

TANDEM DIABETES CARE INC

Form 424B4

March 24, 2017

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File No. 333-216531

PROSPECTUS

18,000,000 Shares

TANDEM DIABETES CARE, INC.

Common Stock

We are offering 18,000,000 shares of our common stock, par value \$0.001 per share.

The offering price is \$1.25 per share of common stock.

Our common stock is listed on the NASDAQ Global Market under the symbol TNDM.

We are an emerging growth company as defined under the federal securities laws and, as such, may continue to elect to comply with certain reduced public company reporting requirements in future reports.

Investing in our common stock involves a high degree of risk. Please read the section entitled **Risk Factors** beginning on page 13 of this prospectus.

	Per Share	Total
Public offering price	\$1.25	\$ 22,500,000
Underwriting discount ⁽¹⁾	\$0.075	\$ 1,350,000
Proceeds, before expenses, to us	\$1.175	\$ 21,150,000

⁽¹⁾ We refer you to the section entitled "Underwriting" beginning on page 154 of this prospectus for additional information regarding total compensation payable to the underwriters.

Kim Blickenstaff, our President, Chief Executive Officer and a member of our board of directors, is purchasing 1,600,000 shares of our common stock in this offering at the public offering price for an aggregate of \$2.0 million.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

Delivery of the shares of common stock is expected to be made on or about March 28, 2017. We have granted the underwriters an option for a period of 30 days to purchase an additional 2,700,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$1.6 million, and the total proceeds to us, before expenses, will be \$24.3 million.

Sole Book-Running Manager

Piper Jaffray

Co-Managers

Oppenheimer & Co.

Wedbush PacGrow

The date of this prospectus is March 23, 2017.

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In considering whether to purchase shares of common stock in this offering, you should rely only on the information contained in this prospectus and any free writing prospectus we file with the Securities and Exchange Commission, or SEC. We and the underwriters have not authorized

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anyone to provide any information different from that contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the

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shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of our common stock.

TRADEMARKS

Our trademark portfolio includes 23 trademark registrations, including 10 U.S. trademark registrations and 13 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.

INVESTORS OUTSIDE THE UNITED STATES

Neither we nor the underwriters have done anything that would permit this offering or the possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of shares of our common stock and the distribution of this prospectus outside of the United States.

MARKET AND INDUSTRY DATA AND FORECASTS

Certain market and industry data and forecasts included in this prospectus were obtained from independent market research, industry publications and surveys, governmental agencies and publicly available information. Industry surveys, publications and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. We have not independently verified any of the data from third-party sources, nor have we ascertained the underlying assumptions relied upon therein. Similarly, independent market research and industry forecasts, which we believe to be reliable based upon our management's knowledge of the industry, have not been independently verified. While we are not aware of any misstatements regarding the market or industry data presented herein, our estimates involve risks and uncertainties and are subject to change based on various factors, including those discussed in the section entitled "Risk Factors" beginning on page 13 of this prospectus.

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PROSPECTUS SUMMARY

This prospectus summary highlights certain information appearing elsewhere in this prospectus. As this is a summary, it does not contain all of the information that you should consider before making a decision to invest in our common stock. You are encouraged to carefully read this entire prospectus, including the information provided under the headings Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and our financial statements and the related notes, before investing in our common stock.

Unless otherwise stated in this prospectus, references to Tandem, we, us, our or the Company refer to Tandem Diabetes Care, Inc.

Overview

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

the t:slim X2 Insulin Delivery System, or t:slim X2, our next-generation flagship product,

the t:flex Insulin Delivery System, or t:flex, for people with greater insulin needs, and

the t:slim G4 Insulin Delivery System, or t:slim G4, the first continuous glucose monitoring, or CGM, enabled pump with touchscreen simplicity.

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

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

Our innovative approach to product design and development is consumer-focused and based on our extensive market research, as we believe the user is the primary decision maker when purchasing an insulin pump. Our market research consists of interviews, focus groups and online surveys to understand what people with diabetes, their caregivers and healthcare providers are seeking in order to improve diabetes therapy management. We also apply the science of human factors to our design and development process, which seeks to optimize our devices, allowing users to successfully operate our devices in their intended environment.

We developed our products to provide the specific features that people with insulin-dependent diabetes seek in a next-generation insulin pump. Our proprietary pumping technology allows us to design the

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slimmest and smallest durable insulin pumps on the market, without sacrificing insulin capacity. Our insulin pump platform features our patented Micro-Delivery technology, and a miniaturized pumping mechanism that draws insulin from a flexible bag within the pump's cartridge, rather than relying on a syringe and plunger mechanism. It also features an easy-to-navigate software architecture, a vivid color touchscreen and a micro-USB connection that supports a rechargeable battery, software updates through the Tandem Device Updater, and uploads to t:connect Diabetes Management Application, or t:connect. The Tandem Device Updater is a new tool that allows pump users to update their pumps software quickly and easily from a personal computer, and has the capability of providing our customers access to new and enhanced features faster than the industry has been able to in the past. We believe it is the only tool of its kind currently available. t:connect is our custom cloud-based data management application that provides customers and healthcare providers a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters.

We began commercial sales of our first insulin pump product, the t:slim Insulin Delivery System, or t:slim, in August 2012. During 2015, we commenced commercial sales of two additional insulin pumps: t:flex in May 2015 and t:slim G4 in September 2015. In October 2016, we commenced commercial sales of t:slim X2, and discontinued new sales of t:slim.

Since our initial commercial launch, we have leveraged our innovative technology platform and consumer-focused approach to expedite the product development cycle and drive our sales growth. This approach has allowed us to commercialize three additional insulin pumps that provide insulin therapy features for different segments of the diabetes market. In addition, we have expanded our sales, clinical and marketing infrastructure, which allows us to continue to provide strong service and support to our customers. We believe that by demonstrating our product benefits and the shortcomings of existing insulin therapies, as well as a consistently high level of customer support, more people will choose our insulin pumps for their therapy needs, allowing us to further penetrate and expand the market. We also believe we are well positioned to address consumers' needs and preferences with our current products and products under development, as well as by offering customers a pathway to our future innovations through the Tandem Device Updater as they are approved by the U.S Food and Drug Administration, or FDA.

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

For the years ended December 31, 2016, 2015 and 2014, our sales were \$84.2 million, \$72.9 million and \$49.7 million, respectively. For the years ended December 31, 2016, 2015 and 2014, our net loss was \$83.4 million, \$72.4 million, and \$79.5 million, respectively. For the year ended December 31, 2016, we recorded net sales deferrals of \$4.3 million and recognized an additional net cost of sales of \$0.3 million as a result of our Technology Upgrade Program. Our accumulated deficit as of December 31, 2016 was \$404.6 million.

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

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The Market

Diabetes is a chronic, life-threatening disease for which there is no known cure. The disease is categorized by improper function of the pancreas when it either does not produce enough insulin or the body cannot effectively use the insulin it produces. Insulin is a life-sustaining hormone that allows cells in the body to absorb glucose from blood and convert it to energy. As a result, a person with diabetes cannot utilize the glucose properly and it continues to accumulate in the blood. If not closely monitored and properly treated, diabetes can lead to serious medical complications, including damage to various tissues and organs, seizures, coma and death.

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

Our target market consists of approximately 3.3 million people in the United States who require daily administration of insulin, which includes approximately 1.6 million people with type 1 diabetes and approximately 1.7 million people with type 2 diabetes who require daily rapid acting insulin. Throughout this prospectus, we refer to people with type 1 diabetes and people with type 2 diabetes who require daily rapid acting insulin as people with insulin-dependent diabetes.

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. Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy.

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

Insulin pump therapy can provide a person with insulin-dependent diabetes with benefits when used independently or in conjunction with CGM. A pump featuring integrated CGM is known as a sensor augmented pump, or SAP, which allows the pump to receive CGM data directly from a wearable sensor. SAPs may feature an automated insulin delivery, or AID, algorithm that is designed to automatically adjust a person's insulin delivery based on their CGM trends to help minimize the frequency and/or duration of hypoglycemia and/or hyperglycemic events.

We believe that the distinct advantages and increased awareness of insulin pump therapy as compared to other available insulin therapies will continue to generate demand for insulin pump devices and pump-related supplies. We also believe that the adoption of insulin pump therapy would have been even greater if not for the significant and fundamental perceived shortcomings of durable syringe-and-plunger insulin pumps currently available, which we refer to as traditional pumps.

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The Opportunity

Based on our research, we believe that the limited adoption of insulin pump therapy by people with insulin-dependent diabetes has been largely due to the shortcomings of traditional pumps currently available. These shortcomings include:

Antiquated style. While consumer electronic devices have rapidly evolved in form and function over the past decade, traditional pumps have not achieved similar advances. Our market research has shown that consumers believe traditional pumps resemble dated consumer technology, such as a pager, as they generally still feature small display screens, push-button interfaces, plastic cases and disposable batteries.

Not adaptable. Traditional pumps are typically sold as a single-product offering that are then iterated to add features, rather than being designed as a technology platform that is easily updatable to support new features and functionality as they are developed and approved by the FDA. We believe the lack of adaptability of traditional pump platforms has been a restricting factor in offering people with diabetes differentiated product features to best meet their therapy needs.

Bulky size. Our market research has shown that consumers view traditional pumps as large, bulky and inconvenient to carry or wear, especially when compared to modern consumer electronic devices, such as smartphones. The size of the pump further contributes to users being embarrassed by the pump.

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.

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. Our research has shown that the complicated nature of the process can lead to confusion, frustration and fear of making mistakes with the pump, which in turn can limit the user's willingness to take advantage of advanced therapy features, or even discourage use entirely.

Pump mechanism limitations. Traditional pumps utilize a syringe and plunger mechanism to deliver insulin. This design limits the ability to reduce the size of the pump, and also potentially exposes the user to the unintended delivery of the full volume of insulin within the pump, which can cause hypoglycemia or death. 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.

We believe that these shortcomings of traditional pumps have limited the adoption of pump therapy. By addressing these issues, there is a meaningful opportunity to not only motivate MDI users to adopt pump therapy, but also to respond to the concerns and unmet needs of traditional insulin pump users.

Our Solution

We developed our proprietary technology platform using a consumer-focused approach by first utilizing extensive market research to ascertain what people with insulin-dependent diabetes require and prefer from their diabetes therapy. We then look to modern consumer technology for inspiration, and design our hardware and software solutions to meet those specific demands. Our development process then applies the science of human factors, which optimizes a device or system to the intended user through iterative usability and design refinement. This multi-step approach has resulted in products that provide users with the distinct product features they seek and in a manner that makes the features usable. We

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believe this approach is fundamentally different from the approach applied to the traditional medical device development process.

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

Contemporary style. Our current products, as well as our products under development, have the look and feel of a modern consumer electronic device, such as a smartphone. Relying on significant consumer input and feedback during the development process, we believe the aesthetically-pleasing, modern design of our products addresses the embarrassing appearance-related concerns of insulin pump users. Key product features such as a high-resolution, color touchscreen with shatter-resistant glass, aluminum casing and rechargeable battery, make our products unique in the insulin pump market.

Adaptable platform. Our products share a pump form factor, as well as an updatable, easy-to-navigate software architecture combined with a touchscreen user interface. This enables us to offer differentiated features and functionality while on a shared technology platform, which allows us to leverage a single sales, marketing and clinical organization, as well as a shared manufacturing and supply chain infrastructure. Our insulin pumps are also compatible with the Tandem Device Updater, a new tool that allows pump users to update their pumps' software quickly and easily from a personal computer. We believe the adaptability of our pump platform uniquely positions us to address the needs and preferences of people with insulin-dependent diabetes, and to do so quickly as those needs and preferences change and the functionality of our products evolves.

Compact size. With a narrow profile, similar to many smartphones, our products can easily and discreetly fit into a pocket. t:slim X2 and t:slim G4 are the slimmest and smallest durable insulin pumps on the market. The size and shape of our products are designed to provide increased flexibility with respect to how and where a pump can be worn. Based on extensive consumer input during development, we believe our products address both the embarrassment and functionality concerns related to the size and inconvenience of carrying a traditional pump.

Easy to learn and teach. Our technology platform allows for the use of a color touchscreen and easy-to-navigate software architecture, providing users intuitive access to the key functions of their pump directly from the Home Screen. Insulin pump users can quickly learn how to efficiently navigate their pumps' software, thereby enabling healthcare providers to spend less time teaching a person how to use the pump and more time improving management of their diabetes. We believe the ease with which our pump can be learned and taught will help attract consumers who may have been frustrated or intimidated by traditional pumps.

Intuitive to use. Similar to what is found in modern consumer electronic devices, the embedded software displayed on our color touchscreen features intuitive and commonly interpreted colors, language, icons and feedback. Our software also features numerous shortcuts, including a simple way to return to the Home Screen and view critical information for therapy management. We believe these features also allow users to more efficiently manage their diabetes without fear or frustration.

Next generation technology platform. Our Micro-Delivery technology is unique compared to traditional pumps. Our technology 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 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.

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

Our Strategy

Our goal is to significantly expand and further penetrate the insulin-dependent diabetes market and become the leading provider of insulin pump therapy by focusing on both consumer and clinical needs. By continually conducting market research to determine what people with insulin-dependent diabetes desire from their insulin therapy, and by offering insulin pump products with different features and functionality, we believe we are uniquely positioned to provide a broad range of insulin pump products that allow us to address multiple segments of the diabetes market.

To achieve our goal, we intend to pursue the following business strategies:

Drive adoption of our products through our expanded sales, marketing and clinical infrastructure and multiple product offerings. We have achieved commercial success since the launch of our first commercial product by investing in the development of our sales, marketing and clinical infrastructure. We believe we are now in a position to leverage this infrastructure to increase our access to people with insulin-dependent diabetes, their caregivers and healthcare providers. We believe that our investment in this infrastructure, combined with the launch of additional product offerings through the same infrastructure and the marketing of new products to our existing customers, will drive continued adoption of our products.

Promote awareness of our differentiated products to consumers, their caregivers and healthcare providers. Our products were specifically designed to address the shortcomings of currently available technologies that we believe have limited the adoption of insulin pump therapy. We intend to broaden our direct-to-consumer marketing to promote the insulin therapy features and functionality offered by our products, as well as to leverage our sales, marketing and clinical infrastructure to cultivate relationships with diabetes clinics, insulin-prescribing healthcare professionals and other key opinion leaders. By promoting awareness of our products, we believe that we will attract users of other pump therapies and MDI to our products.

Advance our clinical activities to further demonstrate that use of our pump products may contribute to improved clinical outcomes. Recent studies suggest that use of our pump products may provide users with improved clinical outcomes, including improved overall glycemic control and reduced risk of hypoglycemia. We plan to continue to invest in clinical activities intended to demonstrate that the use of our pump products contributes to improved clinical outcomes.

Advance our platform of innovative, consumer-focused products to address the unmet needs of people in the insulin-dependent diabetes market. We believe that our proprietary technology platform allows us to provide the most sophisticated and intuitive insulin pump therapy products on the market. The Tandem Device Updater allows pump users to update their pumps' software quickly and easily from a personal computer. We intend to leverage our technology platform to allow t:slim X2 users to update their pumps' software to include CGM integration and AID algorithms. We intend to continue to explore further advancements in our technology platform to expand the features and functionality associated with our products in order to address different segments of the large and growing insulin-dependent diabetes market.

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Invest in our consumer-focused approach. We believe that our consumer-focused approach to product design, marketing and customer care is a key differentiator. This approach allows us to add the product features most requested by people with insulin-dependent 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 also continue to invest in our consumer-focused approach throughout our business.

Broaden direct access to third-party payor reimbursement for our products in the United States. We believe that third-party reimbursement is an important determinant in driving consumer adoption of insulin pump therapy. We intend to intensify our efforts to encourage third-party payors to establish direct reimbursement for our products as we expand our market presence and product offerings. We also plan to participate in clinical studies to demonstrate the benefits of our products relative to other pump products and therapies as a way to gain support from third-party payors.

Leverage our manufacturing operations to achieve cost and production efficiencies. We manufacture our products at our headquarters in San Diego, California. We utilize a semi-automated manufacturing process for our pump products and disposable cartridges. During 2017, we intend to relocate our manufacturing operations to a new larger facility, which will allow us to expand our production capacity further by replicating our production lines and gaining efficiencies from the operation of a facility designed to maximize our manufacturing processes and workflows.

Selected Risk Factors

Our business is subject to numerous risks and uncertainties of which you should be aware before you decide to invest in our common stock. These risks may prevent us from achieving our business objectives, and may adversely affect our business, financial condition, results of operations and prospects. These risks are discussed in greater detail in the section entitled **Risk Factors** beginning on page 13 of this prospectus. Some of these risks include:

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

We currently rely on sales of insulin pumps to generate a significant portion of our revenue, and any factors that negatively impact sales of our insulin pump products may adversely affect our business, financial condition and operating results;

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

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

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

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit cost of our products by increasing production volume and manufacturing efficiency, including by reducing raw material, labor, product-training, expected warranty and manufacturing overhead costs per unit;

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

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

We will need to raise additional funds in the future. If these funds are not available to us, we will not have sufficient cash to fund our operations through December 31, 2017;

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

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

Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As an emerging growth company:

we are exempt from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002;

we are permitted to provide less extensive disclosure about our executive compensation arrangements; and

we are not required to give our stockholders non-binding advisory votes on executive compensation or golden parachute arrangements.

We may take advantage of these provisions until such time that we no longer qualify as an emerging growth company. We will cease to be an emerging growth company upon the earliest of: (i) December 31, 2018, (ii) the last day of the first fiscal year in which our annual gross revenues exceed \$1.0 billion, (iii) December 31 of the fiscal year that we become a large accelerated filer as defined in Rule 12b-2 under the Securities Exchange Act of 1934, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (iv) the date on which we have issued more than \$1.0 billion in non-convertible debt during the preceding three-year period.

We may choose to take advantage of some but not all of these reduced burdens. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different from the information you receive from our competitors that are public companies, or other public companies in which you have made an investment.

Recent Developments

Short-Term Liquidity

The audited financial statements included elsewhere in this prospectus were prepared assuming we would continue as a going concern. In the notes to these financial statements, we disclosed that: (i) we had incurred operating losses since our inception; (ii) we had an accumulated deficit of \$404.6 million as of

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December 31, 2016, which included a net loss of \$83.4 million for the year ended December 31, 2016; and (iii) we used \$61.2 million in cash for operations in the year ended December 31, 2016, which exceeded cash and cash equivalents and short term investments of \$53.5 million at December 31, 2016. Unless we successfully raise additional capital, whether in this offering or otherwise, these and other factors raise substantial doubt about our ability to continue as a going concern.

Corporate Information

We were incorporated in Colorado in January 2006 and reincorporated in Delaware in January 2008. Our principal executive offices are located at 11045 Roselle Street, San Diego, California 92121. The telephone number of our principal executive office is (858) 366-6900. Our website is www.tandemdiabetes.com. The information contained on or accessed through our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be a part of this prospectus or in deciding whether to purchase our common stock. References in this prospectus to our website are to inactive textual references only.

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The Offering

Issuer:	Tandem Diabetes Care, Inc.
Common stock offered by us:	18,000,000 shares
Common stock to be outstanding immediately after this offering:	49,095,598 shares
Option to purchase additional shares:	The underwriters have an option to purchase a maximum of 2,700,000 additional shares of common stock from us. The underwriters can exercise this option at any time within 30 days from the date of this prospectus.
Use of proceeds:	We will receive net proceeds from this offering of approximately \$20.7 million, or \$23.8 million if the underwriters fully exercise their option to purchase additional shares, based on an offering price of \$1.25, after deducting the underwriting discount and estimated offering expenses payable by us. We intend to use the net proceeds from this offering for working capital and other general corporate purposes. See the section entitled "Use of Proceeds" beginning on page 52 of this prospectus for additional information.
Risk factors:	Investing in our common stock involves risks. See the section entitled "Risk Factors" beginning on page 13 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
NASDAQ Global Market symbol	TNDM

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Kim Blickenstaff, our President, Chief Executive Officer and a member of our board of directors, is purchasing 1,600,000 shares of our common stock in this offering at the public offering price for an aggregate of \$2.0 million. The shares purchased by Mr. Blickenstaff will be subject to the lock-up restrictions described in Shares Eligible for Future Sale.

The number of shares of our common stock to be outstanding after this offering is based upon 31,095,598 shares of common stock outstanding as of December 31, 2016, and excludes:

990,031 shares of common stock issuable upon exercise of outstanding warrants as of December 31, 2016, at a weighted average exercise price of \$7.37 per share;

1,825,300 shares of common stock issuable upon exercise of outstanding options to purchase shares of common stock under our 2006 Stock Incentive Plan, or the 2006 Plan, as of December 31, 2016, at a weighted average exercise price of \$2.48 per share (of which options to acquire 1,780,885 shares of common stock are vested as of December 31, 2016);

6,403,087 shares of common stock issuable upon exercise of outstanding options to purchase shares of common stock under our 2013 Stock Incentive Plan, or the 2013 Plan, as of December 31, 2016, at a weighted average exercise price of \$10.09 per share (of which options to acquire 2,457,220 shares of common stock are vested as of December 31, 2016) and 562,282 shares that are reserved for future issuance under the 2013 Plan as of December 31, 2016;

78,459 shares of common stock reserved for future grant or issuance under our 2013 Employee Stock Purchase Plan, or the ESPP, as of December 31, 2016; and

1,937,890 shares of common stock issuable upon exercise of warrants issued to Capital Royalty Partners on March 7, 2017 at an exercise price of \$2.35 per share, the closing price of our common stock on the NASDAQ Global Market on the issuance date. On January 1, 2017, the number of shares of common stock reserved for issuance under the 2013 Plan automatically increased by 1,243,823 additional shares pursuant to the terms of the 2013 Plan, and the number of shares of common stock reserved for issuance under the ESPP automatically increased by 310,955 additional shares pursuant to the terms of the ESPP. These shares are also not included in the number of shares of common stock to be outstanding after this offering.

Unless otherwise indicated, this prospectus reflects and assumes the following:

no exercise of the outstanding options and warrants described above; and

no exercise by the underwriters of their option to purchase additional shares of our common stock.

Table of Contents**Summary Financial Data**

The summary financial data presented below under the heading "Statement of Operations Data" for the years ended December 31, 2016, 2015 and 2014 and the selected financial data presented below under the heading "Balance Sheet Data" as of December 31, 2016 and 2015 have been derived from our audited financial statements included elsewhere in this prospectus. The selected statement of operations data for the years ended December 31, 2013 and 2012 and the balance sheet data as of December 31, 2014, 2013 and 2012 are derived from our audited financial statements not included in this prospectus.

The summary financial data presented below should be read in conjunction with, and is qualified in its entirety by reference to, the information included in the sections entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this prospectus and our financial statements and the related notes included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

Statement of Operations Data:

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

Balance Sheet Data:

(in thousands)	As of December 31,				
	2016	2015	2014	2013	2012
Cash and cash equivalents	\$ 44,678	\$ 43,088	\$ 31,176	\$ 124,385	\$ 17,163
Short-term investments	\$ 8,860	\$ 28,018	\$ 36,106	\$ 5,095	\$

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Working capital	\$ 60,616	\$ 80,464	\$ 72,657	\$ 134,390	\$ 10,762
Property and equipment, net	\$ 18,409	\$ 15,526	\$ 12,581	\$ 9,886	\$ 8,989
Total assets	\$ 112,392	\$ 124,725	\$ 106,464	\$ 162,215	\$ 39,817
Notes payable	\$ 78,960	\$ 29,275	\$ 29,440	\$ 29,397	\$ 4,203
Convertible preferred stock	\$	\$	\$	\$	\$ 124,638
Total stockholders' equity (deficit)	\$ (5,927)	\$ 63,468	\$ 54,572	\$ 115,537	\$ (106,052)

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RISK FACTORS

*An investment in our common stock involves risks. You should carefully consider the risks described below, together with all of the other information included in this prospectus, 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 section of this prospectus entitled *Cautionary Note Regarding Forward-Looking Statements*.*

Risks Relating to our Business and our Industry

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

Since our inception in January 2006, we have incurred a significant net loss. As of December 31, 2016, we had an accumulated deficit of \$404.6 million. To date, we have financed our operations primarily through public and private sales of our equity securities, debt financing with Capital Royalty Partners II L.P. and its affiliated funds, or Capital Royalty Partners, and sales of our products. We have devoted substantially all of our resources to the commercialization of our products, the scaling of our manufacturing operations and commercial organization, the research and development of our current products and products under development, and the assembly of a management team to manage our business.

We began commercial sales of our first commercial product, t:slim, in the third quarter of 2012. We began commercial sales of t:flex in the second quarter of 2015 and t:slim G4 in the third quarter of 2015. In October 2016, we discontinued new shipments of t:slim and launched t:slim X2, our next-generation flagship pump. Since the first quarter of 2013, we have been able to manufacture and sell our insulin pump products at a cost and in volumes sufficient to allow us to achieve a positive overall gross margin. For the years ended December 31, 2016 and 2015, our gross profit was \$23.6 million and \$26.6 million, respectively. Although we have achieved a positive overall gross margin, we still operate at a significant net loss and expect that we will continue to do so for the next several years.

To implement our business strategy we need to, among other things, increase sales and gross profits of our products, maintain an appropriate customer service and support infrastructure, fund ongoing research and development activities, improve and expand our manufacturing capabilities, and obtain regulatory clearance or approval to commercialize our products currently under development. Our expenses may continue to increase as we pursue these objectives and make investments in our business. Additional increases in our expenses without commensurate increases in sales could significantly increase our operating losses.

The extent of our future operating losses and the timing of profitability are highly uncertain in light of a number of factors, including the timing of the launch of new products and product features by us and our competitors, market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers, and the timing of regulatory approval of new products. In addition, our implementation of the Technology Upgrade Program makes forecasting our operating results more difficult, because such forecasts depend on customer behavioral assumptions, such as the likelihood that the trade-in rights will actually be exercised and the timing of any such decisions. Any additional operating losses will have an adverse effect on our stockholders' equity, and we cannot assure you that we will ever be able to achieve or sustain profitability.

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We currently rely on sales of insulin pumps to generate a significant portion of our revenue, and any factors that negatively impact sales of our insulin pump products may adversely affect our business, financial condition and operating results.

We generate a significant majority of our revenue from the sale of our insulin pump products, which currently include our t:slim X2, t:flex and t:slim G4 products. Sales of our insulin pumps may be negatively impacted by many factors, including:

the potential that other technological breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pump products obsolete or less desirable;

adverse regulatory or legal actions relating to our insulin pump products or similar products or technologies;

failure of our Tandem Device Updater to accurately and timely provide customers with remote access to new product features and functionality as anticipated, or our failure to obtain regulatory approval for any such updates;

changes in reimbursement rates or policies relating to insulin pumps or similar products or technologies by third-party payors, such as the decision by UnitedHealthcare during 2016 that restricted a majority of their members from accessing our pumps;

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

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

claims that any of our insulin pump products, or any component thereof or related supplies, infringes on patent rights or other intellectual property rights of third parties.

In addition, sales of any of our current or future insulin pump products with CGM integration are subject to the continuation of our applicable agreements with DexCom, Inc., or DexCom, which under some circumstances are subject to termination by DexCom, with or without cause, on relatively short notice.

Furthermore, sales of our products may be adversely impacted by negative perceptions regarding our financial stability relative to that of our competitors, and our ability to sustain our business operations on a long-term basis. These perceptions may cause people with insulin-dependent diabetes, their caregivers and healthcare providers, as well as independent distributors and third-party payors, to question our ability to continue to sell our products, provide customer service, support our commercial organization, and fulfill our strategic objectives. These concerns may arise from a number of factors, including our recent financial results, recent changes in our stock price, our current level of indebtedness, recent or anticipated competitive product launches, the impact of the Technology Upgrade Program, and uncertainties regarding the regulatory environment. Any such concerns, whether actual or perceived, could cause consumers to delay the purchase of our products or to purchase competitive products.

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

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

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, or other activities of industry participants. We believe our products compete, and will continue to compete, directly with a number of traditional insulin pumps as well as other methods for the treatment of diabetes, including MDI therapy.

Our primary competitors are major medical device companies that are either publicly traded companies or divisions or subsidiaries of publicly traded companies. For instance, Medtronic MiniMed, a division of Medtronic, Inc., has been the market leader for many years and has the majority share of the traditional insulin pump market in the United States. Other significant insulin pump suppliers in the United States include Animas Corporation, a division of Johnson & Johnson, and Insulet Corporation. However, the market for insulin pumps is currently undergoing significant changes. For instance, in late 2016, Roche Diabetes Care, a division of F. Hoffman-La Roche discontinued sales of new insulin pumps in the United States, and in early 2017, Johnson & Johnson announced that it is evaluating strategic options for its diabetes business unit, including Animas. It is too early to evaluate the potential impact of these changes on our competitive landscape. There are also newer companies entering the field.

Some of our competitors enjoy several competitive advantages over us, including:

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

greater financial resources to respond to competitive pressures and regulatory uncertainty;

established relationships with healthcare providers and third-party payors;

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

in some cases, greater market share and established base of customers;

products supported by long-term clinical data;

larger and more established distribution networks;

greater ability to cross-sell products or provide incentives to healthcare providers to use their products; and

more experience in conducting research and development, manufacturing, clinical trials, and obtaining regulatory approval or clearance.

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

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

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

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

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

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

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit cost of our products by increasing production volume and manufacturing efficiency, including by reducing raw material, labor, product-training, expected warranty and manufacturing overhead costs per unit.

We believe that our ability to reduce the per-unit cost of our insulin pump products and related cartridges will have a significant impact on our ability to achieve profitability. Our cost of sales includes raw material procurement costs, labor costs, product-training expenses and expected warranty expenses. It also includes manufacturing overhead costs, including expenses relating to quality assurance, inventory control, facilities, equipment, information technology, and operations management. If we are unable to sustain or reduce our overall cost of sales, including through arrangements such as volume

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purchase discounts, negotiation of improved pricing, more efficient training programs for customers, and improved warranty performance, it will be difficult to reduce our per unit costs and our ability to achieve profitability will be constrained. The per unit cost of our products is significantly impacted by our overall production volumes, and any factors that cause our production volumes to decline, or to grow at a slower rate than we expect, would significantly impact our expected per unit costs. In addition, we may experience disruption in our manufacturing productivity or incur duplicative or incremental costs as we manage the planned relocation of our manufacturing facility over the next 12 months. Furthermore, while we currently believe our proprietary technology platform will allow us to gain efficiencies in the design and development of new products, changes in the market that require us to modify or replace our existing platform will reduce the amount of efficiency gained through our platform and increase our per unit costs. If we are unable to effectively manage our overall costs, while increasing our production volumes, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results.

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

Our current business strategy is highly dependent on our insulin pump products, which currently include t:slim X2, t:flex and t:slim G4, achieving and maintaining market acceptance. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that it is an attractive alternative to competitive products for the treatment of diabetes, including traditional insulin pump products and MDI therapies, as well as alternative insulin treatment methodologies. Market acceptance and adoption of our products depends on educating people with diabetes, as well as their caregivers and healthcare providers, about the distinct features, ease-of-use, positive lifestyle impact, and other perceived benefits of our products as compared to competitive products. If we are not successful in convincing existing and potential customers of the benefits of our products, or if we are not able to achieve the support of caregivers and healthcare providers for our insulin pump products, our sales may decline or we may fail to increase our sales in line with our forecasts.

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

the failure of our products to achieve wide acceptance among people with insulin-dependent diabetes, their caregivers, healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;

the failure of our products to provide the features and functionality that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in an insulin pump, and to incorporate those features into our products in a timely, cost-effective and user-friendly manner;

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

perceived risks or uncertainties associated with the use of our insulin pump products or similar products or technologies generally;

the introduction of competitive products, technologies or treatment techniques and the rate of their acceptance as compared to our insulin pump products;

discounts, rebates and other financial incentives that our competitors may offer for competitive products that make them more attractive than our products; and

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results of clinical studies relating to our existing products or products under development or similar competitive products. In addition, even if we are able to convince people with insulin-dependent diabetes, their caregivers or healthcare providers that our products compare favorably to the products and treatment alternatives offered by our competitors, negative perceptions regarding our financial stability relative to that of our competitors, and our ability to sustain our business operations on a long-term basis, especially in light of our recent financial results and the recent decline in the market price of our common stock, could cause consumers to delay the purchase of our products or to purchase competitive products.

Furthermore, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements, or the perception that advancements could occur, in our products or the products offered by our competitors. For example, we believe that during the second half of 2016, consumers interested in purchasing our insulin pump products may have delayed or changed their purchasing decisions in anticipation of the release of a new product by one of our competitors. It is also possible that consumers interested in purchasing any of our future products currently under development may delay the purchase of one of our current products.

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

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

We have derived nearly all of our revenue from sales of insulin pumps and associated supplies and expect to continue to do so. A substantial portion of the purchase price of an insulin pump is typically paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Future sales of our current and future products will be limited unless our customers can rely on third-party payors to pay for all or part of the associated purchase cost. Access to adequate coverage and reimbursement for our current and future products by third-party payors is essential to the acceptance of our products by customers.

As guidelines in setting their coverage and reimbursement policies, many third-party payors use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the U.S. Medicare program. Medicare periodically reviews its reimbursement practices for diabetes-related products. Medicare previously implemented a competitive bidding process for blood glucose strip reimbursement, which resulted in a significant reduction in the reimbursement rate for those products. More recently, in 2017, Medicare announced, and then shortly thereafter suspended, a competitive bidding process for insulin pumps. As a result, there is uncertainty as to the future Medicare reimbursement rate for our products. In addition, those third-party payors that do not follow the CMS guidelines may adopt different coverage and reimbursement policies for our current and future products. It is possible that some third-party payors will not offer any coverage for our current or future products. For instance, effective July 1, 2016, UnitedHealthcare designated one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18. We expect this decision will prevent a majority of UnitedHealthcare members from purchasing an insulin pump from us for the foreseeable future. It is possible that other third-party payors may adopt similar policies in the future, which would adversely impact our ability to sell our products.

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We currently have contracts establishing reimbursement for our insulin pump products with approximately 150 national and regional third-party payors in the United States. While we anticipate entering into additional contracts with third-party payors and adding coverage for future products under our current agreements, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis. In particular, any negative perceptions among third-party payors regarding our financial stability and our ability to continue to sell and service our products, may make it more difficult to enter into contracts for reimbursement with additional third-party payors. This may be especially true in light of our conclusion that, if we do not successfully raise additional capital, whether in this offering or otherwise, there is substantial doubt about our ability to continue as a going concern and the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern included in the report of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016. In addition, existing contracts with third-party payors generally can be modified or terminated by the third-party payor without cause and with little or no notice to us. Moreover, compliance with the administrative procedures or requirements of third-party payors may result in delays in processing approvals by those third-party payors for customers to obtain coverage for our products. Failure to secure or retain adequate coverage or reimbursement for our current and future products by third-party payors, or delays in processing approvals by those payors, could result in the loss of sales, which could have a material adverse effect on our business, financial condition and operating results.

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

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

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

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

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

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

We have only limited experience marketing and selling our products as well as training new customers on their use. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have only limited experience marketing and selling our products to customers with type 2 diabetes. As a result, we may face unexpected challenges marketing and selling t:flex, which is designed to meet the needs of customers with type 2 diabetes and/or higher insulin requirements.

We expect to derive nearly all of our revenue from the sale of t:slim X2, t:flex, and t:slim G4 Pumps and pump-related supplies unless and until we receive regulatory clearance or approval for other products currently under development. As a result, our financial condition and operating results are and will continue to be highly dependent on the ability of our sales and marketing organization to adequately promote, market and sell our insulin pumps and related products, and the ability of our diabetes educators to train new customers on the use of our products. If our sales and marketing representatives or diabetes educators fail to achieve their objectives, our sales could decrease or may not increase at levels that are in line with our forecasts.

If we are unable to maintain our existing sales, marketing, clinical and customer service infrastructure, we may fail to increase our sales to meet our forecasts.

A key element of our business strategy is the ability of our sales, clinical, marketing and customer service infrastructure to drive adoption of our products, which includes independent diabetes educators that train new customers on the use of our products. We have rapidly increased the number of sales, marketing, clinical and customer service personnel employed by us since the initial commercial launch of t:slim in 2012. However, we have faced considerable challenges in growing and managing these resources, including with respect to recruiting, training and assimilation of new territories and accounts. We expect to continue to face significant challenges as we manage and grow our infrastructure in the future and work to motivate and retain the individuals who make up our existing infrastructure. These challenges may be even greater in light of negative perceptions regarding our financial stability, and the recent decline in our stock price, which may make it more difficult to motivate and retain key personnel. Unexpected turnover among our sales, marketing, clinical and customer service personnel would have a negative impact on our ability to achieve our sales projections. Further, if a sales, marketing or clinical representative was to depart and be retained by one of our competitors, we may fail to prevent him or her from helping competitors solicit business from our existing customers, which could adversely affect our sales. Similarly, if we are not able to recruit and retain a network of diabetes educators and customer service personnel, we may not be able to successfully train and service new customers, which could delay new sales and harm our reputation.

We expect that the management of our sales, marketing, clinical and customer service personnel will continue to place significant burdens on our management team. If we are unable to retain our personnel in line with our strategic plans, we may not be able to effectively commercialize our existing products or products under development, or enhance the strength of our brand, either of which could result in the failure of our sales to increase in line with our projections or could even cause sales to decline.

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

For the year ended December 31, 2016, sales to approximately 40 independent distributors represented approximately 74% of our sales. While our goal is to ultimately reduce the percentage of our sales to independent distributors over time as we enter into contracts with additional third-party payors, we believe that a meaningful percentage of our sales will continue to be to independent distributors for the foreseeable future, and it is possible that the percentage of our sales to independent distributors could even increase in the near term. For example, our dependence upon independent distributors could increase if third-party payors decide to contract with independent distributors directly in lieu of contracting with us to supply our products to their members directly. Our dependence upon independent distributors is also expected to increase following our launch of the t:lock Connector for our insulin cartridge, which we expect will result in greater sales of our infusion sets to distributors. Our dependence upon independent distributors could also increase if customers prefer to purchase all of their diabetes supplies through a single source, instead of purchasing pump-related products through us and other diabetes supplies through other suppliers. However, our conclusion that, unless we successfully raise additional capital, whether in this offering or otherwise, there is substantial doubt about our ability to continue as a going concern, together with the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in our independent registered public accounting firm's report contained in our financial statements for the year ended December 31, 2016, may negatively impact one or more of our distributors' interest in continuing to do business with us. None of our independent distributors has been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements generally have one-year initial terms with automatic one-year renewal terms, and are terminable in connection with a party's material breach. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

For the year ended December 31, 2016, our two largest independent distributors collectively comprised approximately 33% of our sales. If any of our key independent distributors were to cease to distribute our products or reduce their promotion of our products as compared to the products of our competitors, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, or other arrangements pursuant to which independent distributors may purchase product from us, the terms of the arrangements could cause our product margins to be lower than if we directly marketed and sold our products.

If the third parties on which we increasingly rely to assist us with our current and anticipated pre-clinical development or clinical trials do not perform as expected, we may not be able to obtain regulatory clearance or approval or commercialize our products.

As our clinical infrastructure expands, we expect to increasingly rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our current and anticipated pre-clinical investigations and clinical trials. If we are not able to contract with or reach other mutually acceptable agreements with these third parties on a timely basis or on mutually acceptable terms, or these third parties do not successfully carry out their commitments or regulatory obligations or meet expected deadlines, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to agreed upon clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects

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may be adversely affected. In particular, we currently expect to rely on data from the International Diabetes Closed Loop Trial, or IDCL Trial, to support our development of t:slim X2 with TypeZero inControl AID algorithms. The IDCL Trial is being conducted entirely by third parties over which we have little or no control or influence. In the event that the IDCL Trial is not performed on a timely basis, or if the quality or accuracy of the data obtained from the IDCL Trial is compromised due to the failure to adhere to clinical protocols or regulatory requirements or for other reasons, our development activities for t:slim X2 with TypeZero may be negatively impacted.

We are increasingly dependent on clinical investigators and clinical sites to enroll patients in our current and anticipated clinical trials, and the failure to successfully complete the clinical trials could prevent us from obtaining regulatory approvals for or commercializing our products.

As part of our product development efforts, we expect to increasingly rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage such trials and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials, especially with respect to the IDCL Trial that we intend to rely upon for the development of t:slim X2 with TypeZero. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients, fail to ensure compliance by patients with clinical protocols, or fail to comply with regulatory requirements, we may be unable to successfully complete our clinical trials, which could prevent us from obtaining regulatory approvals for our products and commercializing our products, which would have an adverse impact on our business.

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

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

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

Our business strategy was developed based on a number of important assumptions about the diabetes industry in general, and the insulin-dependent diabetes market in particular, any one or more of which may prove to be inaccurate or may change over time. For example, we believe that the benefits of insulin pump therapy as compared to other common insulin treatment alternatives will continue to drive growth in the market for insulin pump therapy. In addition, we believe the incidence of diabetes in the United States and worldwide is increasing. However, each of these assumptions may prove to be inaccurate and limited sources exist to compare treatment alternatives and obtain reliable market data. The actual incidence of diabetes, and the actual demand for our products or competitive products, could differ

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materially from our projections if our assumptions are incorrect. In addition, our strategy of focusing exclusively on the insulin-dependent diabetes market may limit our ability to increase sales or achieve profitability.

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

We have a limited operating history upon which to evaluate our business and forecast our future sales and operating results and may face difficulties frequently encountered by companies early in their commercialization in competitive and rapidly-evolving markets.

We commenced operations in 2006, and began commercial sales of t:slim in the third quarter of 2012, of t:flex in the second quarter of 2015 and of t:slim G4 in the third quarter of 2015. Accordingly, we have a limited operating history upon which to evaluate our business and forecast our future sales and operating results. More recently, our launch of t:slim X2, our adoption of the Technology Upgrade Program, the FDA approval and launch of new products by one of our competitors, and the use of aggressive pricing strategies by our competitors combine to make forecasting our future sales and operating results even more challenging. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies early in their commercialization history in competitive and rapidly evolving markets, particularly companies that develop and sell medical devices. These risks include our ability to:

implement and execute our business strategy;

manage and improve the productivity of our sales, clinical and marketing infrastructure to grow sales of our existing and proposed products;

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

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

expand our manufacturing capabilities, including increasing production of current products efficiently while maintaining quality standards and adapting our manufacturing facilities to the production of new products;

respond effectively to competitive pressures and developments;

enhance our existing products and develop proposed products;

obtain and maintain regulatory clearance or approval to enhance our existing products and commercialize proposed products;

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perform clinical trials with respect to our existing products and proposed products; and

attract, retain and motivate qualified personnel in various areas of our business.

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

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

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

quality or reliability defects in product components that we source from third-party suppliers;

our inability to secure product components in a timely manner, in sufficient quantities and on commercially reasonable terms;

difficulty identifying and qualifying alternative suppliers for components in a timely manner;

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

our failure to increase production of products to meet demand;

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

our inability to manufacture multiple products simultaneously while utilizing common manufacturing equipment; and

potential damage to or destruction of our manufacturing equipment or manufacturing facility.

These risks are likely to be exacerbated by our limited experience with our current products and manufacturing processes.

As demand for our products increases, and as the number of our commercial products expands, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. Over the past year we have implemented several new pieces of equipment that are intended to improve our manufacturing capacity and efficiency and we expect to implement additional equipment and procedures over the next 12-18 months. However, it is possible that we may not achieve the anticipated improvements from these investments. In addition, we recently entered into a new lease agreement for an additional facility to consolidate substantially all of our manufacturing, warehousing and other operational needs, and any transition of our current manufacturing, warehousing and other operations to a new facility is subject to additional risk and uncertainty, and may expose us to duplicative or incremental costs. Furthermore, although we expect some of our products under development to share product features and components with our current products, manufacturing of these products may require the modification of our production lines, the

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hiring of specialized employees, the identification of new suppliers for specific components, the implementation of additional equipment and procedures, or the development of new manufacturing technologies. Ultimately, it may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

If we fail to increase our production capacity to meet consumer demand, while also maintaining product quality standards, complying with regulatory requirements and efficiently managing costs, our sales and operating margins could be negatively impacted.

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

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

We do not have long-term supply agreements with many of our suppliers and, in many cases, we make our purchases on a purchase order basis. Under most of our supply agreements, we have no obligation to buy any given quantity of components or products until we place written orders, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of components or products until they accept an order. As a result, our ability to purchase adequate quantities of our components or products may be limited. Additionally, our suppliers may encounter problems that limit their ability to manufacture components or products for us, including financial difficulties or damage to their manufacturing equipment or facilities. If we fail to obtain sufficient quantities of high quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed and our business could suffer. Our conclusion that, unless we successfully raise additional capital, whether in this offering or otherwise, there is substantial doubt about our ability to continue as a going concern, together with the inclusion of an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern in our independent registered public accounting firm's report contained in our financial statements for the year ended December 31, 2016, may cause one or more of our suppliers to terminate their relationship with us, or claim that our financial condition causes them to demand different payment terms.

We generally use a small number of suppliers for our components or products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. Moreover, in some cases, we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us. We have in the past been, and we may in the future be, required to make significant last time purchases of component inventory that is being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the

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proprietary nature of our products, our quality control standards and applicable regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. Failure of any of our suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business.

We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA, or other regulatory agencies, and the failure of our suppliers to comply with strictly-enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. Such a failure by our suppliers could also require us to cease using the components, seek alternative components or technologies, and modify our products to incorporate alternative components or technologies, which could necessitate additional regulatory approvals. Any disruption of this nature, or any increased expenses associated with any such disruptions, could negatively impact our ability to manufacture our products on a timely basis, in sufficient quantities, or at all, which could harm our commercialization efforts and adversely affect our operating results.

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

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

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

In addition, our independent distributors will need to agree to purchase the compatible infusion sets from us to provide to their customers. We anticipate the transition period for our direct customers and distributors to utilize their inventory on hand before transitioning to the t:lock Connector will be 90 to 120 days following its initial launch. During this period we anticipate offering both styles of cartridges and infusion sets to facilitate the transition of customer supplies. However, due to the variability in purchasing patterns, standard Luer-lok inventory may not be consumed at the predicted rates and we may be required to offer both styles of insulin cartridges and infusion sets for a longer period than anticipated or we may be left with excess quantities of Luer-lok style insulin cartridges that we cannot sell at standard prices or at all.

While the t:lock Connector was designed based on customer feedback, and while all standard Luer-lok infusion sets that we currently offer will initially be made available with the t:lock Connector, it is possible the t:lock Connector may not gain market acceptance by current or potential customers, their caregivers, or healthcare providers. Any negative market response to the t:lock Connector may impact a current customer's decision to purchase a new pump from us at the time of renewal. In addition, new

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potential customers may decide not to purchase our insulin pumps if they do not prefer our t:lock Connector, which may impede our ability to achieve our financial projections.

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

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

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

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

We expect that the management and support of our transition to the new facility will place significant burdens on our management team, particularly in areas relating to operations, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage the completion of construction of the new facility or our transition and commencement of manufacturing operations when planned and we may not achieve the operating efficiencies that we anticipate from the new facility.

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

In order to increase our sales and market share in the insulin-dependent diabetes market, we must enhance and broaden our product offerings in response to the evolving demands of people with insulin-dependent diabetes, their caregivers and healthcare providers, as well as competitive pressures and technologies. We may not be successful in developing, obtaining regulatory approval for, or marketing our proposed products when anticipated, or at all. In addition, notwithstanding our market research efforts, our future products may not be accepted by people with insulin-dependent diabetes, their

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

identify the product features and functionality that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in an insulin pump, and successfully incorporate those features into our products;

develop and introduce products in sufficient quantities and in a timely manner;

offer products at a price that is competitive with other products then available;

work with third-party payors to obtain reimbursement for our products;

adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;

demonstrate the safety and efficacy of proposed products; and

obtain the necessary regulatory approvals for proposed products.

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

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

t:slim X2 and t:flex received pre-market clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA. The 510(k) clearance process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes and does not always require long-term clinical studies. t:slim G4 received FDA approval under a PMA. However, there are no published studies to evaluate the safety or effectiveness of t:slim G4 in a controlled setting.

As a result, we currently lack the breadth of published long-term clinical data supporting the safety and efficacy of our products and the benefits they offer, that might have been generated in connection with other approval processes. For these reasons, people with insulin-dependent diabetes and healthcare providers may be slower to adopt or recommend our products, we may not have comparative data that our competitors have or are generating, third-party payors may not be willing to provide coverage or reimbursement for our products and we may be subject to greater regulatory and product liability risks. These and other factors could slow the adoption of our products and result in our sales being lower than anticipated. In addition, future studies or clinical experience may indicate that treatment with our products is not superior to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability.

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If the results of clinical studies or other experience, such as our monitoring or investigation of customer complaints, indicate that our products may cause or create an unacceptable risk of unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, significant legal liability, and harm to our business reputation.

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

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

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

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

For example, we entered into three separate development agreements with DexCom which provide us non-exclusive licenses to integrate various generations of DexCom CGM technology with our insulin pump products. We currently offer t:slim G4 under an agreement that runs until January 4,

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2018, with automatic one-year renewals. Under certain circumstances, our agreements with DexCom may be terminated by either party without cause or on short notice. Termination of any of our agreements with DexCom could require us to redesign certain current products and products under development, and attempt to integrate an alternative CGM system into our insulin pump systems, which would require significant development and regulatory activities that could result in an interruption or substantial delay in the availability of the product to our customers.

Any significant disruptions to our information technology systems, or failures of our pumps' software to perform as we anticipate, could have an adverse effect on our business, financial condition and operating results.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage sales and marketing data, accounting and financial functions, manufacturing and quality records, inventory management, product development tasks, research and development data, customer service and technical support functions. Our information technology systems, including those that support t:connect, as well as those involved in the operation of our Tandem Device Updater, are vulnerable to damage or interruption from earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures. In addition, our currently-marketed insulin pumps, and our products currently under development contain software which could be subject to computer virus, hacker attacks or other failures. As a result of the recent FDA clearance of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps, these risks are significantly increased.

The failure of our or our service providers' information technology systems or our pumps' software to perform as we anticipate or our failure to effectively implement new information technology systems could disrupt our entire operation or adversely affect our software products. For example, we market our Tandem Device Updater as having the unique capability to deploy software updates to our pumps, which we anticipate may allow customers remote access to new and enhanced features. The failure of our Tandem Device Updater to provide software updates as we anticipate, including as a result of our inability to secure and maintain necessary regulatory approvals, the inability of our pumps to properly receive software updates, errors or viruses embedded within the software being transmitted, or the failure of our customers to properly utilize the system to complete the update, could result in decreased sales, increased warranty costs, and harm to our reputation, all of which could have a material adverse effect on our business, financial condition and operating results.

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

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

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

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

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

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

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

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

problems assimilating the acquired products or technologies;

issues maintaining uniform standards, procedures, controls and policies;

unanticipated costs associated with acquisitions;

diversion of management's attention from our existing business;

risks associated with entering new markets in which we have limited or no experience; and

increased legal and accounting costs relating to the acquisitions or to compliance with regulatory matters.

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

Risks Related to our Financial Results and Need for Financing

We will need to raise additional funds in the future. If these funds are not available to us, we will not have sufficient cash to fund our operations through December 31, 2017.

At December 31, 2016, we had \$55.5 million in cash, cash equivalents and short-term investments, which included \$2.0 million of restricted cash. At the date our financial statements for the year ended December 31, 2016 were issued, we did not have sufficient cash to fund our operations through December 31, 2017 without additional financing and therefore, we concluded there was substantial doubt about our ability to continue as a going concern within one year after the date the financial statements were issued. As a result, the audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. Moreover, the continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers, additional research and development activities, and the transition to our new manufacturing facility, will continue to increase our expenses and capital needs. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Our future capital requirements will depend on many factors, including:

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

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

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

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

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

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

the cost of ongoing compliance with legal and regulatory requirements;

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

our compliance with the covenants in our Amended and Restated Term Loan Agreement with Capital Royalty Partners II L.P. and its affiliate funds, or Capital Royalty Partners, as amended, which we refer to as the Term Loan Agreement;

anticipated or unanticipated capital expenditures; and

unanticipated general and administrative expenses.

As a result of these and other factors, management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock. This offering is being conducted to obtain such funding, although there can be no guarantee that we will successfully

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raise all the funding we require in this offering. Depending on the amount of funding we receive in this offering as well as other factors, we may in the future seek additional capital from public or private offerings of our capital stock or we may elect to borrow additional amounts under new credit lines or from other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

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

Our operating results may fluctuate significantly from quarter to quarter.

There has been and may continue to be meaningful variability in our operating results from quarter to quarter, as well as within each quarter, especially around the time of anticipated new product introductions. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

our ability to increase sales and gross profit of our insulin pump products and pump-related supplies, and to commercialize and sell our future products, and the number of our products sold in each quarter;

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

the financial and accounting impacts of the Technology Upgrade Program;

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

the effect of third-party coverage and reimbursement policies;

our ability to maintain our existing infrastructure;

the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans;

interruption in the manufacturing or distribution of our products;

our ability to simultaneously manufacture multiple products that meet quality and reliability requirements;

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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;

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regulatory clearance or approvals affecting our products or those of our competitors; and

the timing of revenue and expense recognition associated with our product sales pursuant to applicable accounting standards. As a result of our recent product launches, and due to the complexities of the industry in which we operate, it will continue to be difficult for us to forecast demand for our products with any degree of certainty, which means it will be difficult for us to forecast our sales. For example, in the period leading up to the commercial launch of t:slim X2, we believe there were an increasing number of customers anticipating its availability who delayed their purchasing decisions until they could include t:slim X2 in their decision-making process.

In addition, our operating expenses will continue to increase as we expand our business. Accordingly, we may experience substantial variability in our operating results from quarter to quarter. If our quarterly or annual operating results fall below the expectation of investors or securities analysts, the price of our common stock could decline substantially as has occurred over the past several months. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

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

Our ability to continue as a going concern is dependent upon a number of factors, including our ability to increase our sales and gross profits, our ability to generate positive cash flow from operations, and our ability to obtain the necessary financing to meet our obligations and repay our liabilities arising from obligations that become due in the ordinary course of business. Management currently believes that it will be necessary for us to raise additional funding in the form of an equity financing from the sale of common stock. This offering is being conducted to obtain such funding, although there can be no guarantee that we will successfully raise all the funding we require in this offering. However, reports issued by independent registered public accounting firm's expressing substantial doubt about a company's ability to continue as a going concern are generally viewed unfavorably by current and prospective investors, as well as by analysts and creditors. As a result, this report may make it more difficult for us to raise the additional financing necessary to continue to operate our business. In addition, this report may make it more difficult for us to sell our products and meet our sales forecasts, which may further impede our ability to raise additional financing.

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

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

At December 31, 2016, we had \$81.1 million aggregate borrowings outstanding under the Term Loan Agreement with Capital Royalty Partners. Our ability to make scheduled payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves at the time a scheduled payment becomes due and our actual and projected financial and operating performance. The amount of our cash reserves and our financial and operating performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, or interest on our existing or future indebtedness.

If our cash balances or cash flows from operations are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell or license our assets, sell or reduce our operations, seek additional capital on unfavorable terms, or restructure or refinance our indebtedness. We cannot assure you that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Our recent and projected financial results, the explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern contained in the report of our independent registered public accounting firm, and general concerns among potential investors and creditors about our financial well-being may make taking such actions on commercially reasonable terms especially difficult. If we are unable to generate sufficient cash flow or are otherwise unable to obtain the funds necessary to meet required payments of principal, premium, if any, and interest on our indebtedness, we could be in default under the terms of the Term Loan Agreement.

The Term Loan Agreement contains restrictive and financial covenants that may limit our operating flexibility, and our potential inability to comply with such covenants puts us at risk of triggering an event of default under the Term Loan Agreement.

The Term Loan Agreement contains certain restrictive covenants that limit our ability to incur additional indebtedness and liens, merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. We may not be able to engage in any of the foregoing transactions unless we obtain the consent of Capital Royalty Partners or terminate the Term Loan Agreement.

The Term Loan Agreement also contains certain financial covenants, including minimum revenue and cash balance requirements, and financial reporting requirements. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under the Term Loan Agreement. Further, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under the Term Loan Agreement.

The terms of the Term Loan Agreement also require that we deliver audited financial statements that include an unqualified audit report to Capital Royalty Partners. The audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2016 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern. This explanatory paragraph in our auditor's report constitutes a potential event of default under the Term Loan Agreement. As a result, on March 7, 2017, we entered into Waiver and Amendment No. 4 to Term Loan Agreement, or the Fourth Amendment, which includes a limited waiver of a potential event of default that could have resulted from the inclusion of the explanatory paragraph in our auditor's report. The Fourth Amendment also imposes

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additional restrictive and financial covenants on us, which may increase our risk of triggering defaults under the Term Loan Agreement. In particular, the Fourth Amendment provides that we must complete a financing in which our gross proceeds from the sale of equity securities is at least \$30.0 million no later than January 15, 2018.

In the event of a future default triggered by any violations of the covenants in the Term Loan Agreement, including the new covenants in the Fourth Amendment, we will need to obtain additional waivers from Capital Royalty Partners to avoid being in default. If we are unable to obtain additional waivers of those events of default or amendments to the Term Loan Agreement that would allow us to be in compliance with the terms of the agreement, an event of default would result. In the event of our default under of the Term Loan Agreement, including if we fail to complete a \$30.0 million equity financing by January 15, 2018, we may be required to repay any outstanding amounts earlier than anticipated and our capital resources may not be sufficient to meet those obligations. Further, if we are unable to repay our indebtedness and Capital Royalty Partners institutes foreclosure proceedings against our assets, we could be forced into bankruptcy or liquidation, and in such a scenario, the values that we receive for our assets could be significantly lower than the values reflected in our financial statements.

Risks Related to our Intellectual Property and Potential Litigation

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

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of December 31, 2016, our patent portfolio consisted of approximately 50 issued U.S. patents and 46 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2035. We also have and are seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we have one pending U.S. trademark application as well as 23 trademark registrations, including 10 U.S. trademark registrations and 13 foreign trademark registrations.

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

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

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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 incentive to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, pursuing litigation may provoke third parties to assert counterclaims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results.

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

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

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

stop selling our products or using technology that contains the allegedly infringing intellectual property;

incur significant legal expenses;

pay substantial damages to the party whose intellectual property rights we are allegedly infringing;

redesign those products that contain the allegedly infringing intellectual property; or

attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

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

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

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

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

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

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

Risks Related to our Legal and Regulatory Environment

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

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies. The regulations are very complex and are subject to rapid

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change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other U.S. governmental agencies regulate numerous elements of our business, including:

product design and development;

pre-clinical and clinical testing and trials;

product safety;

establishment registration and product listing;

labeling and storage;

marketing, manufacturing, sales and distribution;

pre-market clearance or approval;

servicing and post-market surveillance;

advertising and promotion; and

recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is substantially equivalent to a device legally on the market, known as a predicate device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. We received approval of our PMA for t:slim G4 in September 2015. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis or at all for our proposed products.

We initially received pre-market clearance for t:slim under Section 510(k) of the FDCA in November 2011. We obtained 510(k) clearances for t:connect and t:flex in February 2013 and January 2015, respectively. From time to time, we may make modifications to these products that may require a new 510(k). We have received 510(k) clearance for various modifications to t:slim and its associated cartridge. For instance, in July 2016, we received 510(k) clearance to reduce the age in our indications for use of t:slim to age six. We may pursue 510(k) clearance for additional modifications to t:slim X2 and t:flex in the future. In addition, in July 2016, we received 510(k) clearance for the first use of our Tandem Device Updater. If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our forecasts. We anticipate that our products currently under development will require the more costly, lengthy

and uncertain PMA approval process.

The FDA can delay, limit or deny clearance or approval of one of our devices for many reasons, including:

our inability to demonstrate that our products are safe and effective for their intended users;

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the data from our clinical trials may be insufficient to support clearance or approval; and

failure of the manufacturing process or facilities we use to meet applicable requirements.

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

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

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

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

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

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

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

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

We and our third-party suppliers are required to comply with the FDA's Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality

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assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may impose inspections or audits at any time. If we or our suppliers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us. Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results.

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

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

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

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

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

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

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

the federal healthcare programs Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an

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individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

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

federal and state physician referral laws, such as the federal Stark Law, that prohibit a physician from referring Medicare or Medicaid patients to an entity providing designated health services, including a company that furnishes durable medical equipment, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement;

federal criminal laws enacted as part of HIPAA that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

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

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

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

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

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal or state regulatory authorities