TANDEM DIABETES CARE INC
Form 10-K
March 06, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2013

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 x

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

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

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

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 x (Do not check if a smaller reporting company) Smaller reporting company ¨

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

As of June 30, 2013, the last business day of the registrant s most recently completed second fiscal quarter, the registrant s common stock was not listed for trading on any exchange or over-the-counter market and there was no established public market for the common stock. The common stock began trading on The NASDAQ Global Market on November 14, 2013. As of December 31, 2013, the aggregate market value of the registrant s common stock held by non-affiliates was approximately $284.2 million based on the closing price for the common stock of $25.77 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 28, 2014, there were 22,939,359 shares of the registrant s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive Proxy Statement for the 2014 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 Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements included or incorporated by reference in this Annual Report other than statements of historical fact, are forward-looking statements. You can identify these and other 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 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 of this Annual Report 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 except as required by law.

TRADEMARKS

As of December 31, 2013 our trademark portfolio contains seven pending U.S. trademark applications and seven pending foreign trademark applications, as well as 13 trademark registrations, including four U.S. trademark registrations and nine foreign trademark registrations. All other trademarks or trade names referred to in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus are referred to without the ® and symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto.

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PART I

Item 1. Business

Overview

We are a medical device company with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. 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. 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 has consisted of more than 6,000 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 all segments of the large and growing insulin-dependent diabetes market.

We developed t:slim to offer the specific features that people with insulin-dependent diabetes seek in a next-generation insulin pump. We designed it to have the look and feel of a modern consumer electronic device, such as a smartphone. It is the first and only insulin pump to feature a high resolution, color touchscreen. It 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. The touchscreen and intuitive software architecture make it easy to use, learn and teach, and to update the software without requiring any hardware changes. Similar to modern consumer electronic devices, t:slim incorporates colors, language, icons and feedback that consumers find intuitive to use. We offer a broad range of accessories allowing users to customize t:slim to their individual lifestyle and sense of style.

According to the American Diabetes Association, or ADA, in 2012 approximately 22.3 million people in the United States had diabetes. Close Concerns, Inc., an independent consulting and publishing company that provides diabetes advisory services, or Close Concerns, estimates that there are approximately 1.5 million people with type 1 diabetes in the United States and 4.5 million people with type 2 diabetes in the United States who require daily administration of insulin. Our target market consists of these approximately 6.0 million people in the United States who are insulin-dependent.

The U.S. Food and Drug Administration, or 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. For the years ended December 31, 2013 and 2012, our sales were $29.0 million and $2.5 million, respectively. For the years ended December 31, 2013 and 2012, our net loss was $63.1 million and $33.0 million, respectively. Our accumulated deficit as of December 31, 2013 was $169.2 million. Since the launch of t:slim, the number of units shipped has increased each quarter, and we have shipped approximately 7,500 pumps as of December 31, 2013. Based on customer surveys, the average age of our existing customers that have purchased t:slim is 33 years old, with relatively equal distribution between men and

women.

We believe we have an opportunity to rapidly increase sales by expanding our sales and marketing infrastructure, and by continuing to provide strong customer support. We expanded our sales, clinical and

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marketing organization from approximately 30 people as of December 31, 2012 to approximately 100 as of December 31, 2013. Beginning in January 2014 we have initiated a further expansion of our sales, clinical and marketing organization. We believe our recent and ongoing expansion will allow us to engage with more potential customers, their caregivers and healthcare providers to promote t:slim. By demonstrating the benefits of t:slim and the product and technology shortcomings of existing insulin therapies, we believe more people will choose t:slim for their insulin pump therapy needs, allowing us to further penetrate and expand the market. As of December 31, 2013, a significant percentage of our customers had converted from multiple daily injection to t:slim for their insulin therapy. We also believe we are positioned to address consumers needs in all segments of the insulin-dependent diabetes market with our development projects 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 to appeal to people who seek greater flexibility and discretion; and
- multiple hormone delivery through a single system.

Our headquarters and our manufacturing facility are located in San Diego, California and we employed 324 people as of December 31, 2013.

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 2012 more than 371 million people had diabetes worldwide and that by 2030, this will increase to 552 million people worldwide. According to the ADA, in 2012 approximately 22.3 million people in the United States had 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 injections to survive. According to Close Concerns, approximately 1.5 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 daily rapid-acting insulin therapy. According to Close Concerns, approximately 4.5 million people in the United States with type 2 diabetes are insulin-dependent.

Our target market consists of approximately 6.0 million people in the United States who require daily administration of insulin, which includes approximately 1.5 million people with type 1 diabetes and the approximately 4.5 million people with type 2 diabetes who are insulin-dependent. Throughout this Annual Report, we refer to people with type 1 diabetes and people with type 2 diabetes who are insulin-dependent as people with insulin-dependent diabetes.

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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.

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According to the American Association of Diabetes Educators, insulin pump therapy is considered the gold standard of care for people with insulin-dependent diabetes. It has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. The following chart illustrates some of the key advantages and disadvantages of using MDI therapy versus insulin pump therapy:

Comparison of MDI Therapy vs. Insulin Pump Therapy

Therapy	Advantages	Disadvantages
Multiple Daily Injection or MDI	Less training and shorter time to educate	Requires injections up to seven times per day
	Does not tether the user to a device	Delivers insulin less accurately than insulin pumps
	Lower upfront and ongoing supply costs	Results in greater variability in blood glucose levels or less accurate glycemic control
	Lower risk of technological malfunction	
		Requires more planning around and restrictions regarding meals and exercise
Insulin Pump	Eliminates individual insulin injections	Requires intensive education on insulin pump therapy and management
	Delivers insulin more accurately and precisely than injections	Wearing a pump can be bothersome
		Can be more costly
	Often improves HbA1c, a common measure of blood glucose levels over time	
		Risk of diabetic ketoacidosis if the catheter comes out and insulin infusion is interrupted
	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

According to Close Concerns, more than 400,000 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 75,000 people with type 2 diabetes in the United States use an insulin pump, or less than 2% of the type 2 diabetes population who are insulin-dependent. Close Concerns also estimates that there are approximately 25,000 people in the United States who begin using insulin pump therapy each year, representing a 5% annual increase in pump use. In 2012, the U.S. insulin pump market was approximately $1.2 billion.

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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 6,000 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 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 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.

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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 greatly limited the adoption of pump therapy. By addressing these issues, there is a meaningful opportunity to not only address 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 useability 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. We designed our flagship product, t:slim, to 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 t:slim s aesthetically-pleasing, modern design addresses the embarrassing appearance-related concerns of insulin pump users. Key product features such as a high-resolution, color

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touchscreen with shatter-resistant glass, aluminum casing and rechargeable battery, make our product unique in the insulin pump market. In addition, we designed a broad range of accessories allowing users to customize t:slim 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. With its narrow profile, similar to many smartphones, t:slim can easily and discreetly fit into a pocket. Its size and shape were designed to provide increased flexibility with respect to how and where the pump can be worn. Based on extensive consumer input during development, we believe t:slim addresses both the embarrassment and functionality concerns related to the size and inconvenience of carrying a traditional pump.

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 t:slim directly from the Home Screen. Insulin pump users can quickly learn how to efficiently navigate t:slim 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.

t:slim Insulin Delivery System

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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 pump mechanism. 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

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

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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 with respect to insulin volume capacity, integrated CGM solutions, further device miniaturization 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. We intend to pursue the following business strategies:

Advance our platform of innovative, consumer-focused products to address the unmet needs of people in all segments of 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 all segments of the large and growing insulin-dependent diabetes market.

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

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.

Expand our sales and marketing infrastructure to drive adoption of our products. Despite a limited sales force, we have been able to achieve commercial success since our launch. Our sales and marketing infrastructure is scalable, and we have initiated an expansion and will continue to invest in the expansion of this infrastructure to increase our access to people with diabetes, their caregivers and healthcare providers. We believe that investment in our sales and marketing 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 t:slim 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 a fully-automated manufacturing process for our disposable cartridges. With our existing

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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 also allows easy 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. t:slim is the first and only insulin pump 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 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.

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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. 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 and effectively.

Marketed Products

t:slim Insulin Delivery System

The t:slim Insulin Delivery System is comprised of the t:slim Pump, its disposable 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

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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: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 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.

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We developed t:connect to be intuitive, with the same consumer-focused approach utilized in the development of t:slim. 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 t:slim holds 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

We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products targeted at all segments of the insulin-dependent diabetes market.

t:flex Insulin Pump

The t:flex Insulin Pump, or t:flex, is designed for individuals who require more than 300 units of insulin over a typical three day cycle, which will make it the largest reservoir size currently available. t:flex incorporates the same product platform, technology and user interface as t:slim, but will offer a 480 unit cartridge. Utilizing this larger cartridge, people who require large doses of insulin, such as teenage boys with type 1 diabetes and people with type 2 diabetes, will receive the advantages associated with insulin pump therapy without having to replace disposable insulin cartridges as frequently as they would with a 300 unit cartridge.

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 1 diabetes who require large doses of insulin, or people with type 2 diabetes who require insulin. We believe that offering a 480 unit cartridge will address the typical insulin needs of a person with type 2 diabetes who is insulin-dependent. Our research has also shown that the appearance of traditional pumps is another deterrent to pump adoption. 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. As a result, we believe t:flex provides us with an opportunity to expand the current insulin pump market.

Based on feedback from our previous discussions with the FDA, we currently intend to file a 510(k) submission for t:flex in mid 2014.

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t:sensor Insulin Pump and 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:sensor Insulin Pump with an integrated CGM System, or t:sensor, will incorporate the same pump technology and user interface as t:slim. We intend to market the t:sensor product under the t:slim G4 brand name. 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:sensor.

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 5% to 10% of people with type 1 diabetes use CGM. We believe the DexCom G4 PLATINUM, which is not currently commercially available integrated with an insulin pump in the United States, is the most accurate and easy-to-use CGM technology on the market. We believe that CGM utilization will be significantly increased by offering an accurate CGM sensor in combination with an innovative and consumer-focused insulin pump, such as t:slim.

We held a pre-submission discussion with the FDA in the fourth quarter of 2013. Based on feedback from this discussion, we anticipate submitting a pre-market approval, or PMA application for t:sensor with the FDA in the second quarter of 2014. We expect the application will reference the PMA-approved DexCom G4 PLATINUM and the 510(k)-cleared t:slim, and provide information regarding the safety and effectiveness of t:sensor. The PMA application will also include t:connect, which will allow users to view data retrieved from the t:sensor on the user s computer.

t:sport Insulin Delivery System

The t:sport Insulin Delivery System, or t:sport, will utilize our platform technology to create a pump that is smaller than t:slim. t:sport is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. We anticipate it will include a wireless, touchscreen controller and a small, water-proof insulin pump. We also anticipate that the controller, such as a mobile device, will communicate wirelessly to the pump, and potentially receive and display CGM information.

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.

Current insulin pumps only offer one hormone, while the human pancreas produces several hormones in addition to insulin. We believe that an infusion pump that is capable of simultaneously delivering two or more natural or synthetic hormones will be an important step forward in the development of an artificial pancreas system. JDRF is supporting a portion of the development costs through performance-based milestone funding to complete the development, testing and manufacturing of t:dual.

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Sales and Marketing

Our sales and marketing objectives are to:

- generate demand and acceptance for t:slim 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, 2013, we had a sales, clinical and marketing team of approximately 100 employees. Since January 2014 we have continued to further expand our sales, clinical and marketing organization and anticipate scaling the organization to 60 territories by the end of the second quarter of 2014. 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, 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, 2013, we had executed agreements with 32 independent distributors. 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. For 2012, Edgepark Medical Supplies, Inc. accounted for 19.3% of our sales and Solara Medical Supplies Inc., an independent distributor, accounted for 15.7% of our sales. 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.

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; and

our Demonstration Unit Program, through which we provide healthcare professionals with a t:slim for pump demonstrations to their patients.

Consumer-focused initiatives. We sell t:slim 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 t:slim as an innovative, consumer-focused insulin pump with a unique Micro-Delivery Technology, slim touchscreen design and intuitive user interface. Some of our recent consumer-focused marketing initiatives include:

participation at consumer-focused regional diabetes conferences and events including the JDRF Research Summit, the American Diabetes Association Expo, Children With Diabetes Friends for Life Conference and Taking Control Of Your Diabetes, or TCOYD, Conference;

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redesign of our website 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 TCOYD, Insulin dependence and Diabetes Education & Camping Association; and

community diabetes fundraising and awareness events.

Branding. We developed our comprehensive branding strategy to engage consumers and communicate our identity as a modern and progressive company that works in tandem with the diabetes community, healthcare providers, our employees and business partners. We strive to embody this through our product offerings, marketing efforts and interactions throughout our business. Our product names are 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.

With t:slim s intuitive user interface, we believe healthcare providers will be able to train people to use our pump more efficiently and effectively and have a higher degree of confidence that users can successfully operate it, including t:slim s more advanced features. In addition, the intuitive nature of t:slim 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 t:slim. In other cases, a member of our clinical team will conduct t:slim training one-on-one with the customer. We have also established a network of independent, licensed certified diabetes educators who have been certified to train on t:slim 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 t:slim to result in fewer calls from users requesting support from our technical services team or their healthcare provider.

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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. t:slim is 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 t:slim 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. Our products are described by 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. In fact, in recent years, Medicare has revised the relevant fee schedule with slight increases to the reimbursement codes that describe our products. However, Medicare has also 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 some uncertainty as to the future Medicare reimbursement rate for our current and future products.

As of December 31, 2013, we had entered into commercial contracts with 56 national and regional third-party payors to establish reimbursement for t:slim, its disposable cartridges and other related supplies. We employ a team of managed care managers who are responsible for negotiating and securing contracts with third-party payors throughout the United States. For the year ended December 31, 2013, approximately 22% 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, 2013, we had executed distributor agreements with 32 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.

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We utilize a semi-automated manufacturing process for our pump products and a fully-automated manufacturing process for our disposable cartridges. The pump production line requires 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. t:slim cartridges are manufactured on an automated 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.

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 t:slim. 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.

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:sensor 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 will make two additional $1.0 million payments upon the achievement of certain development 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

February 1, 2015, with automatic one-year renewals. Prior to the commercial

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launch of t:sensor, 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:sensor, 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, 2013, 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. The agreement runs until our receipt of the final milestone payment, which is anticipated to be in 2015. 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.

In addition to our product development efforts, we also have collaborated with leading researchers at facilities such as the University of Virginia, Boston University, Massachusetts General Hospital and Stanford University to advance development of a fully automated artificial pancreas solution. An artificial pancreas system is 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. We believe an artificial pancreas can be achieved 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.

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, 2013, our patent portfolio consisted of approximately 20 issued U.S. patents and 58 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 have licensed 31 other U.S. patents and patent applications owned by Smiths Medical ASD, Inc., or Smiths Medical, under the terms of an agreement described below. We also have seven pending U.S. trademark applications and seven pending foreign trademark applications, as well as 13 trademark registrations, including four U.S. trademark registrations and nine 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, 2013, we had paid $3.0 million of such license fees and have not

entered into any sublicense agreements.

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Our development and commercialization agreement with DexCom provides us with a non-exclusive license to integrate the DexCom G4 PLATINUM into t:sensor. 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

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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. t:sensor is expected to be considered a Class III device that requires a PMA application.

We obtained 510(k) clearance for t:slim, in November 2011. 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.

We held discussions with the FDA in the second quarter of 2013 regarding the appropriate regulatory route for obtaining clearance for t:flex, and accordingly, we currently intend to file a 510(k) submission for this device in mid 2014.

We held discussions with the FDA in the fourth quarter of 2013 regarding the appropriate regulatory requirements for obtaining approval for t:sensor. Based on these discussions, we anticipate filing a PMA application with the FDA for this device that will reference the PMA approved DexCom G4 PLATINUM and our 510(k) cleared t:slim during the second quarter of 2014. The PMA will also need to incorporate support for the additional functionality of t:connect to support t:sensor. The application will provide new information on how these devices interface with each other, 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.

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

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

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

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;

patient follow-up is not at the rate expected;

patients experience adverse side effects;

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

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

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

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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 the 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 the Company s internal product testing and related to a certain piece of equipment used to test cartridges after they are manufactured. We believe that we have modified our cartridge testing process to prevent this issue from occurring in the future.

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 February 28, 2014 we

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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. 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 we or our educators 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.

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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

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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 may 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

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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, 2013, we had 324 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. Our filings may also be read and copied at the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an internet site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

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Item 1A. Risk Factors

An investment in our common stock involves risks. You should consider carefully the risks described below, together with all of the other information included in this Annual Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results and prospects. Certain statements below are forward-looking statements. For additional information, see the information included under the heading 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, 2013, we had an accumulated deficit of $169.2 million. To date, we have financed our operations primarily through sales of equity securities, a debt financing with Capital Royalty Partners, and limited 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, 2013, our gross profit was $6.2 million. 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 at least the next several years.

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 began to commercialize t:slim, 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;

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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 the 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 t:slim 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 achieving and maintaining market acceptance. In order for us to sell t:slim 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 t:slim 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 t:slim as compared to competitive products. If we are not successful in convincing existing and potential customers of the benefits of t:slim, or if we are not able to achieve the support of caregivers and healthcare providers for t:slim, our sales may decline or we may fail to increase our sales in line with our forecasts.

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

the failure of t:slim 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 t:slim over competitive products or other currently available insulin treatment methodologies;

perceived risks associated with the use of t:slim 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

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

In addition, t:slim 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 the 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 t:slim 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.

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If t:slim does 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 projected amounts, 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 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 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. 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 56 national and regional third-party payors in the United States. While we anticipate entering into additional contracts with third-party payors, 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 t:slim. Failure to secure or retain adequate coverage or reimbursement for t:slim 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.

Furthermore, 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 t:slim 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 we have, 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. t:slim competes directly with a number of

traditional insulin pumps as well as other methods for the treatment of diabetes. 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

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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.

These competitors also 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 recently approved 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 existing 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 render t:slim obsolete altogether, which would significantly reduce our sales.

Because of the size of the insulin-dependent diabetes market, 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 may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products. If a competitor develops a product that competes with or is perceived to be superior to t:slim, or if a competitor employs strategies that place downward pressure on pricing within our industry, our sales may decline significantly or may not increase in line with our forecasts, either of which would materially 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

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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, 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 derive nearly all of our revenue from the sale of t:slim and pump-related supplies and we expect that this will continue for the next several years 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 the ability of our diabetes educators to train new customers on the use of t:slim. 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 t:slim. 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 quickly 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 retain the individuals who make up those networks. If any of our sales, marketing or clinical representatives were to leave us, our sales could be adversely affected. If a sales, marketing or clinical representative were to depart and be retained by one of our competitors, we may fail to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. In addition, 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, which could delay new sales and harm our reputation.

As we increase our sales, marketing and clinical expenditures with respect to existing or planned products, we will need to further expand the reach of our sales, marketing and clinical networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales, marketing and clinical representatives with significant industry-specific knowledge in various areas, such as diabetes treatment techniques and technologies, as well as the competitive landscape for our products. Recently hired sales representatives require training and take time to achieve full productivity. If we fail to train recent hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales. In addition, the expansion of our sales, marketing and clinical personnel will continue to place significant burdens on our management team.

If we are unable to expand our sales, marketing and clinical capabilities, 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 forecasts.

Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with t:slim. 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, 2013, approximately 69% of our sales were generated through 32 independent distributors. While we expect that the percentage of our sales generated from independent

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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 generated by independent distributors for the foreseeable future. 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, 2013, our two largest independent distributors comprised approximately 30% 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, t:slim is 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 t:slim, 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 t:slim. 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

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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 and began commercializing t:slim in the third quarter of 2012. 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;

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 reduce our gross margins and negatively affect our operating results.

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 or on commercially reasonable terms;

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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;

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, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. 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 and of our potential future products. 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. 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

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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 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 facility in a single location, and any disruption at this facility could adversely affect our business and operating results.

Our principal offices are presently located in three contiguous 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 facility, 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 our 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;

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

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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.

The product 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. This 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. Further, 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. 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.

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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 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 us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

For example, we have entered into 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:sensor during the term of the agreement. This agreement runs until February 1, 2015, with automatic one-year renewals. The license granted covers the United States and other territories may be added from time to time. Subject to payments of certain of the non-terminating party s development expenses, the agreement may be terminated by either party without cause. Termination of this agreement could require us to redesign t:sensor and attempt to integrate an alternative CGM system into t:sensor, which would require significant development and regulatory activities that might delay the launch and commercialization of this product or, following its launch, might not be completed in time to prevent an interruption in the availability of t:sensor to our customers. For additional information, see Business Research and Development.

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.

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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 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, 2012 and December 31, 2013 our employee base has nearly doubled and we expect to continue to experience rapid growth of our employee base during 2014. 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.

In addition, the sale of our products is logistically complex, requiring us to maintain an extensive sales, marketing and clinical infrastructure consisting of sales representatives, clinical diabetes educators and customer support personnel.

We face considerable challenges in recruiting, training, managing, motivating and retaining the members of these teams, including managing geographically dispersed efforts. These challenges are exacerbated by the fact that our strategic plan requires us to rapidly grow our sales, marketing and clinical infrastructure in order to generate demand for our products. If we fail to maintain and grow a dedicated team of sales and marketing and clinical personnel, we could fail to take advantage of an opportunity to enhance brand recognition and grow sales, and our business, financial condition and operating results could be adversely affected.

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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.

Risks Related to our Financial Results and Need for Financing

We will need to generate significant sales to achieve profitable operations.

We intend to increase our operating expenses substantially in connection with the continued growth of our sales and marketing infrastructure, our ongoing research and development activities, the expansion of our manufacturing capabilities, and the commensurate development of our management team, administrative functions and facilities. We will need to generate significant sales to achieve profitability, and we might not be able to do so. Even if we do generate significant sales, we might not be able to achieve, sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we have forecasted, or if our operating expenses exceed our expectations, our financial performance and results of operations will be adversely affected.

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, 2013, we had $124.4 million in cash and cash equivalents. We believe that our available cash, 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 18 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, especially in light of the recent commercialization of t:slim, and actual sales may not be in line with our forecasts. As a result, we may be required 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 any other future products that we may develop and commercialize;
- the costs associated with expanding our sales and marketing infrastructure;
- the expenses we incur in maintaining our manufacturing facility and adding further 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 regulatory requirements;

expenses we incur in connection with potential litigation or governmental investigations;

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anticipated or unanticipated capital expenditures; and

unanticipated general and administrative expenses.

As a result of these and other factors, we do not know whether and 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. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, 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. Although we have a very limited operating history, there has been and there may continue to be meaningful variability in our operating results among quarters, 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, and 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.

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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 unanticipated quarterly losses. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, 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, 2013, we owed an aggregate principal amount of $30 million to Capital Royalty Partners pursuant to a term loan agreement. Under the agreement, we have the ability to draw up to an additional $15 million provided we are in compliance with the terms of the loan agreement up until May 30, 2014. 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 agreement with Capital Royalty Partners, we may not be allowed to draw additional amounts under the agreement, and we may be required to repay any outstanding amounts earlier than anticipated.

Our existing term loan agreement contains restrictive and financial covenants that may limit our operating flexibility.

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

Prolonged negative economic conditions could adversely affect us, our customers and suppliers, which could harm our financial condition.

We are subject to the risks arising from adverse changes in general economic and market conditions. Uncertainty remains in the U.S. economy as it continues to recover from a severe economic recession. The U.S. economy continues to experience market volatility, difficulties in the financial services sector, diminished liquidity and

availability of credit, reduced property values, concerns regarding inflation, increases in the cost of commodities, continuing high unemployment rates, reduced consumer spending and consumer confidence, and

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continuing economic uncertainties. The economic turmoil and the uncertainty about future economic conditions could negatively impact our existing and potential customers, adversely affect the financial ability of health insurers to pay claims, adversely impact our expenses and ability to obtain financing of our operations, and cause delays or other problems with key suppliers. We cannot predict the timing or impact of the recovery from this economic uncertainty.

Healthcare spending in the United States has been, and is expected to continue to be, negatively affected by the recent recession and continuing economic uncertainty. For example, patients who have lost their jobs or healthcare coverage may no longer be covered by an employer-sponsored health insurance plan, and patients reducing their overall spending may eliminate healthcare-related purchases. The recent recession and continuing economic uncertainty has also impacted the financial stability of many private health insurers. As a result, we believe that some insurers are scrutinizing insurance claims more rigorously and delaying or denying reimbursement more often. Since the sale of t:slim generally depends on the availability of third-party reimbursement, any delay or decline in reimbursement will adversely affect our sales.

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, 2013, our patent portfolio consisted of approximately 20 issued U.S. patents and 58 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 seven pending U.S. trademark applications and seven pending foreign trademark applications, as well as 13 trademark registrations, including four U.S. trademark registrations and nine foreign trademark registrations.

We have applied for patent protection relating to certain existing and proposed products and processes. Currently, three 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 timely file a patent application in any jurisdiction, we may be precluded from doing so at a later date. Furthermore, 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.

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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 we could become 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.

In the future, we could receive communications from various industry participants alleging our infringement of their intellectual property rights. Any potential intellectual property 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

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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 lawsuit 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;

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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 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 in February 2013. From time to time, we make modifications to these products that may require a new 510(k). 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

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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.

Furthermore, 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.

Furthermore, 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 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 or one of our distributors 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 of our products 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.

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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 the 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 expect to file additional MDRs in the future as we collect additional information.

Any adverse event involving our products 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 recently enacted 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

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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.

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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 recently 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 t:slim is 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.

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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 22,925,614 shares of our common stock outstanding as of December 31, 2013, 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.

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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, 2013, we have federal net operating loss, or NOL, carryforwards of approximately $119.7 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. 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. 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 agreement 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 and will continue to increase 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

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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.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, as well as an increase in stockholder activism, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. New or changing laws, regulations and standards in particular are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new or evolving laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Moreover, as a public company that is subject to these rules and regulations, we may find it more difficult and more expensive for us to obtain certain types of insurance, and in particular director and officer liability insurance. We may be required to incur substantial costs to maintain our current levels of such coverage on acceptable terms.

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.

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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.

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.

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the United States, or GAAP. We are currently in the process of reviewing, documenting and testing our internal control over financial reporting, but we are not currently in compliance with, and we cannot be certain when we will be able to implement the requirements of Section 404(a). For instance, in September 2013, it was determined that we did not maintain effective internal controls over the process for calculating the weighted common shares used to compute basic and diluted net loss per share for the years ended December 31, 2011 and 2012, and this deficiency in our internal controls was deemed to be a material weakness. We subsequently have hired additional individuals with accounting expertise within the finance department. We have also developed and implemented new control procedures over the process for calculating the weighted common shares used to compute basic and diluted net loss per share and we concluded that we had remediated this material weakness as of December 31, 2013. These procedures are subject to ongoing management review and the oversight of the audit committee of our board of directors to ensure that they are operating effectively. We may be at risk for future material weaknesses, particularly if these new procedures do not operate effectively.

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 recently enacted 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. 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.

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The price of our common stock might fluctuate significantly.

Prior to our recently completed initial public offering, 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;
- 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 have outstanding 22,925,614 shares of common stock as of December 31, 2013, of which approximately 13,470,317 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. In addition, as of December 31, 2013, we had outstanding options to purchase 4,539,616 shares of common stock and warrants to purchase 1,358,090 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. As of December 31, 2013, there are also an aggregate of 3,302,621 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 will 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.

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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, 2013, we leased an aggregate of approximately 66,000 square feet, of manufacturing, laboratory and office space in San Diego, California under an operating lease, or the First Lease, which was scheduled to expire in May 2017. 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.

On November 5, 2013 we entered into an extension of the First Lease and concurrently entered into a Second Lease, for up to approximately an additional 41,000 square feet for office, laboratory and warehousing space in close proximity to our other facilities. We expect to occupy approximately 24,000 square feet under the Second Lease beginning in the first half of 2014, and to occupy the remaining portion of the space under the Second Lease within 12 months thereafter.

The First Lease and Second Lease will both expire concurrently approximately 60 months following the date we occupy the first portion of the space associated with the Second Lease. We believe that the facilities that we presently occupy together with the additional facilities that we expect to occupy under the Second Lease will be sufficient to support our current operations and that suitable additional facilities would be available to us should our operations require it.

Item 3. Legal Proceedings.
From time to time we 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.

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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

The last sale price for our common stock as reported by The NASDAQ Global Market on February 28, 2014 was $25.75 per share.

Holders of Record

As of February 28, 2014, there were approximately 128 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 agreement 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 of this Annual Report.

Repurchases of Equity Securities

There were no repurchases of equity securities in 2013.

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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, 2013 of the cumulative total return for our common stock, 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 Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference in any of our filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, 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 Securities and Exchange Commission 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 an initial public offering price of $15.00 per share, for aggregate gross offering proceeds of $120.0 million, managed by BofA Merrill Lynch and Piper Jaffray. In addition, on November 15, 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 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. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering

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expenses, were approximately $125.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

The net proceeds from the offering have been invested in money market funds and highly-liquid, highly-rated securities. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our registration statement on Form S-1.

Item 6. Selected Financial Data

The selected financial data presented below under the heading Statements of Operations Data for the years ended December 31, 2013, 2012 and 2011 and the selected financial data presented below under the heading Balance Sheet Data as of December 31, 2013, 2012 and 2011 have been derived from our audited financial statements included elsewhere 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 share and per share data)	**2013**	**2012**	**2011**
Sales	$ 29,007	$ 2,475	$
Cost of sales	22,840	3,823	
Gross profit (loss)	6,167	(1,348)	
Operating expenses:			
Selling, general and administrative	44,522	22,691	15,951
Research and development	11,079	9,009	8,261
Total operating expense	55,601	31,700	24,212
Operating loss	(49,434)	(33,048)	(24,212)
Total other income (expense), net	(13,705)	33	(1,298)
Net loss and comprehensive loss	$ (63,139)	$ (33,015)	$ (25,510)
Net loss per share, basic and diluted:	$ (21.46)	$ (175.88)	$ (149.87)
Weighted average shares used to compute basic and diluted net loss per share:	2,942,002	187,716	170,208

Balance Sheet Data:

	As of December 31,

(in thousands)	2013	2012	2011
Cash and cash equivalents	$ 124,385	$ 17,163	$ 8,657
Working capital	$ 134,390	$ 10,762	$ (6,876)
Property and equipment, net	$ 9,886	$ 8,989	$ 4,171
Total assets	$ 162,215	$ 39,817	$ 13,978
Notes payable	$ 29,397	$ 4,203	$ 12,857
Convertible preferred stock		$ 124,638	$ 67,930
Total stockholders equity (deficit)	$ 115,537	$ (106,052)	$ (71,295)

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

You should read the following discussion and analysis together with Item 6. Selected Financial Data and our financial statements and related notes included elsewhere in this Annual Report. 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 Item 1A. Risk Factors.

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 Securities Exchange Act of 1934, as amended, 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 on Form 10-K. 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. 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 all segments of the large and growing insulin-dependent diabetes market.

The FDA cleared t:slim in November 2011. We commenced commercial sales of t:slim in the United States in the third quarter of 2012. We consider the number of units shipped per quarter to be an important metric for managing our business. Since the launch of t:slim, the number of units shipped has increased each quarter, and we have shipped approximately 7,500 pumps as of December 31, 2013 broken down by quarter as follows:

For the Three Months Ended	Units Shipped

June 2012	9
September 2012	204
December 2012	844
March 2013	852
June 2013	1,363
September 2013	1,851
December 2013	2,406

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For the years ended December 31, 2013 and 2012, our sales were $29.0 million and $2.5 million, respectively. For the years ended December 31, 2013 and 2012, our net loss was $63.1 million and $33.0 million, respectively. Our accumulated deficit as of December 31, 2013 was $169.2 million.

We believe we can achieve profitability because our proprietary technology platform will allow us to maximize efficiencies in the development, production and sales of our products. By leveraging our core technology, we believe we can develop and bring to market products rapidly and greatly reduce our design and development costs. We expect to continue to increase production volume, and to reduce the per unit production cost for the t:slim Pump and its disposable cartridge 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 all 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, 2013, 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 may require additional capital through equity financings and debt financings in order to fund our operations to a level of revenues adequate to support our cost structure.

We have experienced consecutive quarterly revenue growth since the commercial launch of t:slim in the third quarter of 2012, while incurring quarterly operating losses since our inception. Our operating results may fluctuate on a quarterly or annual basis in the future 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 of this Annual Report.

Subsequent Event

Voluntary Recall

On January 10, 2014, we announced a voluntary recall of select lots of cartridges used with the t:slim that may be 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 the t:slim. We incurred approximately $1.6 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 expect to record a cost of sales charge for the remainder in the first quarter of 2014. We do not currently expect any further direct financial impact of the recall beyond these costs. The total cost of the recall consisted of approximately $0.6 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.

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.

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We anticipate our sales will increase as we expand our sales and marketing infrastructure, increase awareness of our products 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 influenced by the summer vacation period. Accordingly, we expect sequential growth of sales from the third quarter to the fourth quarter to be relatively higher than for other quarter-to-quarter growth, and we also expect sequential growth of sales from the fourth quarter to the first quarter to be relatively lower than for other quarter-to-quarter growth. It is also possible that we may see a decline in sales from the fourth quarter to the first quarter due to these seasonal fluctuations.

Cost of Sales

We manufacture the t:slim Pump and its disposable cartridge at our manufacturing facility in San Diego, California. 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 cost and reserves for expected warranty costs, scrap and inventory obsolescence. Due to our relatively low production volumes, compared to our potential capacity for our products, the majority of our per unit costs are currently manufacturing overhead expenses. These expenses include quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment and 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, changes in our manufacturing processes or costs and increased 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 capacity or output, and adjust to expanding our manufacturing facilities. Any new products that we sell in the future may change our future 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, fringe benefits and stock-based compensation for our executive, financial, marketing, sales, business development, regulatory affairs and administrative functions. Other significant expenses include product demonstration samples, trade show expenses, outside legal counsel, independent auditors and other outside consultants, insurance, facilities and information technology expenses.

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, development prototypes, outside design and testing services and milestone payments under our development and commercialization agreements with DexCom and other collaborators.

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Other Income and Expense

Our other income and expense primarily consist of the change in the fair value of outstanding common and preferred stock warrants, as well as interest expense and amortization of debt discount associated with term loan agreements and convertible notes payable. At December 31, 2013, there was $30 million outstanding principal under our term loan with Capital Royalty Partners, which accrues interest at a rate of 14% per annum.

Results of Operations

	Year Ended December 31,		
(in thousands, except percentages)	**2013**	**2012**	**2011**
Sales	$ 29,007	$ 2,475	$
Cost of sales	22,840	3,823	
Gross profit (loss)	6,167	(1,348)	
Gross margin	21%	(54%)	
Operating expenses:			
Selling, general and administrative	44,522	22,691	15,951
Research and development	11,079	9,009	8,261
Total operating expenses	55,601	31,700	24,212
Operating loss	(49,434)	(33,048)	(24,212)
Other income (expense), net:			
Interest and other income	7	2	14
Interest and other expense	(4,710)	(2,525)	(542)
Change in fair value of stock warrants	(9,002)	2,556	(770)
Total other income (expense), net	(13,705)	33	(1,298)
Net loss and comprehensive loss	$ (63,139)	$ (33,015)	$ (25,510)

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 for 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 for 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 5%, 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. We have experienced, and may continue to experience, unanticipated decreases in productivity and other losses due to inefficiencies relating to the production of our products, scale-up of manufacturing capacity and reliance on outside suppliers for key components in the manufacture of our products. This could continue to result in lower than expected manufacturing output and higher than expected product costs.

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As we are in the early stages of commercialization, and since we have not yet been able to meaningfully take advantage of economies of scale in our manufacturing, our gross margins reflect the absorption of overhead as the largest component of our manufacturing costs. Our gross margin on the t:slim Pump was higher than our gross margin on pump-related supplies for the year ended December 31, 2013 and is expected to remain higher in the future. Our future gross margins will be impacted by numerous factors including, 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, changes in our manufacturing processes or costs and increased 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 capacity or output, and adjust to expanding our manufacturing facilities. Any new products that we sell in the future may change our future gross margins.

Selling, General and Administrative Expenses. SG&A expenses increased 96% to $44.5 million for 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 for 2013 from $9.0 million for 2012. The increase in R&D expenses for 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 for 2013 was $13.7 million, compared to $33,000 of other income for 2012. The other expense for 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. $30 million was drawn under the agreement in January 2013.

In comparison, other income for 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 interest expense related to convertible notes payable to certain stockholders that were converted to Series D preferred stock in August 2012 and interest paid on the $5 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.

We performed the final revaluation of the warrant liability in November 2013 in connection with completion of the initial public offering.

Comparison of Years Ended December 31, 2012 and 2011

Sales. We began selling our products in the third quarter of 2012. Sales for 2012 were $2.5 million. There were no sales for 2011. Sales from the t:slim Pump and pump-related supplies accounted for 91% and 9% of sales, respectively, for 2012. Sales of accessories were not material for 2012.

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Cost of Sales and Gross Profit (Loss). Our cost of sales for 2012 was $3.8 million resulting in negative gross profit of ($1.3) million. The gross margin for 2012 was (54%). There were no costs of sales for 2011. The negative gross margin in 2012 resulted primarily from the initial scale up of manufacturing where our fixed and variable overhead costs were allocated to small sales volume and manufacturing output.

Selling, General and Administrative Expenses. SG&A expenses increased 42% to $22.7 million for 2012 from $16.0 million for 2011. At December 31, 2012, our headcount for sales, general and administrative functions nearly doubled compared with December 31, 2011. The increase in SG&A expenses was primarily related to increased costs associated with the August 2012 initiation of commercial operations that included the establishment of a sales force, customer and technical support functions and marketing personnel and programs. During 2012, employee-related expenses increased $3.9 million and facilities and information technology expense related to the SG&A functions increased $1.3 million. Additionally, we expensed $1.8 million relating to the acquisition of patent rights for non-commercialized products.

Research and Development Expenses. R&D expenses increased 9% to $9.0 million for 2012 from $8.3 million for 2011. The increase in R&D expenses for 2012 was primarily due to a $1.0 million milestone payment under a collaboration agreement.

Other Income (Expense). Other income (expense) increased to $33,000 for 2012 from ($1.3) million for 2011. Interest and other expense for 2012 was primarily related to interest associated with convertible notes payable to certain stockholders at a rate of 8% per annum that were converted to Series D preferred stock in August 2012, and interest paid on a $5 million loan from Silicon Valley Bank entered into in March 2012 at a rate ranging from 7.5% to 10% per annum. Interest and other expense for 2011 was primarily related to interest associated with the convertible notes issued in August 2011, which were subsequently converted to Series D preferred stock in August 2012.

The decrease in fair value of the stock warrants was $2.6 million for 2012 compared to an increase of $0.8 million for 2011. The change was due to the revaluation of the fair value of the common and preferred stock warrants.

Liquidity and Capital Resources

At December 31, 2013, we had $129.5 million in cash and cash equivalents and short-term investments. We believe that our cash on hand, cash available under our term loan agreement and proceeds from the exercise of options and warrants will be sufficient to satisfy our liquidity requirements for at least the next 18 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 and available cash will impact our decision to continue to utilize debt arrangements as a source of cash.

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 purchase of inventory, expansion 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.

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The following table shows a summary of our cash flows for the years ended December 31, 2013, 2012, and 2011:

	Year Ended December 31,		
(in thousands)	**2013**	**2012**	**2011**
Net cash provided by (used in):			
Operating activities	$ (47,757)	$ (33,471)	$ (21,547)
Investing activities	(11,105)	(5,529)	5,879
Financing activities	166,084	47,506	13,179
Total	$ 107,222	$ 8,506	$ (2,489)

Operating activities. Net cash used in operating activities was $47.8 million for the year ended December 31, 2013, compared to $33.5 million and $21.5 million for the same periods in 2012 and 2011, respectively. The increase in net cash used in operating activities for the 2012 and 2013 periods presented was primarily associated with increased costs related to the initiation of commercial operations in August 2012 and continued expansion during 2013. Our employee headcount, employee-related expenses and working capital needs, including accounts receivable and inventory, increased significantly as a result of our initiation of commercial operations.

Investing activities. Net cash used in investing activities was $11.1 million for the year ended December 31, 2013, compared to net cash used of $5.5 million in 2012 and net cash generated of $5.9 million in 2011. The increase in net cash used in investing activities for the 2012 and 2013 periods was primarily related to the purchase of short-term investments, the acquisition of patents, and the purchase of capital equipment. The net cash provided in 2011 was primarily related to the sale of securities to fund our operating activities.

Financing activities. Net cash provided by financing activities was approximately $166.1 million for the year ended December 31, 2013, compared to $47.5 million and $13.2 million for the same periods in 2012 and 2011, respectively. The net cash provided in 2013 is a result of net proceeds from our initial public offering of approximately $125.0 million in November 2013, net proceeds from issuance of preferred stock of $28.9 million, net proceeds from issuance of notes payable of $16.0 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 not reoccurring in 2013 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 while 2011 net cash proceeds from financing activities was driven by the issuance of convertible notes payable.

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;
- growth of our sales, marketing and clinical infrastructure;
- new research and product development efforts;
- payment of quarterly interest due under our term debt agreement;

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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. Additional capital, if needed, may not be available on satisfactory terms, if at all. Furthermore, any additional equity financing may be dilutive to stockholders, and debt financing, if available, may include restrictive covenants.

Indebtedness

Capital Royalty Partners Term Loan

In December 2012, we 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 us access 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 our achievement of a 2013 revenue-based milestone. We can elect to draw any amount between $8 million and $15 million at our discretion up until May 30, 2014. In January 2013, $30 million was drawn under the agreement, a portion of which was used to repay all amounts outstanding under our $5 million loan from Silicon Valley Bank.

Silicon Valley Bank Revolving Line of Credit

In January 2013, we entered into an amended loan agreement with Silicon Valley Bank, making available a two year 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, 2013 and 2012. In the event of our breach of the agreement, we may not be allowed to draw amounts under the agreement, and, to the extent we have any amounts outstanding at the time of any breach, we may be required to repay such amounts earlier than anticipated.

Contractual Obligations & Commitments

The following table summarizes our long-term contractual obligations as of December 31, 2013:

		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	$ 14,585	$ 1,991	$ 5,370	$ 5,948	$ 1,276

Capital Royalty Partners term loan, including interest	43,125	4,200	22,613	16,312	
License fees	2,000	2,000			
Firm purchase commitments	10,408	9,000	1,408		
Total contractual obligations	$ 70,118	$ 17,191	$ 29,391	$ 22,260	$ 1,276

(1) In connection with the DexCom development and commercialization agreement, we are contingently obligated to make two $1.0 million payments upon achievement of certain development milestones, that are expected to be met over the next five years.

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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 1 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 the sale in the United States of our t:slim Pump, disposable cartridges and infusion sets to individual customers and third-party distributors that re-sell 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 the Company s 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

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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 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, 2013, $0.2 million was recorded as deferred revenue for the t:connect hosting service. All other undelivered elements at the time of sale are deemed inconsequential or perfunctory.

Product Returns

We offer a 30-day right of return for our 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 the same period. The return rate is then applied to the sales of the 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. Our allowance for product returns at December 31, 2013 was $0.2 million. Actual product returns have not differed materially from estimated amounts reserved. As of December 31, 2012, we lacked sufficient historical data to establish an estimated return allowance and as such we deferred our t:slim Pump sales of $1.9 million that were subject to return as of that date.

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 product cost, 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. Previously, we have estimated the product cost with the current new pump cost. Beginning in the fourth quarter of 2013, we estimated the product cost with a mix of new and refurbished pump costs. This change reduced our liability at December 31, 2013 by $0.5 million, decreased loss from operations and net loss by $0.5 million and decreased the loss per share by $0.17 per share. At December 31, 2013 and 2012, the warranty reserve was $1.1 million and $0.3 million, respectively. Of the $1.1 million warranty reserve at December 31, 2013, $0.5 million was recorded as a component of other current liabilities and $0.6 million was recorded in other long-term liabilities. In addition, of the total $1.1 million warranty reserve at December 31, 2013, $0.3 million was related to potential replacement associated with the voluntary product recall of selected lots of cartridges. Actual warranty costs have not differed materially from estimated amounts reserved.

Inventory Reserve

We periodically review 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. Of the $1.7 million inventory reserve at December 31, 2013, $0.9 million was related to potential inventory scrap related to the voluntary product recall.

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Capitalized Intellectual Property

We capitalize costs associated with the purchase or licensing of patents associated with our commercialized products. We review our capitalized patent costs periodically to determine that they have future value and an alternative future use. We evaluate costs related to patents that we are not actively pursuing and write off any such costs. We amortize patent costs over their estimated useful lives of 10 years, beginning with the date the patents are issued or acquired.

In July 2012, we entered into an agreement with Smiths Medical ASD, Inc. pursuant to which we were granted certain rights to patents and patent applications. Included in these rights are patents related to our commercialized products as well as patents that relate to our products in development or future products. As consideration for these rights, we agreed to pay $5.0 million in license fees and a percentage of any associated sublicense revenues we may receive. As of December 31, 2013, we have paid $3.0 million of the $5.0 million in license fees. To determine the fair value of the licensed and purchased intellectual property, we applied 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, we utilized the relief from royalty approach. 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. We 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 SG&A expenses line item in the statement of operations in the year ended December 31, 2012.

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 grant date fair value of options granted is calculated using the Black-Scholes option-pricing model, which requires the use of subjective assumptions including volatility, expected term, risk-free rate, and the fair value of the underlying common stock. The expected volatility is based on the historical volatility of the Company s common stock over the most recent period commensurate with the estimated expected term of the Company s stock options. The expected term of the Company s stock options is calculated using the simplified method. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield in effect at the time of grant. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future. For awards that vest based on service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures. Prior to our initial public offering, the estimated fair value of these awards was determined at the date of grant based upon the estimated fair value of our common stock. Subsequent to our initial public offering, the fair value of the common stock is based on observable market prices. As of December 31, 2013, there were no outstanding equity awards with market or performance conditions.

We record the expense for stock option grants to non-employees based on the estimated fair value of the stock option 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

We 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. We accounted for these warrants as a liability in the financial statements because either we did not have enough authorized shares to satisfy potential

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exercise of the warrants and the number of shares to be issued upon their exercise was outside of our control or because the underlying instrument into which the warrants were exercisable, Series C or Series D convertible preferred stock, contained deemed liquidation provisions that were outside of our control.

The warrants are 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 is remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the statements of operations and comprehensive loss. In connection with completion of the initial public offering in November 2013, we performed the final remeasurement of the warrant liability. For the year ended December 31, 2013, costs of $9.0 million were recorded as other income (expense) from the revaluations.

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. We reclassified the warrant liability to stockholders equity as the warrants met the definition of an equity instrument.

Off-Balance Sheet Arrangements

We do 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

Some of the securities that we invest in have market risk in that a change in prevailing interest rates may cause the principal amount of the marketable securities to fluctuate. Financial instruments that potentially subject us to significant concentrations of credit risk consist primarily of cash, cash equivalents and short-term investments. We invest our excess cash primarily in commercial paper. The primary objectives of our investment activities are to ensure liquidity and to preserve principal while at the same time maximizing the income we receive from our marketable securities without significantly increasing risk. Additionally, we established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Because of the short-term maturities of our cash equivalents and marketable securities, we do not believe that an increase in market rates would have any significant impact on the realized value of our marketable securities. If a 10% change in interest rates were to have occurred on December 31, 2013, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

The interest rate on our Capital Royalty Partners term loan is fixed and not subject to changes in market interest rates.

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Item 8. Financial Statements and Supplementary Data

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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, 2013 and 2012, 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, 2013. 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 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, 2013 and 2012, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2013, in conformity with United States generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California

March 6, 2014

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TANDEM DIABETES CARE, INC.

BALANCE SHEETS

	December 31, 2013	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 124,385,137	$ 17,162,730
Restricted cash	2,050,000	50,000
Short-term investments	5,095,331	
Accounts receivable, net	5,298,502	2,411,952
Inventory, net	10,330,156	6,260,808
Prepaid and other current assets	1,830,056	1,903,698
Employee note receivable		25,000
Total current assets	148,989,182	27,814,188
Property and equipment, net	9,885,985	8,988,591
Patents, net	2,697,220	3,014,540
Other long term assets	642,746	
Total assets	$ 162,215,133	$ 39,817,319
Liabilities, convertible preferred stock and stockholders equity (deficit)		
Current liabilities:		
Accounts payable	$ 2,352,037	$ 1,693,006
Accrued expense	1,873,565	1,531,446
Employee-related liabilities	5,876,011	1,990,770
Deferred revenue	411,423	1,883,824
Deferred rent current	368,784	598,753
Notes payable current, net of discounts		4,203,190
Preferred stock warrant liability		2,294,963
Common stock subject to repurchase		33,600
Other current liabilities	3,717,412	2,822,813
Total current liabilities	14,599,232	17,052,365
Notes payable long-term	29,396,571	
Deferred rent long-term	1,886,508	2,179,020
Other long-term liabilities	795,640	2,000,000
Commitments and contingencies (Note 11)		
Convertible preferred stock:		
Series A convertible preferred stock, no shares authorized, issued and outstanding at December 31, 2013 and $0.001 par value; 115,281 shares authorized, issued and outstanding at December 31, 2012; liquidation preference of $2,420,901 at December 31, 2012		2,479,245

Series B convertible preferred stock, no shares authorized, issued and outstanding at December 31, 2013 and $0.001 par value; 361,299 shares authorized, issued and outstanding at December 31, 2012; liquidation preference of $13,006,764 at December 31, 2012	12,802,084
Series C convertible preferred stock, no shares authorized, issued and outstanding at December 31, 2013 and $0.001 par value; 1,197,963 shares authorized, 1,187,736 shares issued and outstanding at December 31, 2012; liquidation preference of $52,260,384 at December 31, 2012	52,098,687

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TANDEM DIABETES CARE, INC.

BALANCE SHEETS (continued)

	December 31, 2013	December 31, 2012
Series D convertible preferred stock, no shares authorized, issued and outstanding at December 31, 2013 and $0.001 par value; 19,436,040 shares authorized, 13,033,563 shares issued and outstanding at December 31, 2012; liquidation preference of $57,347,677 at December 31, 2012		57,257,858
Stockholders equity (deficit):		
Preferred stock, $.001 par value, 5,000,000 shares authorized at December 31, 2013 and no shares authorized at December 31, 2012; no shares issued and outstanding at December 31, 2013		
Common stock, $0.001 par value; 100,000,000 and 26,490,000 shares authorized as of December 31, 2013 and 2012, respectively, 22,925,614 and 226,858, shares issued and outstanding at December 31, 2013 and 2012, respectively	22,926	206
Additional paid-in capital	284,705,251	
Accumulated deficit	(169,190,995)	(106,052,146)
Total stockholders equity (deficit)	115,537,182	(106,051,940)
Total liabilities, convertible preferred stock and stockholders equity (deficit)	$ 162,215,133	$ 39,817,319

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TANDEM DIABETES CARE, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year Ended December 31,		
	2013	**2012**	**2011**
Sales	$ 29,006,638	$ 2,474,698	$
Cost of sales	22,840,242	3,822,950	
Gross profit (loss)	6,166,396	(1,348,252)	
Operating expenses:			
Selling, general and administrative	44,521,197	22,690,877	15,950,892
Research and development	11,079,200	9,009,030	8,260,817
Total operating expenses	55,600,397	31,699,907	24,211,709
Operating loss	(49,434,001)	(33,048,159)	(24,211,709)
Other income (expense), net			
Interest and other income	6,636	2,425	13,656
Interest and other expense	(4,709,779)	(2,525,250)	(542,175)
Change in fair value of stock warrants	(9,001,705)	2,555,899	(769,596)
Total other income (expense), net	(13,704,848)	33,074	(1,298,115)
Net loss and comprehensive loss	$ (63,138,849)	$ (33,015,085)	$ (25,509,824)
Net loss per share, basic and diluted	$ (21.46)	$ (175.88)	$ (149.87)
Weighted average shares used to compute basic and diluted net loss per share	2,942,002	187,716	170,208

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TANDEM DIABETES CARE, INC.

STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)

	Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Total Stockholders
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity (Deficit)
Balance at December 31, 2010	1,687,608	$ 67,929,933	183,704	$ 163	$ 1,019,401	$ (47,219,773)	$ (46,200,209)
Issuance of restricted common stock for cash proceeds of $168,000, net of provision for right of repurchase of unvested shares			23,872				
Vesting of restricted common stock and change in fair value of unvested restricted stock subject to repurchase				11	114,764		114,775
Exercise of stock options			4,209	4	47,305		47,309
Stock-based compensation					253,359		253,359
Net loss						(25,509,824)	(25,509,824)
Balance at December 31, 2011	1,687,608	$ 67,929,933	211,785	$ 178	$ 1,434,829	$ (72,729,597)	$ (71,294,590)
Issuance of Series D convertible preferred stock at $4.40 per share, net of issuance costs of $89,819	7,035,628	30,866,847					

Conversion of convertible notes payable and accrued interest into Series D convertible preferred stock at $4.40 per share	5,997,935	26,391,011					
Vesting of restricted common stock and change in fair value of unvested restricted stock subject to repurchase				13	247,617		247,630
Exercise of stock options			3,158	3	34,675		34,678
Conversion of Series A, Series B, and Series C preferred stock into common stock	(23,292)	(549,917)	13,899	14	549,903		549,917
Stock-based compensation					245,827		245,827
Repurchase and retirement of common stock			(1,984)	(2)	(413)	(49,471)	(49,886)
Loss on extinguishment of convertible notes payable					(2,512,438)	(257,993)	(2,770,431)
Net loss						(33,015,085)	(33,015,085)
Balance at December 31, 2012	14,697,879	$ 124,637,874	226,858	$ 206	$	$ (106,052,146)	$ (106,051,940)
Issuance of Series D convertible preferred stock at $4.40 per share, net of issuance costs of $94,581	3,655,789	$ 15,990,891					
Issuance of common stock					437,268		437,268

warrants in connection with term loan							
Exercise of preferred stock warrants	427,776	3,629,175					
Issuance of common stock in initial public offering, net of underwriter s discount and offering costs			9,200,000	9,200	125,030,373		125,039,573
Conversion of preferred stock in connection with initial public offering	(18,781,444)	(144,257,940)	13,403,747	13,404	144,244,536		144,257,940
Vesting of restricted common stock and change in fair value of unvested restricted stock subject to repurchase				21	33,579		33,600
Conversion of preferred stock warrants into common stock warrants					9,549,707		9,549,707
Exercise of common stock warrants			85,096	85	627,294		627,379
Exercise of stock options			9,913	10	65,913		65,923
Stock-based compensation					4,716,581		4,716,581
Net loss						(63,138,849)	(63,138,849)
Balance at December 31, 2013			22,925,614	$ 22,926	$ 284,705,251	$ (169,190,995)	$ 115,537,182

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TANDEM DIABETES CARE, INC.

STATEMENTS OF CASH FLOW

	Year Ended December 31,		
	2013	**2012**	**2011**
Operating activities			
Net loss	$ (63,138,849)	$ (33,015,085)	$ (25,509,824)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization expense	3,166,845	2,032,197	1,276,532
Accretion of discount on notes payable and convertible notes	594,929	1,208,965	158,738
Provision for allowance for doubtful accounts	274,770	46,456	
Provision for inventory reserve	814,909	334,605	
Interest expense related to amortization of debt discount and debt issuance costs		835,659	383,438
Change in fair value of common and preferred stock warrants	9,001,705	(2,555,899)	769,596
Stock-based compensation expense	4,456,432	245,827	253,359
Loss on disposal of property and equipment	62,387		
Other		56,825	35,571
Changes in operating assets and liabilities:			
Accounts receivable	(3,161,320)	(2,458,409)	
Inventory	(4,624,106)	(6,595,413)	
Prepaid and other current assets	106,137	(1,053,934)	389,524
Other long term assets	(85,207)		
Accounts payable	859,498	1,383,047	(33,927)
Accrued expense	342,119	917,591	527,878
Employee-related liabilities	3,885,240	979,069	251,536
Other current liabilities	894,598	2,342,333	105,469
Deferred revenue	(1,472,401)	1,883,824	
Deferred rent	(522,481)	(233,824)	(279,676)
Other long term liabilities	763,144		
Payments received on note receivable from employees	25,000	175,000	125,000
Net cash used in operating activities	(47,756,651)	(33,471,166)	(21,546,786)
Investing activities			
Purchase of short-term investments	(5,095,331)		
Proceeds from sales and maturities of short-term investments			7,200,000
Purchase of property and equipment	(4,009,772)	(4,529,010)	(1,321,047)
Purchase of patents	(2,000,000)	(1,000,000)	
Net cash provided by (used in) investing activities	(11,105,103)	(5,529,010)	5,878,953
Financing activities			
Issuance of convertible notes payable		12,208,041	12,963,873
Issuance of notes payable, net of issuance costs	28,874,504	5,000,000	

Restricted cash in connection with notes payable	(2,000,000)		
Principal payments on notes payable	(4,396,323)	(603,677)	
Proceeds from issuance of preferred stock for cash, net of offering costs	15,990,891	30,866,847	
Proceeds from initial public offering, net of offering costs	125,039,573		
Proceeds from issuance of common stock for cash and exercise of common stock options	65,923	34,678	215,309
Proceeds from exercise of warrants	2,509,593		
Net cash provided by financing activities	166,084,161	47,505,889	13,179,182
Net increase (decrease) in cash and cash equivalents	107,222,407	8,505,713	(2,488,651)
Cash and cash equivalents at beginning of period	17,162,730	8,657,017	11,145,668
Cash and cash equivalents at end of period	$ 124,385,137	$ 17,162,730	$ 8,657,017
Supplemental disclosures of cash flow information			
Interest paid	$ 4,114,849	$ 297,299	$
Supplemental schedule of noncash investing and financing activities			
Conversion of notes payable and accrued interest for Series D convertible preferred stock	$	$ 26,391,011	$
Lease incentive lessor-paid tenant improvements	$	$ 2,018,470	$
Repayment of note receivable from officer	$	$ 49,886	$ 107,500
Loss on extinguishment of debt	$	$ 2,770,431	$
Common and preferred stock warrants issued, including incremental value of modification of warrants	$ 437,268	$ 3,815,446	$ 265,420
Property and equipment included in accounts payable	$	$ 200,467	$
Conversion of preferred stock warrants into common stock warrants	$ 9,549,707	$	$
Conversion of convertible preferred stock into common stock	$ 144,257,940	$	$

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TANDEM DIABETES CARE, INC.

NOTES TO FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

Tandem Diabetes Care, Inc. is a medical device company focused on the design, development and commercialization of products for people with insulin-dependent diabetes. 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, at which time the Company exited the development stage.

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 $169.2 million at December 31, 2013. The Company has relied on its ability to fund its operations through private and public equity financing, and management expects operating losses and negative cash flows to continue for the foreseeable future. The Company s ability to achieve profitable operations primarily depends upon achieving a level of revenues adequate to support its cost structure. If events or circumstances occur such that the Company does not meet its operating plan as expected, the Company may be required to reduce planned increases in compensation related expenses or other operating expenses which could have an adverse impact on its ability to achieve its intended business objectives.

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 July 2012, the Board of Directors approved a 1-for-20 reverse stock split of the Company s common and preferred stock. All share and per share information included in the accompanying financial statement and notes to the financial statements give retroactive effect to this reverse stock split for the Company s common and preferred stock.

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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.

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. Cash and cash equivalents include cash in readily available checking and money market accounts, as well as a certificate of deposit.

Short-Term Investments

The Company carries short-term investments classified as available-for-sale at fair value as determined by prices for identical or similar securities at the balance sheet date. As of December 31, 2013, short-term investments consist of Level 2 financial instruments in the fair value hierarchy. The Company records unrealized gains and losses 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). 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, and 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, 2013 represents a $2.0 million minimum cash balance requirement in connection with the Capital Royalty Term Loan (see Note 6 Loan and Warrant Agreements), and $50,000 cash collateral against the Company s corporate credit card.

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.

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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,	
	2013	**2012**
CCS Medical, Inc.	21.4%	N/A
Edgepark Medical Supplies, Inc.	13.1%	23.9%
Care Centrix Inc.	N/A	14.2%
Solara Medical Supplies Inc.	N/A	10.0%

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

	Year Ended December 31,	
	2013	**2012**
Edgepark Medical Supplies, Inc.	16.1%	19.3%
CCS Medical, Inc.	13.6%	N/A
Solara Medical Supplies Inc.	N/A	15.7%

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, notes receivable, accounts payable, accrued expense, and employee-related liabilities are reasonable estimates of their fair value because of the short maturity of these items. Short-term investments are carried at fair value. The fair value of the preferred stock warrant liability is discussed in Note 4. 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 at cost, including material, labor and overhead costs, at December 31, 2013 and 2012. Cost of inventories are determined using standard cost, which approximates actual cost, on a first-in, first-out basis. 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.

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 are expensed. The Company amortizes patent costs over their estimated useful lives of 10 years, beginning with the date the patents are issued or acquired.

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Long Lived Assets

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.

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, 2013.

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. 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. Historically, additional taxes paid as a result of the resolution of the Company s uncertain tax positions have not been materially different from the Company s expectations. For further information, see Note 8, Income Taxes.

Revenue Recognition

Revenue is generated from the sale 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 payors.

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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 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. Beginning in the first quarter of 2013, the Company began recognizing t:slim Pump revenue when all the revenue recognition criteria above are met, as it 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 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. 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, 2013, $0.2 million was recorded as deferred revenue for the t:connect hosting service. 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 the same period. The return rate is then applied to the sales of the 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.

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As of December 31, 2012, the Company lacked sufficient historical data to establish an estimated return allowance and as such deferred t:slim Pump sales of $1.9 million that were subject to return as of that date. The allowance for product returns at December 31, 2013 was $0.2 million. Actual product returns have not differed materially from estimated amounts reserved.

Warranty Reserve

The Company 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 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. Previously, the Company has estimated the product cost with the current new pump cost. Beginning in the fourth quarter of 2013, the Company estimated the product cost with a mix of new and refurbished pump costs. This change reduced the Company s liability at December 31, 2013 by $0.5 million, decreased loss from operations and net loss by $0.5 million and decreased the loss per share by $0.17 per share. At December 31, 2013 and 2012, the warranty reserve was $1.1 million and $0.3 million, respectively. Of the total $1.1 million warranty reserve at December 31, 2013, $0.5 million was recorded as a component of other current liabilities and $0.6 million was recorded in other long-term liabilities. 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. Actual warranty costs have not differed materially from estimated amounts reserved.

	Year Ended December 31,	
	2013	2012
Balance at the beginning of the year	$ 300,000	$
Provision for warranties issued during the year	3,515,000	541,000
Settlements made during the year	(2,182,000)	(241,000)
Decreases in warranty estimates	(510,000)	
Balance at the end of the year	$ 1,123,000	$ 300,000

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 grant date fair value of options granted is calculated using the Black-Scholes option-pricing model, which 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, 2013, 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 option using the Black-Scholes option-pricing model. The fair value of non-employee awards is re-measured at each reporting period as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant.

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Warrant Liabilities

The Company has 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 are 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 is remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying statements of operations and comprehensive loss. 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, costs of $9.0 million were recorded as other income (expense) from the revaluations.

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, 2013, 2012 and 2011, advertising costs were $0.7 million, $68,000 and $72,000, respectively.

Shipping and Handling Expenses

Shipping and handling expenses 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 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 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.

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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):

	Year Ended December 31,		
	2013	2012	2011
Convertible preferred stock outstanding		10,647,933	993,265
Warrants for convertible preferred stock		1,426,646	
Warrants for common stock	1,358,090		43,955
Common stock options	4,539,318		151,650
Employee Stock Purchase Plan	137,943		
Restricted common stock subject to repurchase		20,888	34,378
	6,035,351	12,095,467	1,223,248

In addition to the potentially dilutive securities noted above, the Company had $13.0 million of outstanding convertible notes payable as of December 31, 2011 that were convertible into convertible preferred stock upon the occurrence of future preferred stock financing event at a price that was not determinable until such occurrence (Note 5). As such, these convertible notes payable were excluded from the table above.

Reclassifications

Certain activities and balances in prior period financial statements have been reclassified to conform to the current period presentation. These reclassifications had no impact on our balance sheets, statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders equity (deficit), or statements of cash flow.

Recent Accounting Pronouncements

In June 2012, the Company adopted the FASB amended requirements for the presentation of comprehensive income. The amended guidance requires companies to disclose the total of comprehensive income, the components of net income, and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The Company adopted the provisions of this guidance for all periods presented and elected to present items of net loss and other comprehensive loss in a continuous statement of comprehensive loss. The adoption of this authoritative guidance did not have an impact on the Company s financial position or results of operations.

In February 2013, the FASB issued an accounting standard update to require reclassification adjustments from other comprehensive income to be presented either in the financial statements or in the notes to the financial statements. This accounting standard became effective for the Company beginning January 1, 2013, and its adoption did not have any impact on the Company s financial statements.

In July 2013, the FASB issued an accounting standards update that provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. We intend to adopt this guidance at the beginning of our first quarter of fiscal year 2014, and do not believe the adoption of this standard will have a

material impact on our financial position, results of operations or related financial statement disclosures.

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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. There were no short-term investments for the year ended December 31, 2012. The following represents a summary of the estimated fair value of short-term investments at December 31, 2013 (in thousands):

	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
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,	
	2013	2012
Accounts receivable	$ 5,516	$ 2,458
Less allowance for doubtful accounts	(217)	(46)
Total	$ 5,299	$ 2,412

Inventory

Inventory consisted of the following at (in thousands):

	December 31,	
	2013	2012
Raw materials	$ 6,363	$ 2,849
Work in process	2,169	1,687
Finished goods	3,535	2,233
	12,067	6,769
Less reserve for excess and obsolete	(1,737)	(508)
Total	$ 10,330	$ 6,261

The reserve for excess and obsolete inventory at December 31, 2013 included $0.9 million associated with the Company s voluntary product recall (see Note 13 Subsequent Event).

Property and Equipment

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

	December 31,	
	2013	**2012**
Leasehold improvements	$ 4,120	$ 3,831
Computer equipment and software	4,155	2,659
Office furniture and equipment	2,681	2,343
Manufacturing and scientific equipment	6,510	5,109
	17,466	13,942
Less accumulated depreciation and amortization	(7,580)	(4,953)
	$ 9,886	$ 8,989

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Depreciation and amortization expense related to property and equipment amounted to $2.8 million, $1.9 million and $1.3 million for the years ended December 31, 2013, 2012 and 2011, 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, 2012 and 2013 (in thousands):

	December 31,	
	2013	**2012**
Gross amount	$ 3,173	$ 3,173
Accumulated amortization	(476)	(158)
Total	$ 2,697	$ 3,015
Weighted average remaining amortization period (in months)	102	114

Amortization expense related to intangible assets subject to amortization amounted to $0.3 million and $0.2 million for the years ended December 31, 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 2014 and periods thereafter.

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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, 2013 and 2012, 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, 2013 Using		
	December 31, 2013	Quoted Prices 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	$	$
Restricted cash	2,050	2,050		
Commercial paper	5,095		5,095	
Total assets	$ 122,257	$ 117,162	$ 5,095	$

		Fair Value Measurements at December 31, 2012 Using		
	December 31, 2012	Quoted Prices in Active Markets for Identical	Significant Other Observable Inputs (Level	Significant Unobservable Inputs (Level 3)

		Assets (Level 1)	2)		
Assets					
Money market funds	$ 201	$ 201	$	$	
Restricted cash	50	50			
Total assets	$ 251	$ 251	$	$	
Liabilities					
Preferred stock warrant liability	$ 2,295	$	$	$	2,295
Total liabilities	$ 2,295	$	$	$	2,295

The preferred stock and common stock warrant liabilities are recorded at fair value using the Black-Scholes option pricing model, or a binomial lattice valuation model, depending on the timing of valuation in relationship to the next round of equity financing.

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The Company used a binomial lattice valuation model to calculate the preferred stock warrants liability during 2012 prior to the closing of Series D preferred stock financing in August 2012 (Series D Financing), when the exercise price and quantity of the warrants would become fixed based on this round of financing. The assumptions used in this valuation model included: (i) management s revenue projections; (ii) probability weighted expected future investment returns; (iii) weighted average cost of capital that included the addition of a company specific risk premium to account for uncertainty associated with the Company achieving future cash flows; (iv) the probability of a change in control occurring; (v) timing, size and probability of a new round of financing; (vi) expected volatility; and (vii) risk-free rate.

Subsequent to the completion of the Series D financing in August 2012 and the terms of the preferred stock warrants becoming fixed, we used a combination of discounted cash flow, guideline company and guideline transaction valuation methods to determine the total enterprise value and then the option pricing method or hybrid method to allocate the enterprise value to the various classes of stock, including preferred stock warrants. The assumptions used in these valuation models included: (i) management s revenue projections; (ii) probability and timing of various liquidity event dates; (iii) weighted average cost of capital that included the addition of a company specific risk premium to account for uncertainty associated with the Company achieving future cash flows; (iv) selection of appropriate market comparable transactions and multiples; (v) expected volatility; and (vi) risk-free rate.

As of December 31, 2012, reasonable changes in the unobservable inputs would not be expected to have a significant impact on the financial statements.

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 our Common Stock. The preferred stock warrant liability was reclassified from current liabilities to equity, as the warrants met the definition of an equity instrument. As a result, the fair value of the preferred stock warrants as of November 14, 2013, estimated to be $9.5 million using the Black-Scholes option-pricing model, was reclassified to additional paid-in capital. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and risk-free interest rates.

For the year ended December 31, 2013, the Company recorded $9.0 million to other income (expense) from the revaluations.

There were no transfers between Level 1 and Level 2 securities during the years ended December 31, 2013 and 2012.

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The following table provides a reconciliation of liabilities measured at fair value using unobservable inputs (Level 3) on a recurring basis (in thousands):

	Preferred Stock Warrant Liability	Common Stock Warrant Liability	Total
Balance at January 1, 2012	$	$ 1,035	$ 1,035
Incremental increase in value due to modification of common stock warrants issued with 2011 Bridge Financing (Note 5)	2,244	(1,035)	1,209
Issuance of preferred stock warrants in connection with 2012 Bridge Financing (Note 5)	2,393		2,393
Issuance of preferred stock warrants in connection with SVB Bridge Loan (Note 6)	214		214
Changes in fair value of preferred stock warrants	(2,556)		(2,556)
Balance at December 31, 2012	$ 2,295	$	$ 2,295
Changes in fair value of preferred stock warrants	9,002		9,002
Reclassification to Series D Preferred Stock upon warrant exercise	(1,747)		(1,747)
Reclassification to additional paid-in-capital upon warrant conversion	(9,550)		(9,550)
Balance at December 31, 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 and expire 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, with the consent of a majority of the 2011 Bridge Financing note holders, 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, with the consent of a majority of the 2011 Bridge Financing note holders, the 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.

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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 is $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 expire 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. On October 31, 2013, Delphi Ventures and Affiliated Entities exercised 427,776 outstanding warrants to purchase shares of Series D Preferred Stock at an exercise price of $4.40 per share, resulting in $1.9 million of proceeds to the Company.

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. On December 30, 2013, HLM Venture

Partners II, L.P. exercised 85,096 outstanding warrants to purchase shares of Common Stock at an exercise price of $7.37 per share, resulting in $0.6 million of proceeds to the Company.

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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), for which interest-only payments at a rate of 7.5% per annum are payable monthly through the maturity date of 90 days from the initial borrowing. In connection with the SVB Bridge Loan, the Company issued 6,818 warrants to purchase shares of Series C Preferred Stock at an exercise price per share of $44.00, subject to anti-dilution adjustments. The warrants were immediately exercisable and expire in March 2022. The warrants fair value of approximately $0.1 million was recorded as a debt discount and amortized to interest expense over the term of the bridge loan using the effective interest method.

Subsequently, the SVB Bridge Loan s maturity date was extended twice to August 2012. Upon such modifications, the interest rate on the bridge loan was increased to 10% and additional warrants to purchase 3,409 shares of Series C Preferred Stock were issued at an exercise price per share of $44.00, subject to anti-dilution adjustments. The warrants were immediately exercisable and expire in June and July 2022. 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 these amendments as a modification and the incremental increase in the fair value of the warrants resulting from the modification of approximately $75,000 was recorded as a discount to the bridge loan and was amortized over the remaining term of the bridge loan using the effective interest method.

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. At December 31, 2013 and December 31, 2012, the balance outstanding under this loan was $0 and $4.2 million, respectively.

Upon the closing of the Series D financing, all SVB preferred stock warrants became warrants to purchase 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 outstanding as of December 31, 2013.

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 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 loan as of December 31, 2013.

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

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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. Additionally, the 2013 revenue milestone was achieved and, therefore, the Company can elect to draw any amount between $8 million and $15 million, at its discretion up until May 30, 2014. The loan accrues interest at an annual rate of 14%. Interest-only payments are due quarterly at March 31, June 30, September 30 and December 31 of each year during 2013 and 2014. Thereafter, in addition to interest accrued during the period, quarterly payments shall include an amount equal to the outstanding principal at December 31, 2014 divided by the remaining number of quarters prior to the maturity of the loan which is December 31, 2017. Because the Company achieved the revenue milestone, the interest only payment period was extended to December 31, 2015, and thereafter, in addition to interest accrued during the period, the quarterly payments shall include an amount equal to the outstanding principal at December 31, 2015 divided by the remaining number of quarters prior to the end of the term of the loan. While interest on the loan is accrued at 14% per annum, the Company may elect to make interest-only payments at 11.5% per annum. The unpaid interest of 2.5% is added to the principal of the loan and is subject to accruing interest. The Company has not elected to utilize this loan feature. The agreement provides for prepayment fees of 5% of the outstanding balance of the loan if the loan is repaid prior to April 1, 2014. The prepayment fee is reduced 1% per year for each subsequent year until maturity.

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. Among them, the Company must attain minimum annual revenues of $25 million in 2013, $50 million in 2014, $75 million in 2015 and $100 million thereafter. 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. At December 31, 2013, the Company was in compliance with all of the covenants.

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 and expire in January 2023. Because the exercise price of these warrants is 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.

At December 31, 2013, the principal balance outstanding under the Capital Royalty Term Loan was $30.0 million, future minimum principal payments under the Term Loan Agreement, are as follows (in thousands):

Year ended December 31,	
2014	$
2015	
2016	15,000
2017	15,000
Total	$ 30,000
Less current portion of notes payable	
Notes payable, net of current portion	$ 30,000

7. Convertible Preferred Stock, Common Stock and Stockholders Equity (Deficit)

In July 2012, the Board of Directors approved a 1-for-20 reverse stock split of the Company s common and preferred stock. All share and per share information included in the accompanying financial statement and notes to the financial statements give retroactive effect to this reverse stock split for common and preferred stock.

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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 of common stock.

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 (deficit) equity 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, 2013, there were 22,925,614 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, 2.7 million and 1.3 million shares of common stock were reserved for issuance to employees, non-employee directors and consultants of the Company as of December 31, 2013 and 2012, respectively.

The 2006 Plan provides 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 Plan and no further options will be granted under the 2006 Plan.

In October 29, 2013, the Company s board of directors approved the 2013 Stock Incentive Plan (the 2013 Plan). The 2013 Plan became effective immediately prior to the completion of the initial public offering. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock and restricted

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stock units to individuals who are then employees, officers, directors or consultants of the Company. A total of 4,809,000 shares of common stock were reserved for issuance under the 2013 Plan as of December 31, 2013. As of December 31, 2013, 2,746,621 shares are available for future issuance under the 2013 Plan.

Restricted Common Stock

The Company issued shares of restricted common stock totaling 23,872 shares in 2011. No shares of restricted common stock were issued in 2013 or 2012. 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 Plan to certain employees and nonemployee directors. Shares of restricted common stock granted under the Plan vest and are subject to repurchase according to the terms of the respective restricted stock agreement.

The outstanding shares of restricted common stock generally vest 25% on the first anniversary of the original grant date, with the balance vesting monthly over the remaining three years. Shares of unvested restricted common stock may be repurchased, at the Company s option, at the lesser of the original purchase price or the current fair market value. Generally, shares of restricted stock which have vested are not subject to repurchase. The Company s right to repurchase automatically terminated upon the closing of an initial public offering. The cash paid for the restricted common stock represented the fair value of the common stock at the time of issuance. The unvested restricted common stock has been reflected as a current liability in the balance sheet, and is reclassified to stockholders equity (deficit) as the restricted common stock vests. 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	Aggregate Intrinsic Value
Outstanding at December 31, 2011	151,596	$ 10.57	7.87	$
Granted	15,319	25.13		
Exercised	(3,158)	10.92		$ 44,000
Canceled/forfeited/expired	(27,855)	9.90		
Outstanding at December 31, 2012	135,902	$ 12.33	7.02	$
Granted	4,430,214	7.92		
Exercised	(9,913)	6.65		$ 117,655
Canceled/forfeited/expired	(16,587)	4.71		
Outstanding at December 31, 2013	4,539,616	$ 8.07	9.49	$ 80,368,997

Vested and expected to vest at December 31, 2013	4,445,639	$	8.05	9.49	$ 78,800,055
Exercisable at December 31, 2013	713,986	$	3.03	8.78	$ 16,241,013

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.

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The ESPP authorizes 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. The ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. As December 31, 2013, no shares of our common stock have been purchased under the ESPP.

The initial offering under the ESPP commenced on November 19, 2013 and has a duration of approximately 24 months, consisting of four approximate six-month purchase periods.

Eligible employee 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.

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,		
	2013	**2012**	**2011**
Cost of sales	$ 204	$ 36	$
Selling, general & administrative	3,583	148	163
Research and development	669	62	90
Total	$ 4,456	$ 246	$ 253

The total stock-based compensation capitalized as part of the cost of our inventory was $0.3 million and $0 at December 31, 2013 and 2012, respectively.

At December 31, 2013, the total unamortized stock-based compensation expense of approximately $31.5 million, is to be recognized over the remaining vesting term of approximately 2.9 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 year ended December 31, 2013, the expense was $88,000 and is included in the table above as a component of selling, general and administrative expense. Option grants to consultants resulted in an immaterial expense for the years ended December 31, 2012 and 2011.

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 an straight-line basis over the requisite service period. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and risk-free interest rates. The expected volatility is based on the historical volatility of the Company s common

stock over the most recent period commensurate with the estimated expected term of the Company s stock options. The expected term of the Company s stock options is calculated using the simplified method. The risk-free interest rate for periods within the contractual life of the option is based on the U.S. Treasury yield in effect at the time of grant. The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

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

	Stock Option			ESPP
	Year Ended December 31,			Year Ended December 31,
	2013	2012	2011	2013
Risk-free interest rate	1.4%	1.1%	1.6%	0.2%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	79.0%	70.2%	69.7%	66.3%
Expected term (in years)	5.8	6.0	6.0	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 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.

The weighted average estimated grant date fair value per share of employee stock options granted during the years ended December 31, 2013, 2012 and 2011 was $7.52, $15.65 and $5.36, respectively.

Common Stock Reserved for Future Issuance

The following shares of common stock are reserved for future issuance at December 31, 2013:

Common stock warrants outstanding	1,358,090
Stock options issued and outstanding	4,539,616
Authorized for future option grants	2,746,621
Employee stock purchase plan	556,000
	9,200,327

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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,		
	2013	2012	2011
Tax at federal statutory rate	$ (21,467)	$ (11,225)	$ (8,673)
State income tax, net of federal benefit	(2,784)	(1,793)	(1,314)
Nondeductible convertible notes payable	3	617	184
Warrants revaluation	3,061	(869)	262
Research and development credits	(649)	209	(553)
Other	792	155	82
Change in valuation allowance	21,044	12,906	10,012
	$	$	$

Significant components of the Company s net deferred income tax assets at December 31, 2013 and 2012 are shown below (in thousands). A valuation allowance has been recorded to offset the net deferred tax asset as of December 31, 2013 and 2012, as the realization of such assets does not meet the more-likely-than-not threshold.

	December 31,	
	2013	2012
Deferred tax assets:		
Net operating loss (NOL)	$ 47,996	$ 32,623
Research and development tax credits	2,349	1,707
Capitalized R&D	7,686	6,072
Deferred rent	119	115
Accrued Compensation	2,490	524
Other	3,188	1,743
Total gross deferred tax assets	63,828	42,784
Less valuation allowance	(63,828)	(42,784)
Net deferred tax assets	$	$

As of December 31, 2013, the Company has accumulated federal and state net operating loss carryforwards of approximately $119.7 million and $128.2 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 $2.2 million and $2.5 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.

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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. 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, 2013 and 2012 (in thousands):

	Year Ended December 31,		
	2013	2012	2011
Gross unrecognized tax benefits at the beginning of the year	$ 1,422	$ 779	$ 554
Increases related to current year positions	349	176	225
Increases related to prior year positions	141	467	
Expiration of unrecognized tax benefits			
Gross unrecognized tax benefits at the end of the year	$ 1,912	$ 1,422	$ 779

As of December 31, 2013, the Company has $1.6 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, 2013 and 2012. 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

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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 which was recorded as research and development cost in 2012 and will make two additional $1.0 million payments 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. For the years ended December 31, 2013 and, 2012, the Company accrued $13,000 and $48,000, respectively, for DexCom s development costs associated with the Agreement.

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 (Collaboration Agreement) with 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 Collaboration Agreement, JDRF will provide research funding of up to $3 million based on the achievement of research and development milestones, not to exceed research costs incurred by the Company. The research and development milestones are anticipated to be reached by September 2015. Payments the Company receives to fund the collaboration efforts under the terms of the Collaboration Agreement will be recorded as restricted cash and current and long term liabilities, and 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. As of December 31, 2013, milestone payment achievements totaled $0.7 million, and research and development costs were offset by $0.2 million. As of December 31, 2013, the Company received $0.7 million from JDRF and has $0 classified as restricted cash.

10. Employee Benefits

The Company has a defined contribution 401(k) plan for employees who are at least 21 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.

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, 2013 and 2012, there were no matters for which the negative outcome was considered probable or estimable, and, as a result, no amounts have been accrued at either date.

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.

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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 with the new lease 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 allowances 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 expires on March 31, 2013, but is automatically extended 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 will commence on or about June 2014 and increase by a fixed percentage each year on the anniversary of the rent commencement date. As a lease incentive from the landlord, the Company has the option to receive a tenant improvement allowance of approximately $0.4 million for nonstructural improvements to the buildings. The Company will also receive an additional tenant improvement allowance of $0.3 million as an incentive under the existing operating 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 $2.3 million and $2.8 million at December 31, 2013 and December 31, 2012, respectively. The rent expense for the years ended December 31, 2013 and 2012, totaled $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, 2013 in thousands are as follows (in thousands):

2014	$ 1,991
2015	2,555
2016	2,815
2017	2,924
2018	3,024

Thereafter	1,276
	$ 14,585

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12. Selected Quarterly Financial Data (Unaudited)

Quarterly financial information for fiscal 2013 and 2012 are presented in the following table, in thousands, except per share data:

	For the Quarter Ending			
	March 31	June 30	September 30	December 31
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)
2012:				
Revenue	$	$	$ 218	$ 2,257
Gross loss			(901)	(447)
Operating expenses	7,793	7,380	8,573	7,954
Operating loss	(7,793)	(7,380)	(9,474)	(8,401)
Net loss	(8,404)	(8,544)	(7,513)	(8,554)
Basic and diluted net loss per share (1)	$ (47.11)	$ (47.31)	$ (39.82)	$ (42.14)

(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 (unaudited)

Voluntary Recall

On January 10, 2014, the Company announced a voluntary recall of select lots of cartridges used with the t:slim that may be 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 the t:slim. The Company incurred approximately $1.6 million in direct costs associated with the recall and recorded $1.3 million of such costs in its 2013 financial results. The total cost of the recall consisted of approximately $0.6 million associated with the return and replacement of affected cartridges in the field and approximately $1.0 million for the write-off and disposal of affected cartridges within our in-house inventory.

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.

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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, control 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, 2013, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2013.

Management s Report on Internal Control over Financial Reporting

This Annual Report does not include a report of management s assessment regarding internal control over financial reporting due to a transition period established by the rules of the SEC for newly public companies.

Changes in Internal Control over Financial Reporting

During the year ended December 31, 2013, we developed and implemented new control procedures to address a previously identified material weakness in our internal control over financial reporting as of December 31, 2012 related to the process for calculating the weighted common shares used to compute basic and diluted net loss per share. After completing our assessment of the design and operating effectiveness of the new procedures, we concluded that we have remediated the previously identified material weakness as of December 31, 2013.

Except as described above, 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 quarter ended December 31, 2013 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not applicable.

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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 2014 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, 2013, and is incorporated herein by reference.

We have adopted a code of 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 Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at *http://www.tandemdiabetes.com* under the Corporate Governance section of the Investor Center portion of the website. Our Code of Business Conduct and Ethics 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 the Code of Business Conduct and Ethics that applies to any covered person, and (ii) the nature of any waiver, including an implicit waiver, from a provision of the Code of Business Conduct and Ethics that is granted to one of the covered persons.

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 section entitled 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.

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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:

	Page
Report of Independent Registered Public Accounting Firm	75
Balance Sheets	76
Statements of Operations and Comprehensive Loss	78
Statements of Convertible Preferred Stock and Stockholders Equity (Deficit)	79
Statements of Cash Flows	80
Notes to Financial Statements	81

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.

(1)	#10.3	Tandem Diabetes Care, Inc. 2006 Stock Incentive Plan.
(1)	#10.4	Form of Stock Option Agreement under 2006 Stock Incentive Plan.
(1)	#10.5	Form of Restricted Stock Agreement under 2006 Stock Incentive Plan.
(1)	#10.6	Tandem Diabetes Care, Inc. 2013 Stock Incentive Plan.
(1)	#10.7	Form of Stock Option Agreement under 2013 Stock Incentive Plan.
(1)	#10.8	Form of Stock Option Agreement under 2013 Stock Incentive Plan (Non-Employee Directors).

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Exhibit Footnote	Exhibit Number	Description of Document
(1)	#10.9	Tandem Diabetes Care, Inc. 2013 Employee Stock Purchase Plan.
(1)	#10.10	Tandem Diabetes Care, Inc. 2013 Cash Bonus Plan.
(1)	10.11	Form of Indemnification Agreement.
(1)	#10.12	Employee Offer Letter, dated July 8, 2013, by and between Tandem Diabetes Care, Inc. and David B. Berger.
(1)	#10.13	Employee Offer Letter, dated February 1, 2013, by and between Tandem Diabetes Care, Inc. and John F. Sheridan.
(1)	#10.14	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Kim D. Blickenstaff.
(1)	#10.15	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and John Cajigas.
(1)	#10.16	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Robert B. Anacone.
(1)	#10.17	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and John F. Sheridan.
(1)	#10.18	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and David B. Berger.
(1)	#10.19	Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Susan M. Morrison.
(1)	10.20	Confidential Intellectual Property Agreement, dated July 10, 2012, by and between Tandem Diabetes Care, Inc. and Smiths Medical ASD, Inc.
(1)	10.21	Lease Agreement, dated November 5, 2013, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC.
	#10.22	Tandem Diabetes Care, Inc. 2014 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.
	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.

# 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.

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

* 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.

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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: March 6, 2014

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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, as 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, 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 that all said attorneys-in-fact and agents, or any of them or their or his substitute or substituted, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
/S/ KIM D. BLICKENSTAFF Kim D. Blickenstaff	President, Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2014
/S/ JOHN CAJIGAS John Cajigas	Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	March 5, 2014
/S/ LONNIE M. SMITH Lonnie M. Smith	Director and Chairman of the Board	March 5, 2014
/S/ DICK P. ALLEN Dick P. Allen	Director	March 3, 2014
/S/ EDWARD L. CAHILL Edward L. Cahill	Director	March 3, 2014
/S/ FRED E. COHEN Fred E. Cohen, M.D., D.Phil	Director	March 6, 2014
/S/ HOWARD E. GREENE, JR. Howard E. Greene, Jr.	Director	March 6, 2014
/S/ DOUGLAS A. ROEDER	Director	March 3, 2014

Douglas A. Roeder		
/S/ JESSE I. TREU	Director	March 6, 2014
Jesse I. Treu, Ph.D.		
/S/ CHRISTOPHER J. TWOMEY	Director	March 6, 2014
Christopher J. Twomey		