the FDA for the t:slim G4 Insulin Pump System, which we have previously referred to as t:sensor.

A substantial portion of the purchase price of an insulin pump is typically paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Access to adequate coverage and reimbursement for our current and future products by third-party payors is essential to the acceptance of our products by customers. Future sales of our current and future products will be limited unless our customers can rely on third-party payors to pay for all or part of the associated purchase cost. In circumstances that we do not have contracts established with third-party payors, to the extent possible, we utilize our network of national and regional distributors to service our customers.

We believe we can achieve profitability because our proprietary technology platform will allow us to maximize efficiencies in the development, production and sale of our products. By leveraging our technology platform, we believe we can develop and bring to market products more rapidly while significantly reducing our design and development costs. We also expect to continue to increase production volume, and to reduce the per-unit production cost for our pump products and their associated disposable cartridges over time. Further, due to shared product design features, our production system is adaptable to new products and we intend to leverage our shared manufacturing infrastructure to reduce our product costs and drive operational efficiencies. By expanding our product offerings to address people in different segments of the large and growing insulin-dependent diabetes market, we believe we can increase the productivity of our sales force, thereby improving our operating margin.

From inception through December 31, 2014, we have primarily financed our operations through sales of equity securities, and, to a lesser extent, debt financings. We expect to continue to incur net losses for the next several years and expect to pursue additional capital through equity and/or debt financings in order to fund our operations to a level of revenues adequate to support our cost structure.

We have experienced considerable revenue growth since the commercial launch of t:slim in the third quarter of 2012, while incurring operating losses since our inception. Our operating results may fluctuate on a quarterly or annual basis in the future, in particular during the initial stages of commercialization of new products, including t:flex, and our growth or operating results may not be consistent with predictions made by securities analysts. We may not be able to achieve profitability in the future. For additional information about the risks and uncertainties associated with our business, see the section entitled “Risk Factors” in Part I, Item 1A.

Voluntary Recall

On January 10, 2014, we announced a voluntary recall of select lots of cartridges used with t:slim that may have been at risk of leaking. The cause of the recall was identified during our internal product testing. The recall was expanded on January 20, 2014 to include additional lots of affected cartridges used with t:slim. We incurred approximately $1.7 million in direct costs associated with the recall. We recorded a cost of sales charge of approximately $1.3 million in the fourth quarter of 2013 and recorded the cost of sales charge for the remainder in the first quarter of 2014 for affected cartridges shipped in the first quarter of 2014. The total cost of the recall consisted of approximately $0.7 million associated with the return and replacement of affected cartridges in the field and approximately $1.0 million for the write-off of affected cartridges within our internal inventory. We do not currently expect any further direct financial impact of the recall beyond these costs.

Components of Results of Operations

Sales

We commenced commercial sales of t:slim in the United States in the third quarter of 2012. The t:slim Insulin Delivery System is comprised of the t:slim pump and pump-related supplies that include disposable cartridges and infusion sets. We also offer accessories including protective cases, belt clips, and power adapters. Sales of accessories since commercial launch have not been material. We primarily sell our products through national and regional distributors on a non-exclusive basis. These distributors are generally providers of medical equipment and supplies to individuals with diabetes. Our primary end customers are people with insulin-dependent diabetes. Similar to other durable medical equipment, the primary payor is generally a third-party insurance carrier and the customer is usually responsible for any medical insurance plan copay or co-insurance requirements.

We anticipate that our sales will increase as we expand our sales and marketing infrastructure, increase awareness of our products, introduce new products into the market, including t:flex, and broaden third-party reimbursement for our products. We also expect that 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. Our sales may also be negatively impacted by the summer vacation period. Accordingly, we have experienced and expect to continue to experience sequential growth of sales in each quarter from the first quarter to the fourth quarter, and we also expect sequential sales from the fourth quarter to the first quarter to be relatively flat or down. 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.

Cost of Sales

We manufacture the t:slim pump and its disposable cartridge at our manufacturing facility in San Diego, California. We will also manufacture the t:flex pump and its disposable cartridge at the same facility. Infusion sets and t:slim accessories are manufactured by third-party suppliers. Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs and reserves for expected warranty costs, scrap and inventory obsolescence. Due to our relatively low production volumes compared to our potential capacity to produce our products, manufacturing overhead expenses are a significant portion of our per-unit costs. These expenses include quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management.

We expect our overall gross margin, which is calculated as sales less cost of sales for a given period divided by sales, to fluctuate in future periods as a result of the changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors, changing mix of products sold with different gross margins, new product launches, warranty and training costs, and changes in our manufacturing processes, costs or manufacturing output. Manufacturing inefficiencies will also impact our gross margins, which we may experience as we attempt to manufacture our products on a larger scale, change our manufacturing processes, change our manufacturing capacity or output, implement additional automated manufacturing equipment and expand our manufacturing facilities. Any new products that we sell in the future, such as the t:flex pump, may also change our gross margins.

Selling, General and Administrative

We expect our selling, general and administrative, or SG&A, expenses to increase as our business expands. Our SG&A expenses primarily consist of salary, cash-based incentive compensation, fringe benefits and stock-based compensation for our executive, financial, marketing, sales, business development, regulatory affairs and administrative functions. Other significant expenses include those incurred for product demonstration samples, commercialization activities associated new product launches, trade shows, outside legal counsel fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs.

Research and Development

We expect our research and development, or R&D, expenses to increase as we initiate and advance our development projects. Our R&D activities primarily consist of engineering and research programs associated with our products under development, as well as R&D activities associated with our core technologies and processes. R&D expenses are primarily related to employee compensation, including salary, fringe benefits, stock-based compensation and temporary employee expenses. We also incur significant expenses for supplies, license fees, development prototypes, outside design and testing services and milestone payments under our development and commercialization agreements with DexCom and other collaborators.

Other Income and Expense

Our other income and expense primarily consists of interest expense and amortization of debt discount and debt issuance costs associated with term loan agreements. At December 31, 2014, there was $30.0 million of outstanding principal under our amended and restated term loan agreement with Capital Royalty Partners, which accrues interest at a rate of 11.5% per annum (see "Indebtedness"). In previous years, other income and expense also included interest expense and amortization of debt discount associated with convertible notes payable and the change in the fair value of outstanding common and preferred stock warrants, for which the final revaluation was performed in connection with our initial public offering in the fourth quarter of 2013.

Results of Operations

(in thousands, except percentages)	Year Ended December 31, 2014	2013	2012
Sales	$ 49,722	$ 29,007	$ 2,475
Cost of sales	34,474	22,840	3,823
Gross profit (loss)	15,248	6,167	(1,348)
Gross margin	31%	21%	(54)%
Operating expenses:			
Selling, general and administrative	75,121	44,522	22,691
Research and development	15,791	11,079	9,009
Total operating expenses	90,912	55,601	31,700
Operating loss	(75,664)	(49,434)	(33,048)
Other income (expense), net:			
Interest and other income	112	7	2
Interest and other expense	(3,901)	(4,710)	(2,525)
Change in fair value of stock warrants	—	(9,002)	2,556
Total other income (expense), net	(3,789)	(13,705)	33
Net loss before taxes	(79,453)	(63,139)	(33,015)
Provision for income taxes	71		
Net loss	$ (79,524)	$ (63,139)	$ (33,015)

Comparison of Years Ended December 31, 2014 and 2013

Sales. For the years ended December 31, 2014 and 2013, sales were $49.7 million and $29.0 million, respectively. Sales from the t:slim pump accounted for 86% and 90% of sales, respectively, for the years ended December 31, 2014 and 2013, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in either year.

The growth in sales was primarily driven by a 67% increase in t:slim pump shipments from 6,472 in 2013 to 10,822 in 2014. We expanded the number of sales territories in the United States from 36 at the end of 2013 to 60 at the end of the second quarter of 2014. As a result of our sales force expansion, our field personnel experienced some initial disruption in their sales productivity as their territories were realigned and responsibilities adjusted.

Sales to distributors accounted for 75% and 69% of our total sales for the years ended December 31, 2014 and 2013, respectively. The mix of sales to distributors versus direct customers is driven by whether or not we have a contracted arrangement with the underlying third-party insurance payor. Typically reimbursement is higher for sales to direct customers as compared to distributors, and we do not capture all of the pump supply sales for distributors. The increase in the percentage of our sales to distributors was primarily attributable to new arrangements between certain insurance payors and distributors that became effective during the third quarter of 2014. As a result of these new arrangements, a portion of our business has transitioned from a direct sale opportunity to a distributor sale, as well as expanding our access to potential customers by providing access to our products as an in-network benefit.

Cost of Sales and Gross Profit. Our cost of sales in 2014 was $34.5 million, resulting in gross profit of $15.2 million, compared to $22.8 million in cost of sales and gross profit of $6.2 million in 2013. The gross margin in 2014 was 31%, compared to 21% in 2013. The improvement in the gross margin was primarily a result of manufacturing efficiencies associated with an increase in production output and improvement in our manufacturing processes. Our manufacturing overhead spending increased by 30% in 2014 versus 2013, while our units produced increased 56% and 143% for pumps and cartridges, respectively.

Included in cost of sales for the year ended December 31, 2014 were costs of $0.4 million associated with our voluntary product recall of selected lots of cartridges initiated in January 2014. The voluntary recall resulted in a less than one percentage point reduction in the gross margin for the year ended December 31, 2014. By comparison, the 2013 gross margin included $1.3 million of recall-associated costs, or a reduction of the gross margin of five percentage points. Also included in cost of sales in 2013 were costs of $1.1 million that were previously deferred at the end of the fourth quarter of 2012 due to our lack of history for estimating product returns at that time. These costs, along with the previously deferred sales of $1.9 million recognized in the first quarter of 2013, resulted in a two percentage point increase in gross margin for the year ended December 31, 2013.

Our future gross margins will be impacted by numerous factors including changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors, changing mix of products sold with different gross margins, new product launches, warranty and training costs, and changes in our manufacturing processes, costs and output. Our gross margin on the t:slim pump was higher than our gross margin on pump-related supplies for the years ended December 31, 2014 and 2013, and is expected to remain higher in the future. We continue to increase our manufacturing operations and costs as we address increasing production volume requirements. Our manufacturing overhead costs have been, and will continue to be, a significant component of the cost of our products. As a result our manufacturing overhead costs have impacted, and may continue to impact, our gross margins as we attempt to manufacture our products on a larger scale, change our manufacturing processes, change our manufacturing capacity or output, implement additional automated manufacturing equipment and expand our manufacturing facilities. Any new products that we sell in the future, such as the t:flex pump, may change our future gross margins.

Selling, General and Administrative Expenses. SG&A expenses increased 69% to $75.1 million in 2014 from $44.5 million in 2013. The increase in SG&A expenses was primarily associated with the expansion of our commercial operations during 2014. As of December 31, 2014, our headcount for sales, general and administrative functions increased 43% compared to December 31, 2013. This includes an expansion from 36 to 60 territories during 2014, as well as the growth of the administrative infrastructure to support operations. Territories are maintained by sales representatives, field clinical specialists, managed care liaisons, additional sales management and other customer support personnel. Employee-related expenses for our sales, general and administrative functions comprise the majority of the SG&A expenses. Such employee-related expenses increased $24.9 million during 2014 compared to 2013, including an increase of $8.3 million in stock-based compensation associated with equity awards. SG&A expenses also increased $5.7 million associated with marketing and promotional activities, tradeshows, travel expenses and facility expansion. We expect our SG&A expenses will continue to increase in 2015, but at a lower rate as compared to 2014.

Research and Development Expenses. R&D expenses increased 43% to $15.8 million in 2014 from $11.1 million in 2013. The increase in R&D expenses in 2014 consisted primarily of an increase of $2.5 million in employee-related expenses. At December 31, 2014, our headcount for research and development functions increased 17% compared to December 31, 2013. The increase in R&D expenses also consisted of a milestone payment of $1.0 million to DexCom under our development and commercialization agreement related to our submission of a PMA for the t:slim G4 to the FDA in July 2014. We expect our R&D expenses will continue to increase in 2015, but at a lower rate as compared to 2014.

Other Income (Expense). Other expense in 2014 was $3.8 million, compared to $13.7 million in 2013. Other expense in 2014 was primarily due to $3.9 million of interest expense associated with the term loan agreement executed with Capital Royalty Partners in December 2012 and subsequently amended and restated in April 2014 and February 2015. We borrowed $30 million under the agreement in January 2013.

In comparison, other expense in 2013 was primarily comprised of $9.0 million of expense associated with the revaluation of the fair value of common and preferred stock warrants and $4.7 million of interest expense associated with the term loan agreement.

We performed the final revaluation of the warrant liability in November 2013 in connection with completion of the initial public offering. The decrease in interest expense during 2014 compared to 2013 was due to the decrease in the interest rate on our outstanding debt from 14.0% to 11.5% in conjunction with the amendment to our term loan agreement.

Comparison of Years Ended December 31, 2013 and 2012

Sales. We began selling our products in the third quarter of 2012. Sales for the years ended December 31, 2013 and 2012 were $29.0 million and $2.5 million, respectively. Sales from the t:slim pump accounted for 90% and 91% of sales, respectively, for the years ended December 31, 2013 and 2012, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in either year. The commercialization of the t:slim pump and pump-related supplies and accessories initially involved a sales force of limited size. During 2013, we expanded the number of our sales territories to 36 from 11 at commercial launch in 2012. Sales to distributors accounted for 69% and 73% of our total sales for the years ended December 31, 2013 and 2012, respectively.

Cost of Sales and Gross Profit (Loss). Our cost of sales in 2013 was $22.8 million resulting in gross profit of $6.2 million, compared to $3.8 million in cost of sales recognized in 2012, resulting in negative gross profit of ($1.3) million. The gross margin in 2013 was 21%, compared to a negative gross margin of (54%) in 2012. The improvement in the gross margin was primarily a result of manufacturing efficiencies associated with an increase in the production output and improvement in our manufacturing processes. The 2013 gross margin included $1.3 million of costs, or a reduction of the gross margin of five percentage points, associated with our voluntary product recall of selected lots of cartridges, including the write-off of affected inventory on hand and the return and replacement of product in the field.

Selling, General and Administrative Expenses. SG&A expenses increased 96% to $44.5 million in 2013 from $22.7 million in 2012. The increase in SG&A expenses was primarily associated with increased costs as we began selling our products in the third quarter of 2012 and the continued expansion of our commercial operations during 2013. At December 31, 2013, our headcount for sales, general and administrative functions more than doubled compared to December 31, 2012. This includes an expansion to 36 territories at the end of 2013, which are maintained by sales representatives, field clinical specialists, managed care liaisons, additional sales management and other customer support personnel, as well as the growth of the administrative infrastructure to support the growing operations. Employee-related expenses for our sales, general and administrative functions comprise the majority of the SG&A expenses. Such employee-related expenses increased $18.5 million during 2013 compared to 2012, including an increase of $3.4 million in stock-based compensation associated with equity awards. SG&A expenses also increased $5.1 million associated with marketing and promotional activities, tradeshows, travel expenses and technological support. The overall increase was offset by a reduction of $1.8 million relating to the acquisition of patent rights in 2012 for non-commercialized products, for which there was no comparable SG&A expense in 2013.

Research and Development Expenses. R&D expenses increased 23% to $11.1 million in 2013 from $9.0 million in 2012. The increase in R&D expenses in 2013 consisted primarily of an increase of $2.4 million in employee-related expenses, as well as an increase of $0.7 million in supplies and facilities expenses, offset by a $1.0 million decrease in collaboration milestone payments.

Other Income (Expense). Other expense in 2013 was $13.7 million, compared to $33,000 of other income in 2012. Other expense in 2013 was primarily comprised of $9.0 million associated with the revaluation of the fair value of common and preferred stock warrants and $4.7 million interest expense associated with the term loan agreement executed with Capital Royalty Partners in December 2012. We borrowed $30 million under the agreement in January 2013.

In comparison, other income in 2012 was primarily comprised of a $2.6 million decrease in the fair value of the common and preferred stock warrants, offset by $2.5 million in interest expense related to convertible notes payable to certain stockholders. The convertible notes were converted to Series D preferred stock in August 2012 and interest was paid on a $5.0 million loan from Silicon Valley Bank. We used proceeds from the Capital Royalty Partners term loan agreement to repay all amounts outstanding under the Silicon Valley Bank loan in January 2013.

Liquidity and Capital Resources

At December 31, 2014, we had $69.3 million in cash and cash equivalents and short-term investments, which included $2.0 million of restricted cash. We believe that our cash on hand, cash available under our new tranche term loan agreement with Capital Royalty Partners and proceeds from the exercise of options and warrants will be sufficient to satisfy our liquidity requirements for at least the next 12 months. We expect that our sales performance and the resulting operating income or loss, as well as the status of each of our new product development programs, will significantly impact our cash management decisions. We have utilized, and may continue to utilize, debt arrangements with debt providers and financial institutions to finance our operations. Factors such as interest rates, repayment terms and available cash will impact our decision to continue to utilize debt arrangements as a source of cash. In November 2013, we completed an initial public offering of common stock that resulted in net proceeds of approximately $125 million. In the future, we may give consideration to additional public offerings of equity securities as a source of financing. In December 2014, we filed a registration statement on Form S-3 with the SEC, which was declared effective on December 19, 2014. Under this shelf registration statement, we may from time to time offer and sell any combination of common stock, preferred stock, warrants or units in one or more offerings.

Historically, our sources of cash have included private placements and a public offering of equity securities, debt arrangements, and cash generated from operations. Our historical cash outflows have primarily been associated with cash used for operating activities such as the expansion and support of our sales and marketing infrastructure, increase in our R&D activities, the acquisition of intellectual property, expenditures related to equipment and improvements used to increase our manufacturing capacity and improve our manufacturing efficiency, overall facility expansion and other working capital needs.

The following table shows a summary of our cash flows for the years ended December 31, 2014, 2013, and 2012:

	Year Ended December 31,		
(in thousands)	**2014**	**2013**	**2012**
Net cash provided by (used in):			
Operating activities	$ (61,378)	$ (47,757)	$ (33,471)
Investing activities	(35,470)	(11,105)	(5,529)
Financing activities	3,639	166,084	47,506
Total	$ (93,209)	$ 107,222	$ 8,506

Operating activities. Net cash used in operating activities was $61.4 million for the year ended December 31, 2014, compared to $47.8 million and $33.5 million for the same periods in 2013 and 2012, respectively. The increase in net cash used in operating activities for the 2014 and 2013 periods presented was primarily associated with increased costs related to the commercial operations and continued expansion of our company during 2014 and 2013. Our employee headcount, employee-related expenses and working capital needs, including accounts receivable and inventory, increased significantly as a result of our initiation and ramp-up of commercial operations.

Investing activities. Net cash used in investing activities was $35.5 million for the year ended December 31, 2014, which was primarily related to the net purchase of $67.1 million in short-term investments and $4.6 million in purchases of long-term assets, offset by proceeds from sales and maturities of short-term investments of $36.2 million. Net cash used in investing activities was $11.1 million for the year ended December 31, 2013, which was primarily related to the purchase of $5.1 million in short-term investments and $4.0 million in purchases of property and equipment. Net cash used in investing activities was $5.5 million for the year ended December 31, 2012, which was primarily related to the purchase of property and equipment and patents.

Financing activities. Net cash provided by financing activities was $3.6 million for the year ended December 31, 2014, compared to $166.1 million and $47.5 million for the same periods in 2013 and 2012, respectively. The net cash provided in 2014 was primarily due to $3.7 million in net proceeds from the exercise of outstanding stock options and warrants, as well as proceeds from employee contributions for the purchase of our common stock through our Employee Stock Purchase Plan. The net cash provided in 2013 was from net proceeds from our initial public offering of approximately $125.0 million in November 2013, net proceeds from issuance of preferred stock of $16.0 million, net proceeds from issuance of notes payable of $28.9 million and proceeds from warrant and stock option exercises of $2.6 million, offset by principal payments on notes payable of $4.4 million and $2.0 million used in restricted cash. The net cash provided by 2012 financing activities included proceeds from issuance of preferred stock of $30.9 million and proceeds from issuance of notes payable and convertible notes payable of $17.2 million.

Our liquidity position and capital requirements are subject to fluctuation based on a number of factors. For example, our cash inflow and outflow may be impacted by the following:

- fluctuations in gross margins and operating margins;
- our ability to generate sales; and
- fluctuations in working capital.

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

- support of our commercialization efforts related to our current and future products;
- improvements in our manufacturing capacity and efficiency;
- new research and product development efforts;
- payment of quarterly interest due under our term debt agreements;
- the acquisition of equipment and other fixed assets;
- facilities expansion needs; and
- potential up-front, milestone payments or reimbursement of costs under R&D collaborations.

Although we believe the foregoing items reflect our most likely uses of cash in the short-term, we cannot predict with certainty all of our particular short-term cash uses or the timing or amount of cash used. If cash generated from operations is insufficient to satisfy our working capital and capital expenditure requirements, we may be required to sell additional equity or debt securities or obtain additional credit facilities. There can be no assurance that equity or debt financing will be available on satisfactory terms, or at all. Further, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants.

Indebtedness

Capital Royalty Partners Term Loans

In December 2012, we executed a term loan agreement (the “Original Term Loan Agreement”) with Capital Royalty Partners II L.P. (“Capital Royalty Partners”) and Capital Royalty Partners II—Parallel Fund “A” L.P. (“CRPPF”, together with Capital Royalty Partners, the “Lenders”), providing us access to $45.0 million under the arrangement, of which $30.0 million was available in January 2013, and an additional amount up to $15.0 million became available upon our achievement of a 2013 revenue-based milestone. In January 2013, $30.0 million was drawn under the agreement, a portion of which was used to repay all amounts outstanding under our $5.0 million loan from Silicon Valley Bank.

In April 2014, we entered into an amended and restated term loan agreement (the "Amended and Restated Term Loan Agreement") with the Lenders and Capital Royalty Partners II (Cayman) L.P. (“CRPC”) under which we may borrow up to $30.0 million. The Amended and Restated Term Loan Agreement amends and restates the Original Term Loan Agreement.

Aggregate borrowings outstanding under the Amended and Restated Term Loan Agreement were $30 million at December 31, 2014. Borrowings under the Amended and Restated Term Loan Agreement were used to refinance amounts outstanding under the Original Term Loan Agreement.

The Amended and Restated Term Loan Agreement primarily amends the terms of the Original Term Loan Agreement to reduce the borrowing limit to $30.0 million, to reduce the applicable interest rate from 14.0% to 11.5%, and to extend the interest only payment period from December 31, 2015 to March 31, 2018. Interest is payable, at our option, (i) in cash at a rate of 11.5% per annum or (ii) in cash at a rate of 9.5% per annum, with the remaining 2.0% per annum added to the principal of the loan and thereafter subject to accruing interest. Interest-only payments are due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period. Thereafter, in addition to interest accrued during the period, the quarterly payments shall include an amount equal to the outstanding principal at March 31, 2018 divided by the remaining number of quarters prior to the end of the term of the loan. The Amended and Restated Term Loan Agreement provides for prepayment fees of 3% of the outstanding balance of the loan if the loan is repaid prior to March 31, 2015. The prepayment fee is reduced by 1% per year for each subsequent year until maturity.

Certain affirmative and negative covenants were also amended to provide us with additional flexibility. The principal financial covenants require that we attain minimum annual revenues of $30.0 million in 2014, $50.0 million in 2015, $65.0 million in 2016, $80.0 million in 2017 and $95.0 million thereafter. We expect to meet the minimum annual revenue covenant of $50.0 million in 2015.

On the same date, we entered into a new term loan agreement (the “New Tranche Term Loan Agreement with the Lenders, CRPC and Parallel Investment Opportunities Partners II L.P. under which we may borrow up to an additional $30.0 million on or before March 31, 2015, at the same interest rate and on the same key terms as the Amended and Restated Term Loan Agreement, provided that we deliver notice of our intention to borrow by March 2, 2015. As of the date of filing of this Annual Report, we have not delivered a borrowing notice.

In the event of our breach of the agreements, we may not be allowed to draw additional amounts under the New Tranche Term Loan Agreement, and we may be required to repay any outstanding amounts earlier than anticipated.

In February 2015, we amended our Amended and Restated Term Loan Agreement, as well as our New Tranche Term Loan Agreement. Pursuant to this amendment, the interest only payment period under both agreements was extended to December 31, 2019 from March 31, 2018, at the same interest rate and on the same key terms as the existing agreements. The principal balance under both agreements will be due in full at the end of the term of the loan, which is March 31, 2020.

Silicon Valley Bank Revolving Line of Credit

In January 2013, we entered into an amended loan agreement with Silicon Valley Bank, making available a revolving line of credit in the amount up to the lesser of $1.5 million or 75% of eligible accounts receivable. Interest-only payments at a rate of 6% per annum are payable monthly through the maturity date 24 months from the initial borrowing. Loans drawn under the agreement are secured by our eligible accounts receivable and proceeds therefrom. Additionally, the terms of the revolving line of credit contain various affirmative and negative covenants. There were no amounts outstanding under this line of credit as of December 31, 2014, and 2013. The line of credit expired in January 2015.

Contractual Obligations & Commitments

The following table summarizes our long-term contractual obligations as of December 31, 2014:

	Payments Due by Period(1)				
(in thousands)	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligation relating to our facility	$ 12,593	$ 2,555	$ 5,739	$ 4,299	$ —
Capital Royalty Partners term loans, including interest(2)	45,094	3,450	6,900	30,886	3,858
Firm purchase commitments	3,222	2,008	1,214	—	—
Total contractual obligations	$ 60,909	$ 8,013	$ 13,853	$ 35,185	$ 3,858

(1) In connection with the DexCom development and commercialization agreement, we are contingently obligated to make a $1.0 million payment upon achievement of FDA approval for the PMA application for the t:slim G4, which was filed in July 2014. The remaining milestone is excluded from the table above due to uncertainty of timing.

(2) The payments due under the Capital Royalty Partners term loans do not reflect the extension of the interest-only period pursuant to the amendment of such agreements in February 2015.

Critical Accounting Policies Involving Management Estimates and Assumptions

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about our financial condition and results of operations that are not readily apparent from other sources. Actual results may differ from these estimates.

While our significant accounting policies are more fully described in Note 2 to our financial statements included in this Annual Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

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

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title passed, the price is fixed or determinable, and collectability is reasonably assured. These criteria are applied as follows:

- The evidence of an arrangement generally consists of contractual arrangements with distributors or direct customers.
- Transfer of title and risk and rewards of ownership are passed upon shipment of the pump to distributors or upon delivery to the customer.
- The selling prices are fixed and agreed upon based on the contracts with distributors, the customer and contracted insurance payors, if applicable. For sales to customers associated with insurance providers with whom we do not have a contract, we recognize revenue upon collection of cash at which time the price is determinable. We do not offer rebates to our distributors and customers.
- We consider the overall creditworthiness and payment history of the distributor, customer and the contracted insurance payor in concluding whether collectability is reasonably assured.

Prior to the first quarter of 2013, t:slim pump sales were recorded as deferred revenue until our 30-day right of return expired because we did not have sufficient history to be able to reasonably estimate returns. At December 31, 2012, we had $1.9 million recorded as deferred revenue. Beginning in the first quarter of 2013, we began recognizing t:slim pump revenue when all the revenue recognition criteria above are met, as we established sufficient history in order to reasonably estimate product returns. As a result of this change, we recorded a one-time adjustment during 2013, to recognize previously deferred revenue and cost of sales of $1.9 million and $1.1 million, respectively.

Revenue Recognition for Arrangements with Multiple Deliverables

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

In February 2013, the FDA cleared t:connect, our cloud-based data management application, which is made available upon purchase by t:slim pump customers. This service is deemed an undelivered element at the time of the t:slim sale. Because we have neither VSOE nor TPE for this deliverable, the allocation of revenue is based on our ESP. We establish our ESP based on estimated cost to provide such services, including consideration for a reasonable profit margin and corroborated by comparable market data. We allocate fair value based on management's ESP to this element at the time of sale and is recognizing the revenue over the four year hosting period. At December 31, 2014 and 2013, $0.7 million and $0.2 million were recorded as deferred revenue for the t:connect hosting service. All other undelivered elements at the time of sale are deemed inconsequential or perfunctory.

Warranty Reserve

We provide a four-year warranty on our t:slim pump to end user customers and may replace any pumps that do not function in accordance with the product specifications. Any pump returned to us may be refurbished and redeployed. Additionally, we offer a six month warranty on t:slim cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. Warranty costs are estimated based on the current new and refurbished product costs, actual experience and expected failure rates from test studies performed in conjunction with the clearance of our product with the FDA to support the longevity and reliability of our t:slim pump. We evaluate the reserve quarterly and make adjustments when appropriate. At December 31, 2014 and 2013, the warranty reserve was $2.0 million and $1.1 million, respectively. Of the total warranty reserve at December 31, 2014 and 2013, zero and $0.3 million was related to potential replacements associated with the voluntary product recall of selected lots of cartridges. Actual warranty costs have not differed materially from estimated amounts reserved.

Off-Balance Sheet Arrangements

As of December 31, 2014, we did not have any off-balance sheet arrangements.

JumpStart Our Business Startups Act of 2012 (JOBS Act)

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

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We invest our excess cash primarily in commercial paper and government-sponsored enterprise securities. Some of the financial instruments in which we invest have market risk associated with them in that a change in prevailing interest rates may cause the principal amount of the instrument to fluctuate. Other financial instruments in which we invest potentially subject us to credit risk in that the value of the instrument may fluctuate based on the issuer's ability to pay.

The primary objectives of our investment activities are to maintain liquidity and preserve principal while at the same time maximizing the income we receive from our financial instruments without significantly increasing risk. We have established guidelines regarding approved investments and maturities of investments, which are primarily designed to maintain liquidity and preserve principal.

Because of the short-term maturities of our financial instruments, we do not believe that an increase or decrease in interest rates would have any significant impact on the realized value of our investment portfolio. If a 10% change in interest rates were to have occurred on December 31, 2014, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

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

We do not have any foreign currency or other derivative financial instruments.

Item 8. Financial Statements and Supplementary Data

Our financial statements as of December 31, 2014 and 2013 and for each of the three years in the period ended December 31, 2014, and the Report of the Registered Independent Public Accounting Firm are included in this report as listed in the index.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheets of Tandem Diabetes Care, Inc. as of December 31, 2014 and 2013, and the related statements of operations and comprehensive loss, convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the three years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Tandem Diabetes Care, Inc. at December 31, 2014 and 2013, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California
February 24, 2015

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

	December 31,	
	2014	2013
Assets		
Current assets:		
Cash and cash equivalents	$ 31,176	$ 124,385
Restricted cash	2,000	2,050
Short-term investments	36,106	5,095
Accounts receivable, net	7,652	5,299
Inventory, net	11,913	10,330
Prepaid and other current assets	1,904	1,830
Total current assets	90,751	148,989
Property and equipment, net	12,581	9,886
Patents, net	2,441	2,697
Other long-term assets	691	643
Total assets	$ 106,464	$ 162,215
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,949	$ 2,352
Accrued expense	2,920	1,874
Employee-related liabilities	9,722	5,876
Deferred revenue	840	411
Other current liabilities	2,663	4,086
Total current liabilities	18,094	14,599
Notes payable—long-term	29,440	29,397
Deferred rent—long-term	2,700	1,887
Other long-term liabilities	1,658	795
Total liabilities	51,892	46,678
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000 shares authorized at December 31, 2014, and 2013, no shares issued and outstanding at December 31, 2014, and 2013 respectively.	—	—
Common stock, $0.001 par value; 100,000 shares authorized as of December 31, 2014 and 2013, respectively, 23,655 and 22,926 shares issued and outstanding at December 31, 2014 and 2013, respectively.	24	23
Additional paid-in capital	303,255	284,705
Accumulated other comprehensive income	8	—
Accumulated deficit	(248,715)	(169,191)
Total stockholders' equity	54,572	115,537
Total liabilities and stockholders' equity	$ 106,464	$ 162,215

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

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

	Year Ended December 31,		
	2014	2013	2012
Sales	$ 49,722	$ 29,007	$ 2,475
Cost of sales	34,474	22,840	3,823
Gross profit (loss)	15,248	6,167	(1,348)
Operating expenses:			
Selling, general and administrative	75,121	44,522	22,691
Research and development	15,791	11,079	9,009
Total operating expenses	90,912	55,601	31,700
Operating loss	(75,664)	(49,434)	(33,048)
Other income (expense), net			
Interest and other income	112	7	2
Interest and other expense	(3,901)	(4,710)	(2,525)
Change in fair value of stock warrants	—	(9,002)	2,556
Total other income (expense), net	(3,789)	(13,705)	33
Loss before taxes	(79,453)	(63,139)	(33,015)
Provision for income tax expense	71	—	—
Net loss	$ (79,524)	$ (63,139)	$ (33,015)
Other comprehensive loss:			
Unrealized gain on short-term investments	$ 8	$ —	$ —
Comprehensive loss	$ (79,516)	$ (63,139)	$ (33,015)
Net loss per share, basic and diluted	$ (3.42)	$ (21.46)	$ (175.88)
Weighted average shares used to compute basic and diluted net loss per share	23,272	2,942	188

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

TANDEM DIABETES CARE, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except per share data)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Income	Deficit	Equity (Deficit)
Balance at December 31, 2011	1,688	$ 67,930	212	$ —	$ 1,435	$ —	$ (72,730)	$ (71,295.00)
Issuance of Series D convertible preferred stock at $4.40 per share, net of issuance costs of $90	7,035	30,867	—	—	—	—	—	—
Conversion of convertible notes payable and accrued interest into Series D convertible preferred stock at $4.40 per share	5,997	26,391	—	—	—	—	—	—
Vesting of restricted common stock and change in fair value of unvested restricted stock subject to repurchase	—	—	—	—	248	—	—	248
Exercise of stock options	—	—	3	—	35	—	—	35
Conversion of Series A, Series B, and Series C preferred stock into common stock	(23)	(550)	14	—	550	—	—	550
Stock-based compensation	—	—	—	—	246	—	—	246
Repurchase and retirement of common stock	—	—	(2)	—	(1)	—	(49)	(50)
Loss on extinguishment of convertible notes payable	—	—	—	—	(2,513)	—	(258)	(2,771)
Net loss	—	—	—	—	—	—	(33,015)	(33,015)
Balance at December 31, 2012	14,697	$ 124,638	227	$ —	$ —	$ —	$ (106,052)	$ (106,052)
Issuance of Series D convertible preferred stock at $4.40 per share, net of issuance costs of $95	3,656	15,991	—	—	—	—	—	—
Issuance of common stock warrants in connection with term loan	—	—	—	—	437	—	—	437
Exercise of preferred stock warrants	428	3,629	—	—	—	—	—	—
Issuance of common stock in initial public offering, net of underwriter's discount and offering costs	—	—	9,200	9	125,030	—	—	125,039
Conversion of preferred stock in connection with initial public offering	(18,781)	(144,258)	13,404	13	144,245	—	—	144,258
Vesting of restricted common stock and change in fair value of unvested restricted stock subject to repurchase	—	—	—	—	33	—	—	33
Conversion of preferred stock warrants into common stock warrants	—	—	—	—	9,550	—	—	9,550
Exercise of common stock warrants	—	—	85	1	627	—	—	628
Exercise of stock options	—	—	10	—	66	—	—	66
Stock-based compensation	—	—	—	—	4,717	—	—	4,717
Net loss	—	—	—	—	—	—	(63,139)	(63,139)
Balance at December 31, 2013	—	$ —	22,926	$ 23	$ 284,705	$ —	$ (169,191)	$ 115,537
Exercise of common stock warrants	—	—	334	1	137	—	—	138
Exercise of stock options	—	—	144	—	325	—	—	325
Issuance of common stock for Employee Stock Purchase Plan	—	—	251	—	3,168	—	—	3,168
Stock-based compensation	—	—	—	—	14,920	—	—	14,920
Unrealized gain on short-term investments	—	—	—	—	—	8	—	8
Net loss	—	—	—	—	—	—	(79,524)	(79,524)
Balance at December 31, 2014	—	$ —	23,655	$ 24	$ 303,255	$ 8	$ (248,715)	$ 54,572

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

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

	Year Ended December 31,		
	2014	**2013**	**2012**
Operating activities			
Net loss	$ (79,524)	$ (63,139)	$ (33,015)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	4,389	3,167	2,032
Accretion of discount on notes payable and convertible notes	—	—	1,209
Interest expense related to amortization of debt discount and debt issuance costs	219	595	836
Provision for allowance for doubtful accounts	188	275	46
Provision for inventory reserve	163	815	335
Change in fair value of common and preferred stock warrants	—	9,002	(2,556)
Amortization of premium/discount on short-term investments	(53)	—	—
Stock-based compensation expense	14,995	4,456	246
Other	41	62	57
Changes in operating assets and liabilities:			
Accounts receivable	(2,541)	(3,161)	(2,458)
Inventory	(1,820)	(4,625)	(6,596)
Prepaid and other current assets	(82)	106	(1,054)
Other long-term assets	(150)	(85)	—
Accounts payable	(1,225)	859	1,383
Accrued expense	973	342	918
Employee-related liabilities	3,846	3,885	979
Deferred revenue	429	(1,472)	1,884
Other current liabilities	(1,575)	895	2,342
Deferred rent	(461)	(522)	(234)
Other long-term liabilities	810	763	—
Payments received on note receivable from employees	—	25	175
Net cash used in operating activities	(61,378)	(47,757)	(33,471)
Investing activities			
Purchase of short-term investments	(67,101)	(5,095)	—
Proceeds from sales and maturities of short-term investments	36,210	—	—
Purchase of property and equipment	(4,406)	(4,010)	(4,529)
Purchase of patents	(173)	(2,000)	(1,000)
Net cash used in investing activities	(35,470)	(11,105)	(5,529)
Financing activities			
Issuance of convertible notes payable	—	—	12,208
Issuance of notes payable, net of issuance costs	29,925	28,874	5,000
Restricted cash in connection with notes payable and corporate credit card	50	(2,000)	—
Principal payments on notes payable	(30,000)	(4,396)	(604)
Proceeds from issuance of preferred stock for cash, net of offering costs	—	15,991	30,867
Proceeds from initial public offering, net of offering costs	—	125,040	—
Proceeds from issuance of common stock	3,664	2,575	35
Net cash provided by financing activities	3,639	166,084	47,506
Net increase (decrease) in cash and cash equivalents	(93,209)	107,222	8,506
Cash and cash equivalents at beginning of period	124,385	17,163	8,657
Cash and cash equivalents at end of period	$ 31,176	$ 124,385	$ 17,163
Supplemental disclosures of cash flow information			
Interest paid	$ 3,369	$ 4,115	$ 297
Income taxes paid	$ 71	$ 19	$ 3
Supplemental schedule of noncash investing and financing activities			
Conversion of notes payable and accrued interest for Series D convertible preferred stock	$ —	$ —	$ 26,391
Lease incentive—lessor-paid tenant improvements	$ 1,604	$ —	$ 2,018
Loss on extinguishment of debt	$ —	$ —	$ 2,770
Common and preferred stock warrants issued, including incremental value of modification of warrants	$ —	$ 437	$ 3,815
Property and equipment included in accounts payable	$ 789	$ —	$ 200
Patent included in accrued expense	$ 74	$ —	$ —
Conversion of preferred stock warrants into common stock warrants	$ —	$ 9,550	$ —
Conversion of convertible preferred stock into common stock	$ —	$ 144,258	$ —

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

1. Organization and Basis of Presentation

The Company

Tandem Diabetes Care, Inc. is a medical device company focused on the design, development and commercialization of products for people with insulin-dependent diabetes. Unless the context requires otherwise, the terms the “Company” or “Tandem” refer to Tandem Diabetes Care, Inc.

The Company designed and commercialized its flagship product, the t:slim Insulin Delivery System, or t:slim, based on its proprietary technology platform and unique consumer-focused approach. The U.S. Food and Drug Administration (FDA) cleared t:slim in November 2011 and the Company commenced commercial sales of t:slim in the United States in August 2012. In January 2015, the Company received clearance from the FDA, to commercialize its next product, the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs. The Company intends to begin commercial sales of t:flex in the United States during the second quarter of 2015.

Tandem was originally incorporated in the state of Colorado on January 27, 2006 under the name Phluid Inc. On January 7, 2008, the Company was re-incorporated in the state of Delaware for the purposes of changing its legal name from Phluid Inc. to Tandem Diabetes Care, Inc. and changing its state of incorporation from Colorado to Delaware.

The Company has incurred operating losses since its inception and had an accumulated deficit of $248.7 million at December 31, 2014. The Company’s ability to achieve profitable operations primarily depends upon achieving a level of revenues adequate to support its cost structure. The Company has relied on its ability to fund its operations through private and public equity and debt financing. Management expects operating losses and negative cash flows to continue for the foreseeable future. The Company may elect to finance future operations using its existing term loan agreements or may pursue equity or debt financing through other sources. If necessary financing is not obtained or achieved, the Company will likely be required to reduce its current planned increases in expenditures, which could have an adverse impact on its ability to achieve its intended business objectives. There can be no assurance that equity or debt financing, beyond what is available under its existing term loan agreements, will be available on acceptable terms, or at all. Any equity financing may result in dilution to existing shareholders holders and any additional debt financing may include restrictive covenants.

Initial Public Offering

In November 2013, the Company completed its initial public offering of 8,000,000 shares of its common stock at a public offering price of $15.00 per share. Net cash proceeds from the initial public offering were approximately $108.3 million, after deducting underwriting discounts, commissions and estimated offering related transaction costs payable by the Company. In November 2013, the underwriters also exercised their overallotment option and purchased an additional 1,200,000 shares of the Company’s common stock, from which the Company received cash proceeds, net of underwriting discounts and commissions, of approximately $16.7 million. In connection with the closing of the initial public offering, all of the Company’s shares of convertible preferred stock outstanding at the time of the offering were automatically converted into 13,403,747 shares of common stock. In addition, all outstanding preferred stock warrants were automatically converted into warrants to purchase an aggregate 1,171,352 shares of our common stock (see Note 4, “Fair Value Measurements”).

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP.

Reverse Stock Splits

In October 2013, the Board of Directors approved a 1-for-1.6756 reverse stock split of the Company’s common stock. All share and per share information included in the accompanying financial statements and notes to the financial statements give retroactive effect to this reverse stock split for the Company’s common stock.

Voluntary Recall

On January 10, 2014, the Company announced a voluntary recall of select lots of cartridges used with t:slim that may have been at risk of leaking. The cause of the recall was identified during the Company's internal product testing. The recall was expanded on January 20, 2014 to include additional lots of affected cartridges used with t:slim. The Company incurred approximately $1.7 million in direct costs associated with the recall. The Company recorded a cost of sales charge of approximately $1.3 million in the fourth quarter of 2013 and recorded a cost of sales charge for the remainder in the first quarter of 2014 for affected cartridges shipped in 2014. The total cost of the recall consisted of approximately $0.7 million associated with the return and replacement of affected cartridges in the field and approximately $1.0 million for the write-off of affected cartridges within the Company's internal inventory. As of December 31, 2014, the FDA has determined that the recall is terminated and the Company does not currently expect any further direct financial impact of the recall beyond these costs.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes as of the date of the financial statements. Actual results could differ from those estimates and assumptions.

Segment Reporting

Operating segments are identified as components of an enterprise about which segment discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, we have viewed our operations and managed our business as one segment operating in the United States.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less from the date of purchase to be cash equivalents.

Short-Term Investments

Based on the nature of the assets, the Company's short-term investment are classified as either available-for-sale or trading securities. Such securities are carried at fair value as determined by prices for identical or similar securities at the balance sheet date. The Company's short-term investments consist of Level 1 and Level 2 financial instruments in the fair value hierarchy. The net unrealized gains or losses on available-for-sale securities, net of tax, are reported as a component of other comprehensive gain (loss) within the statements of operations and comprehensive gain (loss) as a separate component of stockholders' equity (deficit). Unrealized gains or losses on trading securities are reported in interest income. At December 31, 2014 and 2013, the Company had no investments that were classified as held-to-maturity. The Company determines the realized gains or losses of available-for-sale securities using the specific identification method and includes net realized gains and losses in interest income. The Company periodically reviews available-for-sale securities for other than temporary declines in fair value below the cost basis whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Restricted Cash

Restricted cash as of December 31, 2014 and 2013 was primarily composed of a $2.0 million minimum cash balance requirement in connection with the Capital Royalty Term Loan (see Note 6, "Loan and Warrant Agreements).

Accounts Receivable

We grant credit to various customers in the normal course of business. We maintain an allowance for doubtful accounts for potential credit losses. Generally, receivables greater than 120 days past due are deemed uncollectible. Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company maintains deposit accounts in federally insured financial institutions in excess of federally insured limits. The Company also maintains investments in money market funds that are not federally insured. Additionally, the Company has established guidelines regarding investment instruments and their maturities, which are designed to maintain preservation of principal and liquidity.

The following table summarizes customers who accounted for 10% or more of net accounts receivable:

	December 31,	
	2014	2013
Byram Healthcare	19.2%	N/A
Edgepark Medical Supplies, Inc.	12.3%	13.1%
CCS Medical, Inc.	N/A	21.4%

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

	December 31,		
	2014	2013	2012
Edgepark Medical Supplies, Inc.	16.0%	16.1%	19.3%
CCS Medical, Inc.	11.6%	13.6%	N/A
Byram Healthcare	10.9%	N/A	N/A
Solara Medical Supplies, Inc.	N/A	N/A	15.7%

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expense, and employee-related liabilities are reasonable estimates of their fair values because of the short-term nature of these assets and liabilities. Short-term investments are carried at fair value. Based on the borrowing rates currently available for loans with similar terms, the Company believes that the fair value of its long-term debt approximates its carrying value.

Inventory

Inventories are valued at the lower of cost or market (net realizable value), determined under the first-in, first-out method. Inventory is recorded using standard cost, including material, labor and overhead costs, at December 31, 2014 and 2013. The Company periodically reviews inventories for potential impairment based on quantities on hand, expectations of future use, judgments based on quality control testing data and assessments of the likelihood of scrapping or obsoleting certain inventories.

Long Lived Assets

Property and Equipment

Property and equipment, which primarily consist of office furniture and equipment, manufacturing equipment, scientific equipment, computer equipment, and leasehold improvements, are stated at cost. Property and equipment are depreciated over the estimated useful lives of the assets, generally three to seven years, using the straight-line method. Leasehold improvements are amortized over the lesser of the estimated useful lives of the assets or the remaining lease term.

Patents

Costs associated with the purchase or licensing of patents associated with our commercialized products are capitalized. The Company reviews its capitalized patent costs periodically to determine that they have future value and an alternative future use. Costs related to patents that the Company is not actively pursuing for commercial purposes are expensed. The Company amortizes patent costs over the lesser of the duration of the patent term or an estimated useful life of 10 years, beginning with the date the patents are issued or acquired.

The Company periodically re-evaluates the original assumptions and rationale utilized in the establishment of the carrying value and estimated lives of all of its long-lived assets, including property and equipment and acquired patents. The determinants used for this evaluation include management's estimate of the asset's ability to generate positive income from operations and positive cash flow in future periods as well as the strategic significance of the asset to the Company's business objective. The Company has not recognized any impairment losses through December 31, 2014.

Deferred Rent

Rent expense on noncancelable leases containing known future scheduled rent increases is recorded on a straight-line basis over the term of the respective leases beginning when the Company takes possession of the leased property. The difference between rent expense and rent paid is accounted for as deferred rent, current portion of deferred rent was included in other current liabilities on the Company's balance sheet. Landlord improvement allowances and other such lease incentives are recorded as property and equipment and as deferred rent and are amortized on a straight-line basis as a reduction to rent expense.

Research and Development Costs

All research and development costs are charged to expense as incurred. Such costs include personnel-related costs, including stock-based compensation, supplies, services, depreciation, allocated facilities and information services, collaboration payments and other indirect costs.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred income tax assets or liabilities are recognized based on the temporary differences between financial statement and income tax bases of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized.

The Company is required to file federal and state income tax returns in the United States and various other state jurisdictions. The preparation of these income tax returns requires the Company to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid by us. An amount is accrued for the estimate of additional tax liability, including interest and penalties, for any uncertain tax positions taken or expected to be taken in an income tax return. The Company reviews and updates the accrual for uncertain tax positions as more definitive information becomes available. For further information, see Note 8, "Income Taxes."

Revenue Recognition

Revenue is generated from sales, in the United States, of the t:slim pump, disposable cartridges and infusion sets to individual customers and third-party distributors that re-sell the product to insulin-dependent diabetes customers. The Company is paid directly by customers who use the products, distributors and third-party insurance payors.

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title passed, the price is fixed or determinable, and collectability is reasonably assured. These criteria are applied as follows:

- The evidence of an arrangement generally consists of contractual arrangements with distributors or direct customers.
- Transfer of title and risk and rewards of ownership are passed upon shipment of the pump to distributors or upon delivery to the customer.
- The selling prices are fixed and agreed upon based on the contracts with distributors, the customer and contracted insurance payors, if applicable. For sales to customers associated with insurance providers with whom there is no contract, revenue is recognized upon collection of cash at which time the price is determinable. The Company does not generally offer rebates to its distributors and customers.
- The Company considers the overall creditworthiness and payment history of the distributor, customer and the contracted insurance payor in concluding whether collectability is reasonably assured.

Prior to the first quarter of 2013, t:slim pump sales were recorded as deferred revenue until the Company's 30-day right of return expired because it did not have sufficient history to be able to reasonably estimate returns. At December 31, 2012, $1.9 million was recorded as deferred revenue. In the first quarter of 2013, the Company began recognizing t:slim pump revenue when all the revenue recognition criteria above were met, as it had established sufficient history in order to reasonably estimate product returns. As a result of this change, a one-time adjustment was recorded during 2013, to recognize previously deferred revenue and cost of sales of $1.9 million and $1.1 million, respectively.

Revenue Recognition for Arrangements with Multiple Deliverables

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

In February 2013, the FDA cleared t:connect, the Company's cloud-based data management application, which is made available upon purchase by t:slim pump customers. This service is deemed an undelivered element at the time of the t:slim sale. Because the Company has neither VSOE nor TPE for this deliverable, the allocation of revenue is based on the Company's ESP. The Company establishes its ESP based on estimated cost to provide such services, including consideration for a reasonable profit margin and corroborated by comparable market data. The Company allocates fair value based on management's ESP to this element at the time of sale and is recognizing the revenue over the four-year hosting period. At December 31, 2014 and 2013, $0.7 million and $0.2 million were recorded as deferred revenue for the t:connect hosting service, respectively. All other undelivered elements at the time of sale are deemed inconsequential or perfunctory.

Product Returns

The Company offers a 30-day right of return for its t:slim pump customers from the date of shipment, provided a physician's confirmation of the medical reason for the return is received. Estimated return allowances for sales returns are based on historical returned quantities as compared to t:slim pump shipments in those same periods. The return rate is then applied to the sales of the current period to establish a reserve at the end of the period. The return rates used in the reserve are adjusted for known or expected changes in the marketplace when appropriate. The allowance for product returns included in other current liabilities on the Company's balance sheet at December 31, 2014 and 2013 was $0.3 million and $0.2 million, respectively. Actual product returns have not differed materially from estimated amounts reserved.

Warranty Reserve

The Company generally provides a four-year warranty on its t:slim pump to end user customers and may replace any pumps that do not function in accordance with the product specifications. Any pump returned to the Company may be refurbished and redeployed. Additionally, the Company offers a six-month warranty on t:slim cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. Warranty costs are estimated based on the current expected replacement product cost, actual experience and expected failure rates from test studies performed in conjunction with the clearance of the Company's product with the FDA to support the longevity and reliability of its t:slim pump. The Company evaluates the reserve quarterly and makes adjustments when appropriate. During 2013, the Company recorded $0.5 million decrease in warranty estimates due to the first-time availability of refurbished pumps to be used for replacements. In addition, of the $1.1 million warranty reserve at December 31, 2013, $0.3 million was related to potential replacement related to the voluntary product recall of selected lots of cartridges. No reserve existed for the recall at December 31, 2014. Actual warranty costs have not differed materially from estimated amounts reserved.

(in thousands)	December 31, 2014	2013
Balance at beginning of the year	$ 1,123	$ 300
Provision for warranties issued during the period	3,709	3,515
Settlements made during the period	(2,858)	(2,182)
Decreases in warranty estimates	—	(510)
Balance at September 30, 2014	$ 1,974	$ 1,123
Current portion	535	549
Non-current portion	1,439	574
Total	$ 1,974	$ 1,123

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the employee's requisite service period on a straight-line basis. The Company estimates the fair value of stock options and shares issued to employees under the ESPP using a Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model requires the use of subjective assumptions including volatility, expected term, risk-free rate, and the fair value of the underlying common stock. For awards that vest based on service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures. Prior to the Company's initial public offering the estimated fair value of these awards was determined at the date of grant based upon the estimated fair value of the Company's common stock. Subsequent to the Company's initial public offering, the fair value of the common stock is based on observable market prices. As of December 31, 2014, there were no outstanding equity awards with market or performance conditions.

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

Warrant Liabilities

The Company issued freestanding warrants to purchase shares of common stock and convertible preferred stock in connection with the issuance of convertible notes payable in 2011 and 2012. The Company accounted for these warrants as a liability in the financial statements because either the Company did not have enough authorized shares to satisfy potential exercise of the common stock warrants and the number of shares to be issued upon their exercise was outside the control of the Company or because the underlying instrument into which the warrants are exercisable, Series C or Series D convertible preferred stock, contained deemed liquidation provisions that are outside of the control of the Company.

The warrants were recorded at fair value using either the Black-Scholes option pricing model, or a binomial lattice model, depending on the characteristics of the warrants at the time of the valuation. The fair value of these warrants was remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying statements of operations and comprehensive loss. In connection with completion of the initial public offering in November 2013, the Company performed the final remeasurement of the warrant liability. For the year ended December 31, 2013 and 2012, $9.0 million other expense and $2.6 million other income were recorded as other income (expense) from the revaluations, respectively. There was no income or expense recorded for warrant revaluations in 2014.

Upon the closing of the initial public offering, warrants to purchase shares of Series D Preferred Stock automatically converted into warrants to purchase shares of common stock. The Company reclassified the warrant liability to stockholders' equity as the warrants met the definition of an equity instrument.

Advertising Costs

The Company expenses advertising costs as they are incurred. For the years ended December 31, 2014, 2013 and 2012, advertising costs were $1.5 million, $0.7 million, and $68,000, respectively.

Shipping and Handling Expenses

Shipping and handling expenses associated with product delivery are included within cost of sales in the Company's statements of operations.

Comprehensive Loss

All components of comprehensive loss, including net loss, are reported in the financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares that were outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by dividing the net loss by the sum of the weighted-average number of dilutive common share equivalents outstanding for the period determined using the treasury stock method. Dilutive common share equivalents are comprised of convertible preferred stock, preferred stock warrants, common stock warrants, potential Employee Stock Purchase Plan (ESPP) awards, restricted common stock subject to repurchase and options outstanding under our stock plans. The calculation of diluted loss per share requires that, to the extent the average fair value of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of such securities are dilutive to loss per share for the period, adjustments to net loss used in the calculation are required to remove the change in fair value of the warrants for the period. Likewise, adjustments to the denominator are required to reflect the related dilutive shares. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to our net loss position and preferred stock warrants being anti-dilutive.

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

(in thousands)	**Year Ended December 31,**		
	2014	**2013**	**2012**
Convertible preferred stock outstanding	—	—	10,648
Warrants for convertible preferred stock	—	—	1,427
Warrants for common stock	1,007	1,358	—
Common stock options	2,233	4,539	—
Employee Stock Purchase Plan	128	138	—
Restricted common stock subject to repurchase	—	—	20
	3,368	6,035	12,095

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (“FASB”) issued an accounting standards update, which requires management of public and private companies to evaluate whether there are conditions and events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the financial statements are issued (or available to be issued, when applicable) and, if so, disclose that fact. Management will be required to make this evaluation for both annual and interim reporting periods, if applicable. Management is also required to evaluate and disclose whether its plans alleviate that doubt. The standard is effective for annual periods ending after December 15, 2016 and interim periods within annual periods beginning after December 15, 2016. The Company does not believe the adoption of this standard will have a material impact on its financial statement disclosures.

In May 2014, the FASB and the International Accounting Standards Board (“IASB”) issued a comprehensive new revenue recognition standard that will supersede existing revenue guidance under U.S. GAAP and International Financial Reporting Standards (“IFRS”). The standard’s core principle is that a company will recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In doing so, companies will need to use more judgment and make more estimates than under current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each separate performance obligation. The guidance is effective for annual periods beginning after December 15, 2016, including interim periods within that period. The Company is in the process of assessing the future impact of the adoption of the standard on its financial statements.

In April 2014, the FASB issued an accounting standards update, which includes amendments that change the requirements for reporting discontinued operations and require additional disclosures about discontinued operations. Under the new guidance, only disposals representing a strategic shift in operations - that is, a major effect on the organization's operations and financial results - should be presented as discontinued operations. Examples include a disposal of a major geographic area, a major line of business, or a major equity method investment. Additionally, the update requires expanded disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. The guidance is effective prospectively for fiscal years beginning after December 15, 2014 and interim periods within annual periods beginning on or after December 15, 2015. The Company does not believe the adoption of this standard will have a material impact on its financial position, results of operations or related financial statement disclosures.

3. Financial Statements Information

Short-term investments

The Company invests excess cash in investment securities, principally debt instruments of financial institutions and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at December 31, 2014 and 2013 (in thousands):

At December 31, 2014	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale investment securities:					
Commercial paper	Less than 1	$ 32,536	$ 9	$ —	$ 32,545
Government-sponsored enterprise securities	1 to 2	3,504	—	(1)	3,503
		$ 36,040	$ 9	$ (1)	$ 36,048
Trading securities:					
Mutual funds held for nonqualified deferred compensation plan participants		$ 56	$ 2	$ —	$ 58
Total		$ 36,096	$ 11	$ (1)	$ 36,106

At December 31, 2013	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale investment securities:					
Commercial paper	Less than 1	$ 5,095	$ —	$ —	$ 5,095
Total		$ 5,095	$ —	$ —	$ 5,095

Accounts Receivable

Accounts receivable consisted of the following at (in thousands):

	December 31, 2014	December 31, 2013
Accounts receivable	$ 7,905	$ 5,516
Less allowance for doubtful accounts	(253)	(217)
Total	$ 7,652	$ 5,299

Inventory

Inventory consisted of the following at (in thousands):

	December 31, 2014	December 31, 2013
Raw materials	$ 7,085	$ 6,363
Work in process	2,288	2,169
Finished goods	2,856	3,535
	12,229	12,067
Less: reserve	(316)	(1,737)
Total	$ 11,913	$ 10,330

The inventory reserve at December 31, 2013 included $0.9 million associated with the Company's voluntary product recall.

Property and Equipment

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

	December 31,	
	2014	2013
Leasehold improvements	$ 6,002	$ 4,120
Computer equipment and software	5,171	4,155
Office furniture and equipment	3,538	2,681
Manufacturing and scientific equipment	9,110	6,510
	23,821	17,466
Less accumulated depreciation and amortization	(11,240)	(7,580)
Total	$ 12,581	$ 9,886

Depreciation and amortization expense related to property and equipment amounted to $4.1 million, $2.8 million and $1.9 million for the years ended December 31, 2014, 2013 and 2012, respectively.

Intangible Assets Subject to Amortization

In July 2012, the Company entered into an agreement pursuant to which certain rights were granted to patents and patent applications. Included in these rights are patents related to the Company's commercialized products as well as patents that related to the products in development or future products. As consideration for these rights, the Company agreed to pay $5.0 million in license fees and a percentage of any associated sublicense revenues that may be received. To determine the fair value of the licensed and purchased intellectual property, the Company utilized a combination of royalty-relief and cost valuation approaches depending on the type of the patents. For the group of patents related to the commercialized products, the relief from royalty approach was utilized. Significant inputs in the valuation model included our projected revenues, estimated weighted average cost of capital, risk premium associated with the asset, and current market comparable royalty rates. For the patents associated with products in development, the cost approach was applied which utilized the costs associated with the filing and issuance of the patent to estimate the patent's fair value. The Company used the relative fair values to allocate the purchase price between the two groups of patents. The fair value associated with the patents related to the commercialized products of $3.2 million was capitalized and is amortized over the weighted average patent remaining life of 10 years. The fair value associated with the rest of the patents of $1.8 million was expensed at the time of the contract execution and is recorded in the selling, general and administrative expenses line item in the statement of operations as the associated patents did not relate to the commercialized product.

Intangible assets subject to amortization consist of patents purchased or licensed that are related to the Company's commercialized products. The following represents the capitalized patents at December 31, 2014 and 2013 (in thousands):

	December 31,	
	2014	2013
Gross amount	$ 3,247	$ 3,173
Accumulated amortization	(806)	(476)
Total	$ 2,441	$ 2,697
Weighted average remaining amortization period (in months)	90	102

Amortization expense related to intangible assets subject to amortization amounted to $0.3 million, $0.3 million and $0.2 million for the years ended December 31, 2014, 2013 and 2012, respectively. The amortization expense is recorded in the cost of sales line item in the statement of operations. The estimated annual amortization is $0.3 million for 2015 and periods thereafter.

4. Fair Value Measurements

Authoritative guidance on fair value measurements defines fair value, establishes a consistent framework for measuring fair value, and expands disclosures for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets.

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly.

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The following table presents information about the Company's financial assets measured at fair value on a recurring basis as of December 31, 2014 and 2013, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands):

		Fair Value Measurements at December 31, 2014 Using		
	December 31, 2014	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Cash equivalents (1)	$ 30,050	$ 30,050	$ —	$ —
Commercial paper	32,545	—	32,545	—
Mutual funds held for nonqualified deferred compensation plan participants (2)	58	58	—	—
Government-sponsored enterprise securities	3,503	—	3,503	—
Total assets	$ 66,156	$ 33,611	$ 32,545	$ —
Liabilities				
Deferred compensation (2)	$ 58	$ 58	$ —	$ —
Total liabilities	$ 58	$ 58	$ —	$ —

(1) Cash equivalents included money market funds and commercial paper with a maturity of three months or less from the date of purchase.
(2) Deferred compensation plans are compensation plans directed by the Company and structured as a Rabbi Trust for certain executives and non-employee directors. The investment assets of the Rabbi Trust are valued using quoted market prices. The related deferred compensation liability represents the fair value of the investment assets.

		Fair Value Measurements at December 31, 2013		
	December 31, 2013	Quoted Price in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets				
Money market funds	$ 115,112	$ 115,112	$ —	$ —
Commercial paper	5,095	—	5,095	—
Total assets	$ 120,207	$ 115,112	$ 5,095	$ —

There were no transfers between Level 1 and Level 2 securities during the years ended December 31, 2014 and 2013.

5. Convertible Notes Payable and Stock Warrants

2011 Convertible Notes Payable

In August 2011, the Company entered into a Note and Warrant Purchase Agreement (2011 Bridge Financing) with existing stockholders for an aggregate principal amount of approximately $13.0 million under unsecured convertible promissory notes. The convertible promissory notes bore interest at an annual rate of 8%, and all principal and interest were due and payable on March 31, 2012, unless earlier converted into preferred stock of the Company.

In connection with the 2011 Bridge Financing and for cash proceeds of $1,000 (0.01% of the principal amount of the convertible promissory notes), the Company issued warrants to purchase shares of common stock up to the number of shares calculated by dividing 25% of the principal amount of the convertible promissory notes by the lesser of the next qualified equity financing per-share price, or $44.00. The warrants' exercise price per share was $0.17. The warrants were immediately exercisable with an expiration in August 2021. The warrants' fair value of approximately $0.3 million was recorded as a debt discount and amortized to interest expense over the term of the convertible promissory notes using the effective interest method. The estimated number of common shares issuable under the warrants was 43,955, although the actual number was not fixed.

In March 2012, the Company extended the 2011 Bridge Financing maturity date to May 2012. No other terms were modified. The effective interest rate post-modification was less than the effective interest rate before modification and the Company concluded that this modification represented a troubled debt restructuring. The Company accounted for the modification on a prospective basis.

In May 2012, the 2011 Bridge Financing maturity date of the associated convertible promissory notes was extended to August 31, 2012. Additionally, the warrant coverage provided in association with the notes was increased from 25% to 40% of the principal amount of the convertible promissory notes, and the shares purchasable under the warrants were changed from common stock to preferred stock. The preferred stock warrants' exercise price was amended to $44.00 if exercised prior to the close of the next qualified equity financing, or by the per-share price of the next qualified equity financing if exercised after the close of the next qualified equity financing.

The present value of the future cash flows under the modified terms described above did not exceed the present value of the future cash flows under the original terms by more than 10%. The Company treated this amendment as a modification and the incremental increase in the fair value of the warrants resulting from the modification of approximately $1.2 million was recorded as a discount to the convertible promissory notes and amortized over the remaining term of the convertible promissory notes using the effective interest method. The estimated number of preferred stock shares issuable under the warrants at the time of modification was 117,842.

2012 Convertible Notes Payable

In May and July 2012, the Company entered into Note and Warrant Purchase Agreements (2012 Bridge Financing) with existing stockholders for an aggregate principal amount of approximately $12.2 million. The convertible promissory notes bore interest at an annual rate of 8%, and all principal and interest were due and payable on August 31, 2012, unless earlier converted into preferred stock of the Company.

In connection with the 2012 Bridge Financing, the Company issued warrants to purchase shares of preferred stock up to the number of shares calculated by dividing 40% of the principal amount of the convertible promissory notes by $44.00 if exercised prior to the close of the next qualified equity financing, or by the per-share price of the next qualified equity financing if exercised after the close of the next qualified equity financing. The warrants' exercise price was $44.00 if exercised prior to the close of the next qualified equity financing, or by the per-share price of the next qualified equity financing if exercised after the close of the next qualified equity financing. The warrants were immediately exercisable and with an expiration in May and July 2022.

The 2012 Bridge Financing was completed substantially with the same parties as the 2011 Bridge Financing. At the time of each 2012 convertible promissory note issuance, the Company performed a comparison of the present value of the future cash flows under the original 2011 Bridge Financing terms and amended 2011 Bridge Financing terms as impacted by the 2012 Bridge Financing and determined that the change was more than 10%. The Company accounted for the issuance of the 2012 Bridge Financing as a debt extinguishment, and accordingly recorded the 2011 and 2012 Bridge Financing convertible promissory notes at fair value. The loss on extinguishment of $2.8 million was recorded in the statement of convertible preferred stock and stockholders' equity (deficit) as a charge to additional paid-in capital in the period in which the extinguishment occurred as all these transactions were made with related parties. The amount in excess of additional paid-in capital was recorded into accumulated deficit. The loss on extinguishment was determined by calculating the difference between the net carrying amount of the extinguished debt (which includes principal, accrued interest, and unamortized discount, if any) and the fair value of the old and additional debt (which includes fair value of modified debt, fair value of additional warrants and any amendment related fees).

Conversion to Series D Preferred Stock

In August 2012, the Company completed the closing of a Series D financing, and all indebtedness under the 2011 Bridge Financing and 2012 Bridge Financing, aggregating approximately $26.4 million, including accrued interest, was automatically converted into shares of convertible Series D Preferred Stock at a per-share price equal to the per-share price of $4.40. All associated preferred stock warrants became warrants to purchase 2,288,316 shares of convertible Series D Preferred Stock at an exercise price of $4.40 per share.

In November 2013, in connection with the closing of the initial public offering, all associated warrants to purchase shares of Series D Preferred Stock automatically converted into warrants to purchase 1,171,352 shares of our Common Stock at a weighted average exercise price of $7.37 per share. As of December 31, 2014, there were 1,006,577 common stock warrants outstanding.

6. Loan and Warrant Agreements

Silicon Valley Bank Loan

In March 2012, the Company entered into a Loan and Security Agreement with Silicon Valley Bank, drawing a bridge loan in the amount of $5.0 million (“SVB Bridge Loan”). Subsequent to the closing of the Series D financing, the SVB Bridge Loan was converted into a 24-month term loan (“SVB Term Loan”) in September 2012. The term loan accrued interest at an annual rate of 4%, with principal and accrued interest payments due monthly throughout the 24 month term. The SVB Term Loan also required a final payment of $0.3 million and a fee of $0.2 million if the loan was prepaid in its entirety prior to the end of the term of the loan.

In connection with the SVB Bridge Loan and SVB Term Loan, the Company issued an aggregate of 102,270 shares of Series D convertible preferred stock at an exercise price of $4.40 per share. In November 2013, in connection with the closing of the initial public offering, all SVB Series D Preferred Stock warrants automatically converted into warrants to purchase 61,033 shares of our Common Stock at a weighted average exercise price of $7.37 per share. The warrants were exercised in the first quarter of 2014.

In conjunction with the Capital Royalty Term Loan closing in January 2013, all principal, interest due and pre-payment fee amounts due under the SVB Term Loan were paid by the Company.

SVB Revolving Line of Credit

In January 2013, the Company entered into an amended loan agreement with Silicon Valley Bank, making available a revolving line of credit in the amount up to the lesser of $1.5 million or 75% of eligible accounts receivable. Interest-only payments at a rate of 6% per annum are payable monthly through the maturity date 24 months from the initial borrowing. Loans drawn under the agreement would be secured by the Company’s eligible accounts receivable and proceeds therefrom. Additionally, the terms of the revolving line of credit contain various affirmative and negative covenants. There were no amounts outstanding under this loan as of December 31, 2014 and 2013. The SVB revolving line of credit expired unused in January 2015.

Capital Royalty Term Loan

In December 2012, the Company executed a term loan agreement with Capital Royalty Partners II L.P. and Capital Royalty Partners II—Parallel Fund “A” L.P., together, Capital Royalty Partners, providing the Company access to up to $45 million under the arrangement, of which $30 million was available in January 2013, and an additional amount up to $15 million was available upon achievement of a 2013 revenue-based milestone. In January 2013, $30 million was drawn under the Agreement. The loan accrued interest at an annual rate of 14%.

The loan is collateralized by all assets of the Company. Additionally, the terms of the Term Loan Agreement contain various affirmative and negative covenants agreed to by the Company. Borrowings under the term loan are subject to non-occurrence of a material adverse change in our business or operations (financial or otherwise), or a material impairment of the prospect of repayment of obligations.

In connection with the Term Loan Agreement, in January 2013, the Company issued warrants to purchase 271,834 shares of the Company's Common Stock at an exercise price of $0.02 per share. The warrants were immediately exercisable with an expiration in January 2023. Because the exercise price of these warrants was nominal, the Company used the fair value of the common stock of $1.61 at December 31, 2012 to value these warrants. The Company also paid $0.4 million financing fee to Capital Royalty Partners. The warrants' fair value of approximately $0.4 million and financing fee of $0.4 million were recorded as a debt discount. Additionally, the Company paid $0.7 million to a third party for sourcing the Capital Royalty Term Loan, which was recorded as debt issuance cost. All fees and warrants value are amortized to interest expense over the remaining term using effective interest method. The warrants were exercised in the second quarter of 2014.

In April 2014, the Company entered into an Amended and Restated Term Loan Agreement (the "Amended and Restated Term Loan Agreement") with the Lenders and other parties affiliated with Capital Royalty Partners. The Amended and Restated Term Loan Agreement primarily amended the terms of the Original Term Loan Agreement to reduce the borrowing limit to $30.0 million, to reduce the applicable interest rate from 14.0% to 11.5%, and to extend the interest only payment period from December 31, 2015 to March 31, 2018. Interest is payable, at the Company's option, (i) in cash at a rate of 11.5% per annum or (ii) 9.5% of the 11.5% per annum in cash and 2.0% of the 11.5% per annum added to the principal of the loan and is subject to accruing interest. Interest-only payments are due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period. Thereafter, in addition to interest accrued during the period, the quarterly payments shall include an amount equal to the outstanding principal at March 31, 2018 divided by the remaining number of quarters prior to the end of the term of the loan which is March 31, 2020. The Amended and Restated Term Loan Agreement provides for prepayment fees of 3% of the outstanding balance of the loan if the loan is repaid prior to March 31, 2015. The prepayment fee is reduced by 1% per year for each subsequent year until maturity.

Certain affirmative and negative covenants were also amended. The principal financial covenants require that the Company attain minimum annual revenues of $30.0 million in 2014, $50.0 million in 2015, $65.0 million in 2016, $80.0 million in 2017 and $95.0 million thereafter. At December 31, 2014, the Company was in compliance with all of the covenants and has met the minimum annual revenue threshold for 2014.

At December 31, 2014, the principal balance outstanding under the Capital Royalty Term Loan was $30.0 million. Borrowings under the Amended and Restated Term Loan Agreement were used to refinance amounts outstanding under the Original Term Loan Agreement. The present value of the future cash flows under the modified terms described above did not exceed the present value of the future cash flows under the original terms by more than 10%. The Company treated this amendment as a modification and the facility fee of approximately $0.1 million recorded as a discount to the Amended and Restated Term Loan. The facility fee and the remaining balance of debt issuance costs and debt discount of the Original Term Loan are amortized to interest expense over the remaining term of the Amended and Restated Term Loan using the effective interest method.

Concurrently, the Company also entered into a new Term Loan Agreement (the "New Tranche Term Loan Agreement") with the Lenders and other parties affiliated with Capital Royalty Partners, under which the Company may borrow up to an additional $30.0 million on or before March 31, 2015 at the same interest rate and on the same key terms as the Amended and Restated Term Loan Agreement.

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

Year ended December 31,		
2015	$	—
2016		—
2017		—
2018		11,250
2019		15,000
Thereafter		3,750
Total	$	30,000
Less current portion of notes payable		—
Notes payable, net of current portion	$	30,000

In February 2015, the Company amended its Amended and Restated Term Loan Agreement, as well as its New Tranche Term Loan Agreement. Pursuant to this amendment, the interest only payment period was extended to December 31, 2019 from March 31, 2018 at the same interest rate and on the same key terms as the existing agreements. The principal balance will be due in full at the end of the term of the loan which is March 31, 2020 (see Note 13 "Subsequent Events").

7. Stockholders' Equity (Deficit)

Convertible Preferred Stock

Prior to the conversion in the initial public offering in November 2013, the Company's convertible preferred stock was classified as temporary equity on the accompanying balance sheets instead of in stockholders' equity (deficit) in accordance with authoritative guidance for the classification and measurement of redeemable securities. Upon certain change in control events that were outside of our control, including liquidation, sale or transfer of control of the Company, holders of the convertible preferred stock could cause its redemption.

As of December 31, 2013, all outstanding convertible preferred stock had converted to common stock in conjunction with the initial public offering. Following its initial public offering, the Company filed an amended and restated certificate of incorporation to authorize 5,000,000 shares of undesignated preferred stock.

Common Stock

In November 2013, the Company completed its initial public offering of 8,000,000 shares of its common stock at a public offering price of $15.00 per share. Net cash proceeds from the initial public offering were approximately $108.3 million after deducting underwriting discounts, commissions and estimated offering related transaction costs payable by the Company. In November 2013, the underwriters also exercised their overallotment option and purchased an additional 1,200,000 shares of the Company's common stock, from which the Company received cash proceeds, net of underwriting discounts and commissions, of approximately $16.7 million. In connection with the closing of the initial public offering, all of the Company's shares of convertible preferred stock outstanding at the time of the offering were automatically converted into 13,403,747 shares of common stock. In addition, all outstanding preferred stock warrants were automatically converted into warrants to purchase an aggregate 1,171,352 shares of our common stock (see Note 4, "Fair Value Measurements").

As of December 31, 2014, there were 23,654,745 shares of common stock outstanding. Each share of common stock is entitled to one vote. The holders of the common stock are also entitled to receive dividends whenever funds are legally available and when declared by our Board of Directors. Following our initial public offering, we filed an amended and restated certificate of incorporation to authorize 100,000,000 shares of common stock.

Stock Plans

In September 2006, the Company adopted the 2006 Stock Incentive Plan (the "2006 Plan") under which, as amended, 2,685,605 shares of common stock were reserved for issuance to employees, non-employee directors and consultants of the Company.

The 2006 Plan provided for the grant of incentive stock options, non-statutory stock options, rights to purchase restricted common stock, stock appreciation rights, dividend equivalents, stock payments, and restricted stock units to eligible recipients. Recipients of incentive stock options and restricted common stock shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The 2006 Plan was closed in 2013 with the approval of the 2013 Stock Incentive Plan (the "2013 Plan") and no further options will be granted under the 2006 Plan.

In October 2013, the Company's board of directors approved the 2013 Plan. The 2013 Plan became effective immediately prior to the completion of the initial public offering. An initial 4,809,000 shares of common stock were reserved for issuance under the 2013 Plan. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock and restricted stock units to individuals who are then employees, officers, directors or consultants of the Company. Effective January 1, 2015, the shares available for issuance under the 2013 Plan were increased by 946,189 shares in accordance with an "evergreen" provision under the 2013 Plan.

As of December 31, 2014, 1,985,982 shares are available for future issuance under the 2013 Plan, and options to purchase 5,011,063 shares have been granted and are outstanding under the 2006 Plan and 2013 Plan.

Restricted Common Stock

The Company issued shares of restricted common stock totaling 23,872 shares in 2011. Proceeds from the issuance of the shares of restricted common stock totaled $0.2 million in 2011. The shares of restricted common stock were issued under the 2006 Plan to certain employees and nonemployee directors. Shares of restricted common stock granted under the 2006 Plan vested and were subject to repurchase according to the terms of the respective restricted stock agreement. Upon the closing of the initial public offering in November 2013, 11,935 shares of the Company's unvested restricted common stock were automatically vested.

Common Stock Options

The maximum term of stock options granted under the 2006 Plan and 2013 Plan is ten years. The options generally vest 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years.

The following table summarizes stock option transactions for the 2006 Plan and 2013 Plan:

	Total Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2012	135,902	$ 12.33	7.02	$ —
Granted	4,430,214	$ 7.92		
Exercised	(9,913)	$ 6.65		$ 118
Canceled/forfeited/expired	(16,587)	$ 4.71		
Outstanding at December 31, 2013	4,539,616	$ 8.07	9.49	$ 80,369
Granted	760,639	$ 21.26		
Exercised	(143,779)	$ 2.26		$ 1,959
Canceled/forfeited/expired	(145,413)	$ 12.10		
Outstanding at December 31, 2014	5,011,063	$ 10.20	8.62	$ 23,534
Vested and expected to vest at December 31, 2014	4,943,856	$ 10.15	8.62	$ 23,385
Exercisable at December 31, 2014	2,322,666	$ 5.86	8.32	$ 17,590

Employee Stock Purchase Plan

In October 2013, the Company adopted the 2013 Employee Stock Purchase Plan (the “ESPP”), which enables eligible employee to purchase shares of the Company’s common stock using their after tax payroll deductions, subject to certain conditions.

The ESPP initially authorized the issuance of 556,000 shares of common stock pursuant to purchase rights granted to employees. The number of shares of common stock reserved for issuance increases on January 1 of each calendar year, from January 1, 2014 through January 1, 2023, by the least of (a) one percent (1%) of the number of Shares issued and outstanding on the immediately preceding December 31, or (b) such lesser number of Shares as determined by the Administrator. On January 1, 2014, the number of shares of common stock reserved for issuance under our ESPP was automatically increased by 229,256 shares. On January 1, 2015, the number of shares of common stock reserved for issuance under our ESPP was automatically increased by an additional 236,547 shares. The ESPP is intended to qualify as an “employee stock purchase plan” within the meaning of Section 423 of the Code. As December 31, 2014, 251,390 shares of our common stock have been purchased under the ESPP and 533,866 shares remain available for issuance under the ESPP as of December 31, 2014.

Eligible employees may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of common stock under the ESPP. The purchase price of common stock under the ESPP will be the lesser of: (a) 85% of the fair market value of a share of the Company’s common stock on the first date of an offering or (b) 85% of the fair market value of a share of the Company’s common stock on the date of purchase. Generally, the ESPP consists of a two-year offering period with four six-month purchase periods.

Stock-Based Compensation.

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

	Year Ended December 31,		
	2014	2013	2012
Cost of sales	$ 1,317	$ 204	$ 36
Selling, general & administrative	11,886	3,583	148
Research and development	1,792	669	62
Total	$ 14,995	$ 4,456	$ 246

The total stock-based compensation capitalized as part of the cost of our inventory was $0.2 million and $0.3 million at December 31, 2014 and 2013, respectively.

At December 31, 2014, the total unamortized stock-based compensation expense of approximately $24.7 million will be recognized over the remaining vesting term of approximately 2.7 years.

Option grants to non-employees are valued using the fair-value-based method and are then quarterly re-measured and expensed over the period services are provided. For the years ended December 31, 2014 and 2013, the expense was $0.3 million and $0.1 million, respectively, and are included in the table above as component of selling, general and administrative expenses. Option grants to consultants resulted in an immaterial expense for the year ended December 31, 2012.

The Company estimates the fair value of stock options and shares issued to employees under the ESPP using a Black-Scholes option-pricing model on the date of grant. The fair value of equity instruments that are expected to vest are recognized and amortized on a straight-line basis over the requisite service period. The Black-Scholes option-pricing model incorporates various highly sensitive assumptions including expected volatility, expected term and risk-free interest rates.

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

	Stock Option		
	Year Ended December 31,		
	2014	2013	2012
Weighted average grant date fair value (per share)	$ 14.29	$ 7.52	$ 15.60
Risk-free interest rate	1.8%	1.4%	1.1%
Expected dividend yield	0.0%	0.0%	0.0%
Expected volatility	76.3%	79.0%	70.2%
Expected term (in years)	5.9	5.8	6.0

	ESPP	
	Year Ended December 31,	
	2014	2013
Weighted average grant date fair value (per share)	$ 6.86	$ 6.50
Risk-free interest rate	0.3%	0.2%
Expected dividend yield	0.0%	0.0%
Expected volatility	50.0%	66.3%
Expected term (in years)	1.3	1.3

Risk-free Interest Rate. The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

Expected Dividend Yield. The expected dividend yield is zero because we have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future.

Expected Volatility. Due to limited historical data, the expected volatility is estimated based on volatilities of a peer group of similar companies whose share prices are publicly available. The peer group consisted of other publicly-traded companies in the same industry and in a similar stage of development. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Expected Term. The Company utilized the simplified method for estimating the expected term of stock option grants. Under this approach, the weighted-average expected term is presumed to be the average of the vesting term and the contractual term of the option. The Company estimate the expected term of ESPP using expected life for each tranche during the two year offering period.

The Company is also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from its estimates. Historical data was used to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

Common Stock Reserved for Future Issuance

The following shares of common stock are reserved for future issuance at December 31, 2014:

Common stock warrants outstanding	1,006,577
Stock options issued and outstanding	5,011,063
Authorized for future option grants	1,985,982
Employee stock purchase plan	533,866
	8,537,488

8. Income Taxes

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

	Year Ended December 31,		
	2014	2013	2012
Tax at federal statutory rate	$ (27,065)	$ (21,467)	$ (11,225)
State income tax, net of federal benefit	(3,912)	(2,784)	(1,793)
Nondeductible convertible notes payable	—	3	617
Warrants revaluation	—	3,061	(869)
Research and development credits	(646)	(649)	209
Stock-based compensation	1,973	831	82
Other	355	(39)	73
Change in valuation allowance	29,366	21,044	12,906
	$ 71	$ —	$ —

Significant components of the Company's net deferred income tax assets at December 31, 2014 and 2013 are shown below (in thousands). A valuation allowance has been recorded to offset the net deferred tax asset as of December 31, 2014 and 2013, as the realization of such assets does not meet the more-likely-than-not threshold.

	December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss (NOL)	$ 69,600	$ 47,996
Research and development tax credits	2,934	2,349
Capitalized R&D	10,750	7,686
Deferred rent	154	119
Stock-based and Accrued Compensation	6,481	2,490
Other	3,272	3,188
Total gross deferred tax assets	93,191	63,828
Less valuation allowance	(93,191)	(63,828)
Net deferred tax assets	$ —	$ —

The California NOL carry forwards will expire as follows (in thousands):

Year ended December 31,	
2016	$ 624
2017	$ 2,052
Thereafter	$ 106,758

As of December 31, 2014, the Company has accumulated federal and state net operating loss carryforwards of approximately $177.2 million and $190.6 million, respectively. The federal and state tax loss carryforwards begin to expire in 2026 and 2016, respectively, unless previously utilized. The Company also has federal and California research credit carryforwards of approximately $2.8 million and $3.2 million, respectively. The federal research credit carryforwards will begin expiring in 2028 unless previously utilized. The California research credit will carry forward indefinitely.

Utilization of the net operating losses and R&D credit carryforwards are subject to annual limitations due to ownership change limitations that have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state and foreign provisions. These ownership changes may limit the amount of net operating losses and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percentage points of the outstanding stock of a company by certain stockholders.

The Company updated their Section 382/383 analysis, from January 1, 2012 through December 31, 2013, regarding the limitation of the net operating losses and research and development credits. Based upon the analysis, the Company determined that no ownership changes occurred during that period. The Company does not believe an ownership change has occurred through December 31, 2014. However, previous analysis determined that ownership changes have occurred in years prior to 2012, but will not have a material impact on the future utilization of such carryforwards.

The evaluation of uncertainty in a tax position is a two-step process. The first step involves recognition. The Company determines whether it is more likely than not that a tax position will be sustained upon tax examination, including resolution of any related appeals or litigation, based on only the technical merits of the position. The technical merits of a tax position derive from both statutory and judicial authority (legislation and statutes, legislative intent, regulations, rulings, and case law) and their applicability to the facts and circumstances of the tax position. If a tax position does not meet the more-likely-than-not recognition threshold, the benefit of that position is not recognized in the financial statements. The second step is measurement. A tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate resolution with a taxing authority.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits at the beginning and end of the years ended December 31, 2014 and 2013 (in thousands):

	Year Ended December 31,		
	2014	2013	2012
Gross unrecognized tax benefits at the beginning of the year	$ 1,912	$ 1,422	$ 779
Increases related to current year positions	476	349	176
Increases related to prior year positions	1,151	141	467
Expiration of unrecognized tax benefits	—	—	—
Gross unrecognized tax benefits at the end of the year	$ 3,539	$ 1,912	$ 1,422

As of December 31, 2014, the Company has $3.0 million of unrecognized tax benefits that, if recognized and realized would impact the effective tax rate.

The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on the Company's balance sheets and has not recognized interest and penalties in the statements of operations for the years ended December 31, 2014 and 2013. The Company does not expect any significant increases or decreases to its unrecognized tax benefits within the next 12 months.

The Company is subject to taxation in the United States and state jurisdictions. The Company's tax years from 2006 (inception) are subject to examination by the United States and state authorities due to the carry forward of unutilized net operating losses and research and development credits.

The American Taxpayer Relief Act of 2012 was enacted into law during the first quarter of 2013 and reinstated the United States federal research and development tax credit retroactively from January 1, 2012 through December 31, 2013. The effective tax rate for 2013 reflects a benefit of $0.4 million related to 2012 resulting from the retroactive extension of the United States research and development tax credit.

9. Collaborations

DexCom Development and Commercialization Agreement

In February 2012, the Company entered into a Development and Commercialization Agreement with DexCom, Inc. (DexCom Agreement) for the purpose of collaborating on the development and commercialization of an integrated system which incorporates the t:slim Insulin Delivery System with DexCom's proprietary continuous glucose monitoring system. Under the DexCom Agreement, the Company paid DexCom $1.0 million at the commencement of the collaboration in 2012, and an additional $1.0 million in 2014, upon the achievement of a PMA submission to the FDA. Both payments were recorded as research and development costs in their respective years. The Company will make one additional $1.0 million payment upon the achievement of certain milestones. Additionally, the Company will reimburse DexCom up to $1.0 million of its development costs and is solely responsible for its own development costs. As of December 31, 2014, the Company had reimbursed DexCom $0.2 million of its development costs. For the years ended December 31, 2014, 2013, and 2012, the Company recognized research and development costs of $32,000, $95,000, and $39,000, respectively.

Upon commercialization and as compensation for the non-exclusive license rights, the Company will also pay DexCom a royalty calculated at $100 per integrated system sold.

JDRF Collaboration

In January 2013, the Company entered into a research, development and commercialization agreement ("JDRF Agreement") with the Juvenile Diabetes Research Foundation ("JDRF") to develop the t:dual Infusion System, a first-of-its-kind, dual-chamber infusion pump for the management of diabetes. According to the terms of the JDRF Agreement, JDRF will provide research funding of up to $3.0 million based on the achievement of research and development milestones, not to exceed research costs incurred by the Company. Payments the Company receives to fund the collaboration efforts under the terms of the JDRF Agreement were recorded as restricted cash and current and long-term liabilities. The liabilities are recognized as an offset of research and development expenses straight-line over the remaining months until anticipated completion of the final milestone, only to the extent that the restricted cash is utilized to fund such development activities. The estimated completion date is re-evaluated each reporting period based on development progress through that date. As of December 31, 2014, we estimated the completion date to be September 2016.

As of December 31, 2014, milestone payment achievements totaled $0.7 million, and research and development costs were offset cumulatively by $0.4 million. The research and development costs were offset by $0.2 million and $0.2 million for the years ended December 31, 2014 and 2013, respectively. The Company did not have any restricted cash balances related to the JDRF Agreement at December 31, 2014 or 2013.

10. Employee Benefits

Employee 401(k) Plan

The Company has a defined contribution 401(k) plan for employees who are at least 18 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar quarter following their date of hire. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. The Company does not provide a matching contribution program.

Nonqualified Deferred Compensation Plan

On June 16, 2014, the Company's Board of Directors adopted and approved the Tandem Diabetes Care, Inc. Deferred Compensation Plan (the "Plan"). The Deferred Compensation Plan is a nonqualified deferred compensation program sponsored by the Company to provide its non-employee directors and certain of its management employees designated by the Board (or a committee appointed by the Board to administer the Plan) the opportunity to defer compensation under the Plan. The effective date for the Plan for the first year was July 1, 2014, and thereafter the plan year will be from January 1 to December 31.

There is no limit to the amount that a participant may defer under the Plan whether in a particular plan year or in aggregate. In the discretion of the Board (or a committee appointed by the Board to administer the Plan), the Company may make additional contributions to be credited to the account of any or all participants in the Plan. All contributions by the participant, and any contributions that may be made by the Company, will be immediately fully vested. As of December 31, 2014, the Company has not made any contributions.

Under the terms of the Plan, the Company has established a rabbi trust for the purpose of reserving any benefits that may become payable under the Plan. Distributions from the Plan will be governed by the Internal Revenue Code and the terms of the Plan. Company assets designated to pay benefits under the plan are held by a rabbi trust and are subject to the general creditors of the Company. The amounts deferred are invested in assets at the direction of the employee.

The assets and liabilities of the rabbi trust are recorded at fair value and are accounted for as assets and liabilities of the Company. As of December 31, 2014, the Company held $58,000 in deferred compensation plan assets in short-term investments on its balance sheet that were invested in mutual funds. The fair market value of the assets held in the Deferred Compensation Plan was based on unadjusted quoted prices in active markets. The Company carries a corresponding deferred compensation liability of $58,000 as of December 31, 2014 in other long-term liabilities on its balance sheet.

11. Commitments and Contingencies

From time to time, the Company may be subject to legal proceedings or regulatory encounters or other matters arising in the ordinary course of business, including actions with respect to intellectual property, employment, product liability, and contractual matters. In connection with these matters, the Company assesses, on a regular basis, the probability and range of possible loss based on the developments in these matters. A liability is recorded in the financial statements if it is believed to be probable that a loss has been incurred and the amount of the loss can be reasonably estimated. Because of the uncertainties related to the occurrence, amount, and range of loss on any pending actions, the Company is currently unable to predict their ultimate outcome, and, with respect to any pending litigation or claim where no liability has been accrued, to make a meaningful estimate of the reasonably possible loss or range of loss that could result from an unfavorable outcome. At December 31, 2014 and 2013, there were no material matters for which the negative outcome was considered probable or estimable.

Operating leases

In 2008, the Company entered into a noncancelable operating lease agreement to lease the Company’s corporate headquarters in San Diego, California, through August 2013.

In September 2009, the Company entered into a noncancelable operating lease agreement to expand the Company’s corporate headquarters to an adjacent building, as well as to extend the term of the aforementioned operating lease to co-terminate both leases in 2015.

In March 2012, the Company entered into a noncancelable operating lease agreement to increase the square footage of the Company’s corporate headquarters, as well as to consolidate all of the existing operating leases into a single lease agreement. The new agreement extends the term of the lease of all buildings to May 2017. Under the new lease, the monthly rent payments total approximately $0.1 million, excluding common area maintenance and related charges, and increase by a fixed percentage each year. Additionally, as a lease incentive from the landlord, the Company received a tenant improvement allowance of approximately $2 million for non-structural improvements to the building. The Company recorded this incentive as an increase to both property and equipment and deferred rent and it is amortized on a straight-line basis over the life of the lease.

In connection with the lease, the Company entered into a $0.4 million unsecured standby letter of credit arrangement with a bank under which the landlord of the building is the beneficiary. The standby letter of credit expired on March 31, 2013, but automatically extends for additional one-year periods unless notice of nonextension is provided. The final expiration of the standby letter of credit is August 31, 2017. The standby letters of credit previously entered into in connection with the pre-existing leases were canceled in March 2012.

On November 5, 2013, the Company entered into a noncancelable operating lease agreement to further extend the Company’s corporate headquarters to adjacent buildings (the “New Lease”), as well as to extend the term of the existing operating lease to terminate concurrently with the New Lease in 2019. There were no changes to the original lease payment schedule with the exception of extending the term for which the monthly rent would be increased by a fixed percentage each year on the anniversary of the rent commencement date of the New Lease.

Among the provisions of the New Lease, the monthly rent payments commenced in June 2014 and will increase by a fixed percentage each year on the anniversary of the rent commencement date. As a lease incentive from the landlord, the Company received a tenant improvement allowance of approximately $1.6 million for nonstructural improvements to the buildings. The Company recorded the incentives as increase to both property and equipment and deferred rent and it is amortized on a straight-line basis over the life of the lease.

In connection with the New Lease, the Company amended the existing standby letters of credit by increasing the value of the letter of credit to $0.5 million. The expiration of the standby letter of credit is July 14, 2019.

Deferred rent arising from rent escalation provisions and lease incentives totaled $3.4 million and $2.3 million at December 31, 2014 and 2013, respectively. Rent expense for the three years ended December 31, 2014 and 2013, was $2.1 million, $1.1 million, and $0.9 million respectively.

Future minimum payments under the aforementioned noncancelable operating leases for each of the five succeeding years following December 31, 2014 are as follows (in thousands):

2015	$ 2,555
2016	$ 2,815
2017	$ 2,924
2018	$ 3,024
2019	$ 1,275
Thereafter	$ —
	$ 12,593

12. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for fiscal 2014 and 2013 are presented in the following table, in thousands, except per share data:

	For the Quarter Ending			
	March 31	June 30	September 30	December 31
2014:				
Revenue	$ 8,066	$ 10,254	$ 13,513	$ 17,889
Gross profit	$ 867	$ 3,448	$ 4,396	$ 6,537
Operating expenses	$ 21,704	$ 21,766	$ 23,403	$ 24,039
Operating loss	$ (20,837)	$ (18,318)	$ (19,007)	$ (17,502)
Net loss	$ (21,961)	$ (19,197)	$ (19,901)	$ (18,465)
Basic and diluted net loss per share (1)	$ (0.96)	$ (0.83)	$ (0.85)	$ (0.78)
2013:				
Revenue	$ 5,458	$ 5,528	$ 7,776	$ 10,245
Gross profit	$ 2,040	$ 406	$ 2,533	$ 1,188
Operating expenses	$ 9,207	$ 14,083	$ 14,660	$ 17,651
Operating loss	$ (7,167)	$ (13,677)	$ (12,127)	$ (16,463)
Net loss	$ (11,163)	$ (15,301)	$ (13,061)	$ (23,613)
Basic and diluted net loss per share (1)	$ (53.77)	$ (72.50)	$ (60.96)	$ (2.14)

(1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per-share calculations will not necessarily equal the annual per share calculation.

13. Subsequent Event

In February 2015, the Company amended its Amended and Restated Term Loan Agreement, as well as its New Tranche Term Loan Agreement. Pursuant to this amendment, the interest only payment period was extended to December 31, 2019 from March 31, 2018 at the same interest rate and on the same key terms as the existing agreements. The principal balance will be due in full at the end of the term of the loan which is March 31, 2020.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of December 31, 2014, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2014.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principle financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2014, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013 Framework). Based on this assessment, our management concluded that, as of December 31, 2014, our internal control over financial reporting was effective based on those criteria.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the year ended December 31, 2014 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item and not set forth below will be set forth in the sections entitled “Election of Directors” and “Executive Officers” in our Proxy Statement for our 2015 Annual Meeting of Stockholders, or Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2014, and is incorporated herein by reference.

We have adopted a code of business conduct and ethics that applies to our Chief Executive Officer and other senior financial officers (our Chief Financial Officer, Vice President of Finance, Controller and other senior financial officers performing similar functions), which we refer to as the Code of Ethics (Senior Financial Officers). Our Code of Ethics (Senior Financial Officers) is designed to meet the requirements of Section 406 of Regulation S-K and the rules promulgated thereunder. We will promptly disclose on our website (i) the nature of any amendment to this Code of Ethics (Senior Financial Officers) that applies to any covered person, and (ii) the nature of any waiver, including an implicit waiver, from a provision of this Code of Ethics that is granted to one of the covered persons. We have also adopted a code of business conduct and ethics that applies to all of our directors and employees, which we refer to as the Code of Ethics (Directors and Employees). The Code of Ethics (Senior Financial Officers) and the Code of Ethics (Directors and Employees) are available on our website at www.tandemdiabetes.com under the Corporate Governance section of the Investor Center portion of the website. However, the information contained on or accessed through our website does not constitute part of this Annual Report, and references to our website address in this Annual Report are inactive textual references only.

Item 11. Executive Compensation

The information required by this item will be set forth in the section entitled “Executive Compensation” in our Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be set forth in the sections entitled “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation” in our Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be set forth in the sections entitled “Corporate Governance” and “Certain Relationships and Related Transactions” in our Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be set forth in the section entitled “Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report:

1. *Financial Statements.* The following documents are included in Part II, Item 8 of this Annual Report and are incorporated by reference herein:

2. *Financial Statement Schedules.* Financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. *Exhibits.*

Exhibit Footnote	Exhibit Number	Description of Document
(1)	3.1	Amended and Restated Certificate of Incorporation as currently in effect.
(1)	3.2	Amended and Restated Bylaws as currently in effect.
(1)	4.1	Form of Common Stock Certificate.
(1)	4.2	Third Amended and Restated Investor Rights Agreement, dated August 30, 2012.
(1)	4.3	Form of Preferred Stock Warrant issued to Silicon Valley Bank.
(1)	4.4	Form of Preferred Stock Warrant.
(1)	4.5	Warrant to Purchase Stock, dated January 14, 2013, issued to Capital Royalty Partners II L.P.
(1)	4.6	Warrant to Purchase Stock, dated January 14, 2013, issued to Capital Royalty Partners II—Parallel Fund "A" L.P.
(1)	10.1	Lease Agreement, dated March 7, 2012, as amended through November 7, 2013, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC.
(1)	10.2	Term Loan Agreement, dated December 24, 2012, by and between Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P. and Capital Royalty Partners II—Parallel Fund "A" L.P.
(3)	10.3	Amended and Restated Term Loan Agreement, dated April 4, 2014, by and between Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P. and Capital Royalty Partners II—Parallel Fund "A" L.P.
(3)	10.4	Term Loan Agreement, dated April 4, 2014, by and between Tandem Diabetes Care, Inc., Capital Royalty Partners, Capital Royalty Partners II—Parallel Fund "A" L.P, Capital Royalty Partners II (Cayman) L.P., Capital Royalty Partners II – Parallel Fund "B" (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.
(4)	10.5	Consent and Amendment Agreement, dated June 20, 2014, by and between Tandem Diabetes Care, Inc., Capital Royalty Partners II L.P., Capital Royalty Partners II—Parallel Fund "A" L.P., Capital Royalty Partners II (Cayman) L.P. and Parallel Investment Opportunities Partners II L.P.

Exhibit Footnote	Exhibit Number	Description of Document
(1)	#10.6	Tandem Diabetes Care, Inc. 2006 Stock Incentive Plan.
(1)	#10.7	Form of Stock Option Agreement under 2006 Stock Incentive Plan.
(1)	#10.8	Form of Restricted Stock Agreement under 2006 Stock Incentive Plan.
(1)	#10.9	Tandem Diabetes Care, Inc. 2013 Stock Incentive Plan.
(1)	#10.10	Form of Stock Option Agreement under 2013 Stock Incentive Plan.
(1)	#10.11	Form of Stock Option Agreement under 2013 Stock Incentive Plan (Non-Employee Directors).
(1)	#10.12	Tandem Diabetes Care, Inc. 2013 Employee Stock Purchase Plan.
(2)	#10.13	Tandem Diabetes Care, Inc. 2014 Cash Bonus Plan.
(1)	10.14	Form of Indemnification Agreement.
(1)	#10.15	Employee Offer Letter, dated July 8, 2013, by and between Tandem Diabetes Care, Inc. and David B. Berger.
(1)	#10.16	Employee Offer Letter, dated February 1, 2013, by and between Tandem Diabetes Care, Inc. and John F. Sheridan.
(1)	#10.17	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Kim D. Blickenstaff.
(1)	#10.18	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and John Cajigas.
(1)	#10.19	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Robert B. Anacone.
(1)	#10.20	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and John F. Sheridan.
(1)	#10.21	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and David B. Berger.
(1)	#10.22	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Susan M. Morrison.
(1)	†10.23	Confidential Intellectual Property Agreement, dated July 10, 2012, by and between Tandem Diabetes Care, Inc. and Smiths Medical ASD, Inc.
(1)	10.24	Lease Agreement, dated November 5, 2013, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC.
	#10.25	Tandem Diabetes Care, Inc. 2015 Cash Bonus Plan.
(1)	14.1	Code of Business Conduct and Ethics.
	23.1	Consent of Independent Registered Public Accounting Firm.
	24.1	Power of Attorney (included on the signature page)
	31.1	Certification of Kim D. Blickenstaff, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

Exhibit Footnote	Exhibit Number	Description of Document
	31.2	Certification of John Cajigas, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
	*32.1	Certification of Kim D. Blickenstaff, Chief Executive Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
	*32.2	Certification of John Cajigas, Chief Financial Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
	101.INS	XBRL Instance Document.
	101.SCH	XBRL Taxonomy Extension Schema Document.
	101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
	101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
	101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
	101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

# Indicates management contract or compensatory plan.

† Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to an application for confidential treatment sent to the Securities and Exchange Commission. Such portions are omitted from this filing and have been filed separately with the Securities and Exchange Commission.

(1) Filed as an exhibit to the registrant's Registration Statement on Form S-1 (File No. 333-191601) and incorporated herein by reference.

(2) Filed as an exhibit to the registrant's Annual Report on Form 10-K filed with the SEC on March 6, 2014.

(3) Filed as an exhibit to the registrant's Quarterly Report on Form 10-Q filed with the SEC on May 6, 2014.

(4) Filed as an exhibit to the registrant's Quarterly Report on Form 10-Q filed with the SEC on July 31, 2014.

* This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the registrant specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Tandem Diabetes Care, Inc.

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

Dated: February 24, 2015

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Kim D. Blickenstaff and John Cajigas, and each of them, his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/S/ KIM D. BLICKENSTAFF Kim D. Blickenstaff	President, Chief Executive Officer and Director (Principal Executive Officer)	February 24, 2015
/S/ JOHN CAJIGAS John Cajigas	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 24, 2015
/S/ LONNIE M. SMITH Lonnie M. Smith	Director and Chairman of the Board	February 19, 2015
/S/ DICK P. ALLEN Dick P. Allen	Director	February 24, 2015
/S/ EDWARD L. CAHILL Edward L. Cahill	Director	February 24, 2015
/S/ FRED E. COHEN Fred E. Cohen, M.D., D.Phil	Director	February 24, 2015
/S/ HOWARD E. GREENE, JR. Howard E. Greene, Jr.	Director	February 24, 2015
/S/ DOUGLAS A. ROEDER Douglas A. Roeder	Director	February 21, 2015
/S/ JESSE I. TREU Jesse I. Treu, Ph.D.	Director	February 24, 2015
/S/ CHRISTOPHER J. TWOMEY Christopher J. Twomey	Director	February 24, 2015

Exhibit 10.25

Tandem Diabetes Care, Inc.

2015 Cash Bonus Plan

The Tandem Diabetes Care, Inc. 2015 Cash Bonus Plan (the "***Bonus Plan***") has been designed to align plan participants with the business goals and strategies of Tandem Diabetes Care, Inc. ("***Tandem***" or the "***Company***") and to further the objectives of the Company's executive compensation program. This Bonus Plan is an important part of the Company's commitment to recognizing key employees who contribute to the achievement of important Company performance goals. Specifically, the objectives of the Bonus Plan are as follows:

- Attract, retain and reward highly skilled individuals, including executive officers, with the background and experience required for the Company's future growth and success by providing meaningful cash incentive payments to plan participants who are in a position to contribute significantly to Company success.

- Align the interests of plan participants with those of the Company's stockholders by tying a meaningful portion of their total compensation opportunity to the achievement of specific Company performance objectives, such as an annual revenue target.

- Together with base salary, long-term equity incentives and other components of compensation, create an appropriate balance of cash versus non-cash, and guaranteed versus at risk compensation opportunities.

Performance Period

The Bonus Plan is primarily intended to reward plan participants for their individual contributions to the Company's achievement with respect to Company performance objectives for the 2015 fiscal year. However, the Company's Board of Directors or the Compensation Committee of the Board of Directors (the "***Compensation Committee***") also has the discretion to consider individual or Company performance after December 31, 2015 and until the date of any actual bonus determination under the Bonus Plan in measuring performance and determining the amount of an award, if any, under the Bonus Plan.

Eligibility

Employees of the Company eligible for an award under this Bonus Plan will be limited to individuals serving as a Vice President or more senior management role within the Company, as determined by the Board of Directors or the Compensation Committee. If, following January 1, 2015, an individual is promoted or hired and becomes an eligible participant under the Bonus Plan at any time during the 2015 calendar year, then the individual will be eligible to participate under the Bonus Plan on a pro-rata basis, calculated in the reasonable discretion of the Compensation Committee, unless otherwise specifically provided by the Board of Directors or the Compensation Committee.

Bonus Opportunity

A target cash incentive amount (a "***Target Bonus Amount***") for each eligible plan participant will be set as a percentage of the participant's base salary. Cash incentives may be earned under the Bonus Plan based on the achievement of both financial performance objectives and product development objectives. The financial performance objectives will collectively represent 80% of the overall Target Bonus Amount and the product development objectives will collectively represent 20% of the overall Target Bonus Amount.

Company Product Development Milestones

The portion of the cash bonuses that relate to the Company product development milestones generally require the Company to submit regulatory filings or obtain regulatory clearance or approval for certain products under development, within specified time periods. Subject to the Committee's final discretion, an individual product development milestone must be achieved within a required time period for the applicable portion of the 2015 Cash Bonus Plan to be achieved. Overall goal achievement of the Company's product development milestones will be based on the portion of the product development milestones that the Company actually achieves during fiscal year 2015.

Financial Performance Objectives

The portion of the cash bonuses that relate to the Company financial objectives may be earned based on the Company's actual revenue for fiscal year 2015 as compared to a pre-established 2015 revenue target (the "***Revenue Target***"), provided the Company also achieves at least a minimum operating margin percentage (the "***Minimum Operating Percentage Target***"). Subject to the foregoing, the Company financial objective portion of the cash bonuses may be earned under the 2015 Cash Bonus Plan as follows:

- A minimum percentage growth rate over the Company's actual 2014 revenue, which places the Company's revenue for 2015 at 75% of the Revenue Target (the ***"Minimum Revenue Target"***), must be achieved for any bonus to be earned under the financial performance objectives portion of the 2015 Cash Bonus Plan.

- If the Company's actual revenues are between this Minimum Revenue Target and the Revenue Target, the goal achievement for the financial performance objectives will be calculated proportionately in a straight-line from 0% to 100%, respectively. If the Company's actual revenues exceed the Revenue Target, the goal achievement for the financial performance objectives will be calculated proportionately as a percentage of the Revenue Target.

Potential Incremental Bonus

If the Company's actual revenues are above 105% of the Revenue Target, and provided that the Company also achieves at least a secondary minimum operating margin percentage, then the 2015 Cash Bonus Plan has two levels of potential incremental overall goal achievement:

- If the Company's actual revenues are above 105% of the Revenue Target and up to 115% of the Revenue Target, the percentage of overall goal achievement under the 2015 Cash Bonus Plan will first be calculated as described above, and then for each percent of revenue achievement above 105% of the Revenue Target and up to 115% of the Revenue Target, an additional 1% will be added to the overall goal achievement under the 2015 Cash Bonus Plan, and the cash bonus will be calculated based on this modified level of goal achievement; or

- If the Company's actual revenues are above 115% of the Revenue Target of the Revenue Target, the percentage of overall goal achievement under the 2015 Cash Bonus Plan will first be calculated as described above, and then for each percent of revenue achievement above 105% of the Revenue Target, an additional 2% will be added to the overall goal achievement under the 2015 Cash Bonus Plan, and the cash bonus will be calculated based on this modified level of goal achievement.

Award Determination

Bonus payments under the Bonus Plan, if any, will be made at the discretion of the Board of Directors or the Compensation Committee. The financial performance component and product development component of the Bonus Plan may be earned independent of one another. If the Company does not achieve either the financial performance component or the product development component of the Bonus Plan, no payouts will be made unless the Board of Directors or the Compensation Committee, in their sole discretion, determine that there are other factors that merit consideration in the determination of bonus awards, which may be determined on an individual basis. All determinations and decisions made by the Compensation Committee and the Board of Directors pursuant to the provisions of the Bonus Plan shall be final, conclusive and binding on all persons, and shall be given the maximum deference permitted by law.

Payout and Administration

Payment of bonuses will be made as soon as practical after the end of the plan year, but not later than March 15, 2015. Participants must be actively employed at the time of payout to be eligible for any bonus payment. Only the Board of Directors may approve a payment under this Bonus Plan to the Company's Chief Executive Officer. The Board of Directors or the Compensation Committee may approve payments to any other eligible plan participant. The Board of Directors or the Compensation Committee can modify the Bonus Plan, including timing and form of payments, at any time in their sole discretion. Amounts payable under the Bonus Plan are intended to comply with the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations and thus be exempt from the provisions of Section 409A of the Internal Revenue Code of 1986, as amended. The Board of Directors and the Compensation Committee intend to administer the Bonus Plan in a manner consistent with this rule. Any amounts paid hereunder shall be subject to recoupment in accordance with The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company or as is otherwise required by applicable law.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-3 No. 333-200686 and Form S-8 No. 333-192406) of Tandem Diabetes Care, Inc. and in the related Prospectuses of our report dated February 24, 2015, with respect to the financial statements of Tandem Diabetes Care, Inc. included in this Annual Report (Form 10-K) for the year ended December 31, 2014.

/s/ Ernst & Young LLP

San Diego, California
February 24, 2015

Exhibit 31.1

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

I, Kim D. Blickenstaff, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Tandem Diabetes Care, Inc.

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

Dated: February 24, 2015

Exhibit 31.2

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

I, John Cajigas, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Tandem Diabetes Care, Inc.

By: */S/* John Cajigas
John Cajigas
Chief Financial Officer and Treasurer

Dated: February 24, 2015

Exhibit 32.1

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

In connection with the Annual Report on Form 10-K of Tandem Diabetes Care, Inc. (the "Company") for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kim D. Blickenstaff, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: February 24, 2015

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

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

Exhibit 32.2

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

In connection with the Annual Report on Form 10-K of Tandem Diabetes Care, Inc. (the "Company") for the year ended December 31, 2014, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John Cajigas, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Date: February 24, 2015

/S/ John Cajigas
John Cajigas
Chief Financial Officer and Treasurer

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