

TANDEM DIABETES CARE INC  
Form S-1/A  
January 29, 2018  
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As filed with the Securities and Exchange Commission on January 29, 2018

Registration No. 333-222553

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

Amendment No. 1  
to  
FORM S-1  
REGISTRATION STATEMENT  
*UNDER*  
*THE SECURITIES ACT OF 1933*

**Tandem Diabetes Care, Inc.**  
**(Exact name of registrant as specified in its charter)**

<b>Delaware</b> <b>(State or other jurisdiction of</b>	<b>3841</b> <b>(Primary Standard Industrial</b>	<b>20-4327508</b> <b>(I.R.S. Employer</b>
<b>incorporation or organization)</b>	<b>Classification Code Number)</b> <b>11075 Roselle Street</b>	<b>Identification Number)</b>

**San Diego, California 92121**

**(858) 366-6900**

**(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)**

**Kim D. Blickenstaff**

**President and Chief Executive Officer**

**11075 Roselle Street**

**San Diego, California 92121**

**(858) 366-6900**

**(Name, address, including zip code, and telephone number, including area code, of agent for service)**

*Copies to:*

**Bruce Feuchter, Esq.**

**Ryan C. Wilkins, Esq.**

**Stradling Yocca Carlson & Rauth,  
P.C.**

**660 Newport Center Drive, Suite  
1600**

**Newport Beach, California 92660**

**(949) 725-4000**

**David B. Berger, Esq.**

**Executive Vice President, General  
Counsel**

**and Secretary**

**Tandem Diabetes Care, Inc.**

**11075 Roselle Street**

**San Diego, California 92121**

**(858) 366-6900**

**Per B. Chilstrom, Esq.**

**Clifford Chance US LLP**

**31 West 52nd Street**

**New York, New York 10019**

**(212) 878-8000**

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of Securities Act.

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee <sup>(2)</sup>
Common Stock, \$0.001 par value per share	\$46,000,000	\$5,727 <sup>(3)</sup>

- (1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended, and includes shares of our common stock that the underwriters have an option to purchase.
- (2) Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.
- (3) \$4,980 of this amount was previously paid in connection with the original filing of this registration statement.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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**The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**Subject to Completion, dated January 29, 2018**

**13,513,514 Shares**

**TANDEM DIABETES CARE, INC.**

**Common Stock**

**\$ per share**

We are offering 13,513,514 shares of our common stock, par value \$0.001 per share. Our common stock is listed on the NASDAQ Global Market under the symbol TNDM. On January 26, 2018, the last reported sale price of our common stock on the NASDAQ Global Market was \$2.96 per share. The actual offering price per share will be as determined between us and the underwriters at the time of pricing, and may be at a discount to the current market price. Accordingly, the recent market price used throughout this prospectus may not be indicative of the actual public offering price.

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 15.**

	<b>Per Share</b>	<b>Total</b>
Public offering price	\$	\$
Underwriting discount <sup>(1)</sup>	\$	\$
Proceeds, before expenses, to us	\$	\$

<sup>(1)</sup> We have agreed to pay the underwriters a commission of 2.0% of the gross proceeds of this offering attributable to participation by certain predetermined investors and 6.5% of the gross proceeds of this offering to the remaining investors. We refer you to the section entitled Underwriting beginning on page 146 of this prospectus for additional information regarding total compensation payable to the underwriters.

We have granted to the underwriters an option to purchase additional shares. Under this option, the underwriters may elect to purchase a maximum of 2,027,027 additional shares from us within 30 days following the date of this prospectus.

Certain of our existing stockholders and directors have indicated an interest in purchasing up to an aggregate of approximately \$        million in shares of our common stock in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these potential investors and any of these potential investors could determine to purchase more, less or no shares in this offering.

**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        , 2018.

*Sole Book-Running Manager*

**Oppenheimer & Co.**

*Co-Manager*

**National Securities Corporation**

The date of this prospectus is        , 2018.

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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 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 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.



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**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, (i) references to Tandem, we, us, our or the Company refer to Tandem Diabetes Care, Inc. and (ii) all share amounts, exercise prices and other amounts set forth in this prospectus supplement have been adjusted to reflect the impact of the 1-for-10 reverse stock split of our common stock that became effective on October 9, 2017.*

**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 our competitive advantage is rooted in our unique consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing and sales activities primarily focus on our flagship product, the t:slim X2 Insulin Delivery System, or t:slim X2, which is based on our proprietary technology platform. The simple-to-use t:slim X2 is the smallest durable insulin pump available, and the only pump currently available that is capable of remote feature updates, which positions us well to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. By delivering innovative hardware and software solutions, as well as best-in-class customer support, we aim to improve and simplify the lives of people with diabetes and their healthcare providers.

We have commercially launched five insulin pumps in the past four years, all of which have been developed using our proprietary technology platform. Two of these pumps have featured continuous glucose monitoring technology, or CGM. Since the launch of our first product in August 2012, through December 2017, we have shipped nearly 68,000 pumps to customers in the United States. In 2017, we announced plans to begin commercialization of t:slim X2 in select geographies outside the United States, including Canada, during 2018.

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. By doing so, we seek to optimize our products, which allows for them to be successfully operated by users in their intended environment.

We have developed our products to provide the specific features that people with insulin-dependent diabetes and healthcare providers seek in a next-generation insulin pump. Our use of modern consumer technologies, and a proprietary pumping technology, has allowed us to design the slimmest and smallest durable insulin pump on the market, without sacrificing insulin capacity. t:slim X2 features our patented Micro-Delivery technology, a miniaturized pumping mechanism that draws insulin from a flexible bag within the pump's cartridge, rather than relying on a lead screw driven syringe mechanism. It also features an easy-to-navigate software architecture, a vivid color touchscreen, an advanced Bluetooth radio capable of communicating with multiple compatible devices, such as a CGM sensor, blood glucose meter or mobile applications, and a micro-USB connection that supports a rechargeable battery, software updates through the Tandem Device Updater, as well as uploads to t:connect Diabetes Management Application, or t:connect. The Tandem Device Updater is a unique tool that allows our 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 and functionality faster than the

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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 our 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, the t:slim Insulin Delivery System, or t:slim, in August 2012. During 2015, we commenced commercial sales of two additional insulin pumps: the t:flex Insulin Delivery System, or t:flex, in May 2015 and the t:slim G4 Insulin Delivery System, or t:slim G4, in September 2015. In October 2016, we commenced commercial sales of t:slim X2 and discontinued new sales of t:slim. In September 2017, we commenced commercial sales of t:slim X2 integrated with the Dexcom G5 Mobile CGM system, which is manufactured by Dexcom, Inc., or Dexcom, and discontinued new sales of t:slim G4. In 2017, t:slim X2 represented approximately 95% of our new pump shipments. In September 2017, we also commenced commercial sales of cartridge and infusion set products using our custom t:lock Connector, or t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to our cartridge.

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. In addition, we expanded our sales, clinical and marketing infrastructure 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, as they are approved by the U.S. Food and Drug Administration, or FDA, through the Tandem Device Updater.

For the nine months ended September 30, 2017 and 2016 our sales were \$67.3 million and \$55.3 million, respectively. 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 nine months ended September 30, 2017 and 2016, our net loss was \$61.6 million and \$68.6 million, respectively. For the nine months ended September 30, 2017, this included incremental net sales of \$4.8 million with a corresponding increase of \$3.2 million in gross profit as a result of our Technology Upgrade Program, which we offered between July 2016 and September 2017 to provide eligible customers a pathway to ownership of a t:slim X2. For the nine months ended September 30, 2016, this included a deferral of sales of \$8.4 million with a corresponding deferral of \$1.4 million in cost of sales as a result of our Technology Upgrade Program. 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 September 30, 2017 and December 31, 2016 was \$466.2 million and \$404.6 million, respectively. Pump sales accounted for 65% and 74% of sales, respectively, for the nine months ended September 30, 2017 and 2016, while pump-related supplies primarily accounted for the remainder in each period.

Our headquarters and our manufacturing facility are located in San Diego, California and we employed 574 full-time employees as of December 31, 2017.

## **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.

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The International Diabetes Federation, or IDF, estimates that in 2017, approximately 425 million people had diabetes worldwide and that by 2045, this number will increase to 629 million people worldwide. According to the Centers for Disease Control and Prevention, or CDC, 2017 National Diabetes Statistics Report, approximately 23 million people in the United States have diagnosed diabetes, of which type 1 diabetes accounts for approximately 5% to 10%, or approximately 1.2 to 2.3 million people. Of people with type 2 diabetes in the United States, the CDC reports that approximately 14%, or 3.2 million people, manage their diabetes with insulin only.

Our target market consists of people in the United States, and select geographies worldwide beginning in 2018, who require daily rapid acting insulin. All people with type 1 diabetes require daily rapid acting insulin, but only a subset of people with type 2 diabetes require daily rapid-acting insulin, as a majority manage their therapy through improvements in diet and exercise, oral medications, or injectable therapies such as long acting insulin. 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.

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. In addition, 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. We further believe that recent and ongoing developments in the use of CGM technology and AID algorithms in conjunction with insulin pump therapy will continue to provide people with insulin-dependent diabetes benefits that will make insulin pump therapy an even more attractive treatment alternative.

## **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

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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 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 pump features, or even discourage use entirely.

***Pump mechanism limitations.*** Traditional pumps utilize a mechanism in which a lead screw drives a plunger to deliver insulin. This design limits the ability to reduce the size of the pump due to the length and diameter of the syringe and lead screw.

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 thereby encouraging increased demand for our pumps.

## **Our Solution**

We develop our insulin pump technology and related product offerings using a consumer-focused approach. We initially rely on 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 features and functionality they seek and in a manner that makes the features usable and intuitive. We believe this approach is fundamentally different from the approach applied to the traditional medical device development process.

Our flagship t:slim X2 platform, which we believe addresses the shortcomings of currently available traditional pumps, features:

***Contemporary style.*** t:slim X2, as well as our products under development, have the look and feel of a modern consumer electronic device, such as a smartphone. Relying on extensive consumer input and feedback received during the development process, we believe the modern and innovative 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 t:slim X2 unique in the insulin pump market.



***Adaptable platform.*** The t:slim X2 platform is highly adaptable as a result of a number of features that are inherent within our proprietary technology, including our easy-to-navigate software architecture and touchscreen

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user interface. t:slim X2 is also compatible with the Tandem Device Updater, which is a 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, t:slim X2 can easily and discreetly fit into a pocket. t:slim X2 is the slimmest and smallest durable insulin pump 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 pumps 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.

***Innovative technology.*** Our Micro-Delivery technology is unique compared to traditional pumps. 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 compared to any pump currently available. Our insulin pumps also feature a micro-USB connection that supports a rapid rechargeable battery, uploads to t:connect and connectivity to the Tandem Device Updater.

We believe the t:slim X2 platform will allow us to further penetrate and expand the insulin pump therapy market by addressing the specific product and technology limitations associated with traditional pumps that have been raised by people with diabetes, their caregivers and healthcare providers. We also believe our technology under development provides us with the opportunity to address unmet needs in the insulin-dependent diabetes market, including advancements in AID and the potential for further device miniaturization.

## **Our Strategy**

Our goal is to expand significantly 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 offering an adaptable insulin pump that can provide features and functionality to respond to evolving needs and preferences, we believe we are uniquely positioned to address differentiated segments of the insulin-dependent diabetes market.

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

***Drive adoption of our products through our sales, marketing and clinical infrastructure.*** We have achieved commercial success by investing in the development of our sales, marketing and clinical infrastructure. With this

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base infrastructure, we believe we are well-positioned to introduce our products to more people with insulin-dependent diabetes, their caregivers and healthcare providers, while continuing to provide the highest level of customer service. We believe our early investments in this infrastructure, when combined with the launch and marketing of new products, will drive continued adoption of our products, while efficiently increasing our revenues over the long-term.

***Promote awareness of our products to consumers, their caregivers and healthcare providers.*** Our products were specifically designed to address the shortcomings of currently available technologies that we believe have limited the adoption of insulin pump therapy. We intend to continue our direct-to-consumer marketing to promote the insulin therapy features and functionalities offered by our products, as well as to leverage our sales and marketing force, together with our clinical specialists to cultivate relationships with diabetes clinics, insulin-prescribing healthcare professionals and other key opinion leaders. By promoting awareness of our products, we believe we will be able to attract users of our competitors' insulin pump products, as well 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. In addition, we are actively involved in multiple clinical trials supporting the use of our AID products in development, which were designed to demonstrate the clinical benefits associated with our products under development. We plan to continue to invest in clinical activities intended to demonstrate that the use of our products contributes to improved clinical outcomes combined with the data collected from our t:connect platform.

***Continue to innovate to provide products that address the unmet needs of people in the insulin-dependent diabetes market.*** We believe that the t:slim X2 platform allows us to provide the most sophisticated and intuitive insulin pump therapy on the market. We intend to leverage the t:slim X2 platform to continue to pursue advances in AID, including through strategic agreements and commercial product development efforts. The Tandem Device Updater is designed to allow pump users to quickly and easily update their pumps' software from a personal computer. We successfully demonstrated the utility of this tool in the third quarter of 2017 when, following FDA approval, we simultaneously offered Dexcom G5 Mobile integration to both existing and new t:slim X2 users. We intend to leverage the t:slim X2 platform to allow users to update their pumps' software to include AID algorithms, which also eliminates the need for disruptive and costly trade-in programs to upgrade hardware to newer platforms. We also intend to continue to explore additional features, functionality and mobile applications for the t:slim X2 platform, as well as a next generation pump platform, in order to address differentiated segments of the insulin-dependent diabetes market.

***Invest in our consumer-focused approach.*** We believe that our consumer-focused approach to product design, marketing and customer care is a key differentiator. 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.



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***Leverage our manufacturing operations to achieve cost and production efficiencies.*** We manufacture our products at our facilities located in San Diego, California. We utilize a semi-automated manufacturing process for our pump products and disposable cartridges. During 2017, we relocated our manufacturing operations to our new, 50,000 square foot Barnes Canyon facility, which became fully operational at the beginning of 2018. This facility doubles our previous manufacturing capacity for both insulin pumps and cartridges and expands warehousing for additional infusion set supplies related to our launch of t:lock. The facility is also designed to maximize efficiencies in our manufacturing processes and workflows, and allow us to further expand our production capacity by replicating our production lines, without increasing the cost of overhead from our facilities.

## **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;

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

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 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;

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 for the next twelve months;

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;

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 may not be able to generate sufficient cash to service our indebtedness, which currently consists of our Amended and Restated Term Loan Agreement with Capital Royalty Partners II, L.P. and its affiliated funds, or Capital Royalty Partners, which we refer to as the Term Loan Agreement;

Our ability to commercialize our products outside of the United States;

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.

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### **Recent Developments**

#### ***Commencement of Manufacturing Operations at Barnes Canyon Facility***

We recently obtained regulatory clearance to operate and have commenced full manufacturing operations at our Barnes Canyon facility. The facility is expected to double our previous manufacturing capacity for both insulin pumps and cartridges, and expand warehousing for additional infusion set supplies related to the launch of t:lock. Our Barnes Canyon facility will initially house two pump production lines and four cartridge manufacturing lines, with room for two additional cartridge lines, in addition to warehousing operations and office space. We plan to relocate our remaining production equipment and personnel from our existing facilities to our Barnes Canyon facility by early February.

#### ***Lease Amendments for Corporate Headquarters***

On December 27, 2017, we entered into an amendment to the lease covering the warehouse and office space located at 11065 and 11075 Roselle Street in San Diego, California, which extends the term of our lease through May 31, 2022, an additional 36 months from its previous expiration date, and makes certain changes to our monthly base rent payments.

On December 27, 2017, we also entered into an amendment to the lease covering the manufacturing, laboratory and office space located at 11025, 11035 and 11045 Roselle Street in San Diego, California, which extends the term of the lease with respect to the buildings located at 11025 and 11035 Roselle Street through May 31, 2022, an additional 36 months from its previous expiration date, and makes certain changes to our monthly base rent payments. The amendment also terminates the lease with respect to the building located at 11045 Roselle Street as of January 31, 2018. The building located at 11045 Roselle Street, which primarily housed our manufacturing and related operations, will largely be replaced by our Barnes Canyon facility. We expect to derive cost savings of approximately \$2.1 million over a period of approximately 16 months as a result of the termination of the lease of this building.

#### ***Animas Will Discontinue the Manufacture and Sale of Insulin Pumps***

In October 2017, Johnson & Johnson announced that it intends to discontinue the operations of Animas Corporation, or Animas, and exit the insulin pump business entirely, and that, in connection with these activities, it designated Medtronic as a preferred partner to facilitate the transition of Animas insulin pump customers. As part of this transition, Medtronic is offering a portion of Animas customers the option of acquiring a prior-generation Medtronic insulin pump, the 630G, at no charge. As a result of this change in the insulin pump market, we now offer the only alternative durable insulin pump to those sold by Medtronic in the United States. While this announcement represents a significant change within our industry, and we have seen a recent increase in sales to people who report being former Animas pump users, it is too early to know how it will influence our business or the competitive landscape in which we operate over the longer term.

#### ***Clinical Trial Updates***

All participants in our clinical trial for t:slim X2 featuring a predictive low glucose suspend algorithm have been enrolled. We anticipate the trial will be completed by the end of January 2018, and we plan to use this data in a Premarket Approval, or PMA, submission to the FDA in the first quarter of 2018.

Recently, the first pilot study using a hybrid closed loop system featuring t:slim X2 with embedded algorithms from TypeZero Technologies and integration with Dexcom G6 CGM was successfully completed, demonstrating that the



system worked as intended. This pilot study was the first of three in the National Institute of Health-funded International Diabetes Closed Loop Trial using t:slim X2, running the algorithm directly on the pump.

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The second study is now moving forward with enrollment at seven clinical sites, and is anticipated to begin in the first quarter of 2018. The IDCL Trial is expected to conclude with a pivotal study in 2018, and we plan to use this data in a PMA submission to the FDA.

### **Preliminary Fourth Quarter and Full Year 2017 Financial Results**

Our financial statements for the fiscal quarter ended December 31, 2017, or the fourth quarter, and for the full year ended December 31, 2017, or the full year 2017, are not yet complete. We expect to report complete information for the fourth quarter and for full year 2017 after the completion of this offering. Accordingly, we are presenting preliminary estimates of certain financial information related to our company, including our expected sales and cash, cash equivalents, short-term investments and restricted cash, that we expect to report for the fourth quarter and the full year 2017.

In the fourth quarter, we shipped an aggregate of approximately 7,000 pumps, of which more than 95% were t:slim X2. For the fourth quarter, we estimate our sales were approximately \$39.0 million - \$40.0 million, with no material impact from the Technology Upgrade Program. We estimate that pump sales accounted for approximately 68% of sales during the fourth quarter, while infusion sets accounted for approximately 20%, and cartridges accounted for the remainder of sales.

We believe our preliminary sales results for the fourth quarter were impacted by a number of factors, including:

We received FDA approval to market t:slim X2 with G5 on August 25, 2017 and discontinued new sales of t:slim G4. Following the launch, we experienced a meaningful increase in the demand for our insulin pumps. Pump shipments grew more than 80% to approximately 7,000 in the fourth quarter compared to 3,868 in the third quarter of 2017, which is the largest sequential quarterly increase since the fourth quarter of 2015 when we received approval and launched t:slim G4.

We began the transition of our customers to t:lock in the third quarter of 2017. This substantially increased our infusion set sales in the fourth quarter to an estimated \$8.0 million, compared to \$5.0 million in the third quarter of 2017 and \$3.9 million in the fourth quarter of 2016. Prior to announcing our plans to launch this product, only a small percentage of our customers and distributors purchased infusion sets from us as compared to purchases of our cartridges. In particular, the ratio of our sales volume of infusion sets relative to sales volume of cartridges during the third quarter was approximately 66%, as compared to 61% during the second quarter of 2017, 51% during the first quarter of 2017 and 31% for all of 2016. This ratio increased to approximately 88% in the fourth quarter of 2017, nearing 100% in December 2017.

While the largest percentage of our new customers still report being new to pump therapy, with approximately half converting from MDI, we experienced an increase in the fourth quarter of 2017 in the percentage of sales to people who reported switching from an Animas pump following Johnson & Johnson's announcement that it intends to discontinue the operations of Animas and exit the insulin pump business.

We continue to be subject to negative perceptions regarding our financial stability relative to that of our competitors, including concerns among healthcare providers and potential customers regarding our ability to

sustain our business operations on a long-term basis. In some cases, these perceptions and concerns have caused potential customers to delay the purchase of our products or purchase competitors' products and have negatively impacted the willingness of healthcare providers to recommend our products over those of our competitors.

We expect to continue to incur an operating loss for the fourth quarter and full year ended December 31, 2017.

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In the full year 2017, we shipped an aggregate of approximately 17,100 pumps. For the full year 2017, we estimate our sales were approximately \$106.0 million - \$107.0 million including approximately \$5.0 million of sales previously deferred in prior periods and upgrade fees received as a result of our Technology Upgrade Program. We estimate that pump sales accounted for approximately 65% of sales during the full year 2017, while pump-related supplies primarily accounted for the remainder of sales.

Our cash, cash equivalents, short-term investments and restricted cash as of December 31, 2017 was approximately \$24.2 million, of which \$10.0 million was restricted. Our cash balance reflects our completion of a registered public offering in October 2017, or the October Financing, of 4,630,000 shares of our common stock, Series A warrants to purchase up to 4,630,000 shares of our common stock and Series B warrants to purchase up to 4,630,000 shares of our common stock at a public offering price of \$3.50 per share and accompanying warrants. The gross proceeds were approximately \$16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. The Series A warrants have an exercise price of \$3.50 per share, are immediately exercisable, and will expire on the 5-year anniversary of the date of issuance. The Series B warrants have an exercise price of \$3.50 per share, are immediately exercisable, and will expire on the 6-month anniversary of the date of issuance. Each series of warrants, if exercised by all holders in full, may result in additional gross proceeds to us of \$16.2 million.

Our sales (including deferred sales and infusion set sales) and cash, cash equivalents, short-term investments and restricted cash estimates presented above, as well as our expectations regarding our operating loss, are preliminary and subject to revision based upon the completion of our year-end financial closing process and our financial statements. The estimated amounts are not intended to convey final results for the fourth quarter or the full year 2017. These preliminary estimates have been prepared by, and are the responsibility of, our management based upon the most current information available to them as of the date of this prospectus. Such preliminary estimates have not been subject to any audit procedures, review procedures or any other procedures by our independent registered public accounting firm. In addition, these estimates and expectations are subject to risks and uncertainties. See the sections of this prospectus entitled Risk Factors and Cautionary Note Regarding Forward-Looking Information. Accordingly, following the completion of our year-end financial closing process, we may report financial results that could differ from these estimates. Factors that could cause the preliminary financial data and estimates to differ include, but are not limited to: (i) additional adjustments in the calculation of, or application of accounting principles, for the financial results; and (ii) discovery of new information that affects accounting estimates and management's judgment underlying these estimated results. The information presented herein should not be considered a substitute for the financial information to be filed with the SEC in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 once it becomes available. We have no intention or obligation to update the estimated financial results in this prospectus prior to filing our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

## **Trends Impacting 2018 Financial Results**

We believe our expected sales growth in 2018 will be positively influenced by the following factors:

Renewal opportunities exist for some portion of the 10,822 pumps we originally shipped in 2014, based on the typical four-year insurance reimbursement cycle for insulin pumps. This opportunity may be limited by many factors, such as the ability to obtain approval for reimbursement from insurance payors and the potential for customers to choose competitive products, to use their existing insulin pump on an out-of-warranty basis or to discontinue insulin pump therapy.

As a result of the launch of t:lock in 2017, the ratio of our sales volume of infusion sets relative to sales volume of cartridges increased to nearly 100% in December 2017. We expect to maintain a ratio of approximately 100% in the full year of 2018.

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Our goal is to launch t:slim X2 with Basal IQ in the summer of 2018, subject to the completion of our clinical trial with a satisfactory outcome, timely submission to the FDA and future FDA approval.

As a result of the announcement of Animas' exit from the insulin pump market, we now offer the only alternative durable insulin pump to those sold by Medtronic in the United States.

We expect our 2018 sales will include sales from our planned international expansion in select geographies, including Canada, in the second half of 2018. Unlike our approach domestically, with the exception of Canada, we currently plan to partner with distributors who will carry out the selling efforts, as well as the service and support of customers in geographies outside the United States. Currently, we anticipate having a direct sales and clinical infrastructure in Canada beginning in 2018, with customer support and services shared with our domestic organization.

Even with our growth expectations, in 2018, we intend to leverage our existing infrastructure investments and realize additional manufacturing cost improvements to increase our operating margins. Our operating expense goal for 2018, including our international launch plans, is to manage annual growth of our operating expenses to less than 10%.

We believe we can ultimately achieve profitability by driving incremental sales, achieving our pump renewal sales objectives, increasing gross profits from higher sales of infusion sets, maximizing manufacturing efficiencies on increased production volumes and leveraging the early investments made in our sales, clinical and marketing organization, as well as our customer support infrastructure. Our goal is to reach the milestone of cash flow breakeven in the second half of 2019 when we expect to have an installed base of more than 80,000 customers and a gross margin of approximately 55%. We believe this will require us to raise \$50.0 million - \$60.0 million through this offering and through holders' exercise of our outstanding warrants. However, there can be no assurance that our warrants will be exercised. Certain statements above, including with respect to our expected financial results for 2018 and the various trends that may impact those results, our expected operating and gross margins and operating expense goals for 2018, and our timeline to reach cash flow breakeven, are forward-looking statements that are subject to considerable risks and uncertainties. Our ability to achieve these results and goals is highly dependent on a number of variables, including our financial performance in 2018, our ability to raise capital, manage our expenses and reduce our use of cash and the continued adoption of our products and products in development. See sections of this prospectus entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Information."

## **Short-Term Liquidity**

At the date the most recent financial statements in this prospectus were issued, our management believed that we did not have sufficient cash to fund our operations for the next twelve months 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 most recent financial statements were issued.

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.

In addition, the terms of the Term Loan Agreement require that we deliver audited financial statements that include an unqualified audit report to Capital Royalty Partners. If the audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2017

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includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern, it could constitute a potential event of default under the Term Loan Agreement. We will obtain a waiver of any such event of default under the Term Loan Agreement in connection with this offering.

## **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, or the Sarbanes-Oxley Act;

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 \$1.07 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, as amended, 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.

## **Corporate Information**

We were incorporated in Colorado in January 2006 and reincorporated in Delaware in January 2008. Our principal executive offices are located at 11075 Roselle Street, San Diego, California 92121. The telephone number of our principal executive office is (858) 366-6900. Our website is [www.tandemdiabetes.com](http://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:	13,513,514 shares
Common stock to be outstanding immediately after this offering:	23,632,918 shares
Option to purchase additional shares:	The underwriters have an option to purchase a maximum of 2,027,027 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 estimate that we will receive net proceeds from this offering of approximately \$37.1 million, or \$42.7 million if the underwriters fully exercise their option to purchase additional shares, assuming an offering price of \$2.96, the last reported sale price of our common stock on the NASDAQ Global Market on January 26, 2018 and after deducting the underwriting discount and estimated offering expenses payable by us. The actual offering price per share will be as determined between us and the underwriters at the time of pricing, and may be at a discount to the current market price. Accordingly, the recent market price used throughout this prospectus may not be indicative of the actual public offering price. 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 47 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

Certain of our existing stockholders and directors have indicated an interest in purchasing up to an aggregate of approximately \$ million in shares of our common stock in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could

determine to sell more, less or no shares to any of these potential investors and any of these potential investors could determine to purchase more, less or no shares in this offering.

The number of shares of our common stock to be outstanding after this offering is based upon 10,119,404 shares of common stock outstanding as of December 31, 2017, and excludes:

9,552,753 shares of common stock issuable upon exercise of outstanding warrants as of December 31, 2017, at a weighted average exercise price of \$4.63 per share;

151,087 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, 2017, at a weighted average exercise price of \$24.32 per share (of which options to acquire 151,087 shares of common stock are vested as of December 31, 2017);

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1,180,182 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, 2017, at a weighted average exercise price of \$50.03 per share (of which options to acquire 451,559 shares of common stock are vested as of December 31, 2017) and 0 shares that are reserved for future issuance under the 2013 Plan as of December 31, 2017; and

13 shares of common stock reserved for future grant or issuance under our 2013 Employee Stock Purchase Plan, or the ESPP, as of December 31, 2017.

On January 1, 2018, the number of shares of common stock reserved for issuance under the 2013 Plan automatically increased by 404,776 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 101,194 additional shares pursuant to the terms of the ESPP. These shares are 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.

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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 Related 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 September 30, 2017, we had an accumulated deficit of \$466.2 million. To date, we have financed our operations primarily through public and private sales of our equity securities, debt financing with 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, the t:slim Insulin Delivery System, or 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. In August 2017, we commenced commercial sales of t:slim X2 with G5 integration and discontinued new sales of t:slim G4. 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, and for the nine months ended September 30, 2017 and 2016, our gross profit was \$26.6 million and \$13.5 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 at least the next two years.

To implement our business strategy we need to, among other things, increase sales of our products and the gross profit associated with those sales, 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 our 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. 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. During 2017, our insulin pump products included our t:slim X2, t:flex and t:slim G4 products. In August 2017, we discontinued sales of t:slim G4 in connection with our commercial launch of t:slim X2 with G5 during the third quarter of 2017. Sales of our insulin pumps may be negatively impacted by many factors, including:

market acceptance of the insulin pumps and related products manufactured and sold by our key competitors, including Medtronic;

the potential that other technological breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pumps 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 its 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, 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 and projected financial results, recent changes in and volatility of our stock price, concerns regarding our ability to maintain the continued listing of our common stock on the NASDAQ Global Market, or NASDAQ, perceptions about the dilutive impact of our financing transactions, our current level of indebtedness and debt service costs, our conclusion that there is substantial doubt about our ability to continue as a going concern, the competitive environment in our industry, and uncertainties regarding the regulatory environment. Any such concerns, whether actual or perceived, could cause consumers to delay the purchase of our products or 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.



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***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 or technologies, 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, which could have a material adverse effect on 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 medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, as well as 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. However, the market for insulin pumps continues to experience significant changes. For instance, in 2016, Roche Diabetes Care, a division of F. Hoffman-La Roche, discontinued sales of new insulin pumps in the United States. In October 2017, Johnson & Johnson announced its plans to discontinue the operations of Animas and to exit the insulin pump business entirely. Both Roche and Animas designated Medtronic as a preferred partner to facilitate the transition of their respective insulin pump customers. Most recently, in late 2017, Eli Lilly & Co. announced that it is developing an insulin pump with AID technology that it intends to launch in the next two to three years. There are also a number of other companies developing and marketing their own insulin delivery systems, including insulin pumps and Bluetooth-enabled insulin pens to support MDI therapy. While these industry changes are significant, it is too early to know how it will influence our business or the competitive landscape in which we operate in the long-term.

Our key competitors, most notably Medtronic, 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, third-party payors and regulatory agencies;

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

greater market share and established base of customers;

products supported by long-term clinical data;

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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 offers a traditional insulin pump with automated insulin delivery functionality and a new CGM system and Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set. These specific features may make the competitive products more desirable to customers and healthcare providers, which could negatively impact sales of our products.

In addition, the competitive environment in which we operate has resulted and may continue to result in competitive pressures on our manufacturers, suppliers, distributors, collaboration partners and other business constituents. For example, we have entered into development agreements with Dexcom, which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. Abbott Laboratories recently launched a new blood glucose monitoring system, which competes with the Dexcom technology. Competitive pressures within our industry could negatively impact our relationship with our business partners, impact their ability to fulfil their obligations to us, and result in harm to our financial condition and operating results.

For these and other reasons, we may not be able to compete successfully against our current or potential future competitors. As a result, our product sales may be negatively affected, which could have a material adverse impact on our financial condition and operating results.

***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 otherwise 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 and technologies. 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 financial 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.

***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 achieving and maintaining market acceptance. Our products include t:slim X2 with G5 integration and t:flex. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that our products are 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 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 and maintain 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;

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

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

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, could cause consumers to delay the purchase of our products or to purchase competitive products.

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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. 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.

***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 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 not achieve anticipated improvements in manufacturing productivity following the relocation of our manufacturing operations to our Barnes Canyon facility. Furthermore, while we currently believe our proprietary technology platform will allow us to efficiently design and develop new products, changes in the market that require us to modify or replace our existing platform, such as any accelerated development of our next generation t:sport product, will reduce the efficiencies gained through our platform and could increase our per unit costs. If we are unable to effectively manage our overall costs while increasing our production volumes and lowering our per unit costs, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results.

***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 in the foreseeable future. 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, both domestically and internationally, is essential to the acceptance of our products by customers.

As guidelines in setting their coverage and reimbursement policies, many third-party payors in the United States 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. 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



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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.

We currently have contracts establishing reimbursement for our insulin pump products with approximately 176 national and regional third-party payors in the United States. While we may enter into additional contracts both domestically and internationally, 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, we do not have experience in securing reimbursement in international markets. Also, any negative perceptions among third-party payors regarding our financial stability, including 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 the conclusion that there is substantial doubt about our ability to continue as a going concern. 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.

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

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 expect to continue to 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 with G5 and t:flex, as well as 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.



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***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 involves our sales, clinical, marketing and customer service personnel driving adoption 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 decline in our stock price, especially over the past two years, 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 cause sales to decline.

***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 nine months ended September 30, 2017, sales to approximately 35 independent distributors represented approximately 73% of our sales. While our goal in the United States 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 majority 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, particularly in light of our plans to primarily rely on independent distributors outside of the United States and Canada. 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 has also increased following our launch of the t:lock for our insulin cartridge, which may continue to 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, negative perceptions among independent distributors regarding our financial stability, and our conclusion that there is substantial doubt about our ability to continue as a going concern, may negatively impact the willingness of our distributors to continue 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 nine months ended September 30, 2017, our two largest independent distributors collectively comprised approximately 33.6% 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

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could be adversely affected. In that case, 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 result in 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 reach mutually acceptable agreements with these third parties on a timely basis, 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 may be adversely affected. In particular, we currently expect to rely on data from the National Institute of Health-funded International Diabetes Closed Loop Trial, or IDCL Trial, to support our development of t:slim X2 with Control IQ. 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 Control IQ 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 Control IQ. 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.

***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

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

Another key element of our business strategy is utilizing market research to understand what people with diabetes are seeking to improve their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed our current products and are pursuing the development of new products. However, our market research is based on interviews, focus groups and online surveys involving people with insulin-dependent diabetes, their caregivers and healthcare providers that represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we received may not be reflective of the broader market and may not provide us accurate insight into the desires of people with insulin-dependent diabetes. In addition, understanding the meaning and significance of the responses received during our market research necessarily requires that analysis be conducted and conclusions be drawn. We may not be able 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 in competitive and rapidly-evolving markets.***

We have a limited operating history upon which to evaluate our business and forecast our future sales and operating results. We 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. More recently, our commercial launch of t:slim X2 with G5, the FDA approval and launch of new products by one of our competitors, and the announcement by Johnson & Johnson that it is discontinuing the operations of Animas and exiting the insulin pump business, combine to make it more difficult for us to predict our future sales and operating results. In assessing our business prospects, you should consider the various risks and difficulties frequently encountered by companies in competitive and rapidly evolving markets, particularly those facing emerging growth companies that manufacture 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;

gain acceptance of our products and increase awareness of our brand among people with insulin-dependent diabetes, their caregivers and healthcare providers;

comply with a broad range of regulatory requirements within a highly regulated industry;

expand our manufacturing capabilities, increase production of products efficiently while maintaining quality standards, and adapt 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;

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.



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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.

### ***The Technology Upgrade Program resulted in accounting complexities that may lead to confusion when comparing our historical and future financial results.***

While our Technology Upgrade Program expired on September 30, 2017, it resulted in a number of accounting complexities that will continue to make comparisons of our historical and future financial results more difficult. In particular, during the term of the Technology Upgrade Program, United States generally accepted accounting principles, or GAAP, prevented us from recognizing, at the time of sale, up to 100% of the sales and cost of sales associated with the sale of our insulin pumps to eligible customers. Instead, depending on the type of pump sold, we were required to defer some or all of the sales and cost of sales until a later date. In light of the expiration of the Program, we are no longer subject to these accounting deferrals; however, in evaluating our 2017 financial results through September 30, 2017, as a result of the Technology Upgrade Program we recorded incremental GAAP net sales of \$4.8 million that were previously deferred, with a corresponding increase of \$3.2 million in gross profit.

Despite our efforts to explain the required accounting treatment for the Technology Upgrade Program, it is possible that there may be confusion when comparing our historical and future financial results, which may cause our stock price to decline. For example, any revenue growth in 2018 on a GAAP basis is expected to be lower than the rate of growth on a product volume basis. In addition, the complexities associated with the Program may cause investors to avoid purchasing our common stock until our financial results and trends are more predictable, which may also adversely impact our stock price.

### ***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 related 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;

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 and expand manufacturing facilities to enable us to efficiently produce future products or implement changes in current products in response to consumer demand or regulatory requirements;

delays in transitioning our manufacturing operations to our Barnes Canyon facility or additional costs associated with the transition;

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.

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

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 two years we have implemented several new pieces of equipment that are intended to improve our manufacturing capacity and efficiency. However, it is possible that we may not achieve the anticipated improvements from these investments.

In addition, 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 modification of our production lines, hiring of specialized employees, identification of new suppliers for specific components, implementation of additional equipment and procedures, obtaining new regulatory approvals, 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, obtaining and maintaining regulatory approvals, and efficiently managing costs, our sales and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results.

***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 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. For example, we have implemented a business strategy intended to increase our future sales of infusion sets, and any increase in the sales of our infusion sets could strain the ability of our suppliers to deliver products in a manner that meets our 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. Furthermore, negative perceptions among our suppliers regarding our financial stability, and our ability to sustain our business operations on a long-term basis, 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

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to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us. We have in the past been, and we may in the future be, required to make significant last time purchases of component inventory that is being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and 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 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 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 disruption, 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 have a material adverse impact on our operating results.

***If we cannot reliably manufacture our new infusion set connector, or if it does not achieve market acceptance, we may not achieve our financial projections.***

In September 2017, we began commercial sales of products with t:lock, which replaced the standard Luer-lok connector that historically joined an infusion set to our proprietary disposable insulin cartridges. Concurrently, we began selling infusion sets that are compatible with t:lock. Our supplier of infusion sets must manufacture a variety of lengths and styles of infusion sets with t:lock that matches our cartridges. Failure to do so, or to do so at the necessary production volumes, may result in our inability to convert customers to t:lock when anticipated, which would negatively impact our sales and operating margins.

In addition, our independent distributors will need to continue 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 t:lock is substantially complete; however, we are aware of exceptional circumstances that may require additional time for some direct customers and distributors to complete the transition. Accordingly, we still anticipate offering both styles of cartridges and infusion sets to facilitate the transition of customer supplies early in 2018. 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 t:lock was designed based on customer feedback, and all standard Luer-lok infusion sets that we currently offer are also available with t:lock, it is possible that t:lock may not continue to gain market acceptance by current or potential customers, their caregivers, or healthcare providers. Any negative market response to t:lock may impact a current customer's decision to purchase a new pump from us at the time of renewal. In addition, potential customers may decide not to purchase our insulin pumps if they do not prefer t:lock or t:lock compatible infusion sets, which could have a material, adverse impact on our business, financial condition and operating results.



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***We currently operate primarily at two locations in San Diego, California, and any disruption at these locations could adversely affect our business and operating results.***

Substantially all of our operations are either conducted, or expected to be conducted, at two locations in San Diego, California, 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 are held at these locations. 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, result in reduced sales, 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 our new facility may result in further delays or expenses, and we may not experience the anticipated operating efficiencies.***

We recently completed the transition of our manufacturing operations to our Barnes Canyon facility that we expect will allow for future product manufacturing expansion. However, we may not experience the anticipated operating efficiencies as we commence manufacturing operations at the new facility. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which would have a material adverse impact on our operating results.

In September 2017, following a site inspection of our Barnes Canyon facility, the FDA issued a Form 483, List of Inspectional Observations, containing two observations. Following our receipt of the Form 483, we began implementing corrective and preventive actions to fully address the FDA observations, and in October 2017, we provided a written response to the FDA. In December 2017, we received a letter from the FDA stating that our initial written response did not fully address the FDA observations, and that the FDA would address the observations during its next regularly scheduled inspection of our facilities. It is possible that the FDA will conclude that our corrective and preventive actions are inadequate. If the FDA is not satisfied, it may issue a warning letter to us or may take other actions, any of which could have a material adverse effect on our business.

We expect that the management and support of our new manufacturing facility will place significant burdens on our management team, particularly in areas relating to operations, quality, regulatory, facilities and information technology. If we experience unanticipated employee turnover in any of these areas, we may not be able to effectively manage our ongoing manufacturing operations 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, which may impede our ability to 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 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;



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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 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 and t:slim X2 with G5 received FDA approval under a PMA. However, there are no published studies to evaluate the safety or effectiveness of t:slim G4 or t:slim X2 with G5 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. 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.

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 required to inform our customers of these risks or complications or, in more serious circumstances, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, which could result in significant legal liability, harm to our reputation, and a decline in our product sales.

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 and seriousness of the problem, degree of

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publicity, reaction of our customers and healthcare professionals, 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. We may not identify or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. In addition, we may not realize the anticipated benefits of any such transaction or arrangement that we do identify and complete. In particular, these collaborations may not result in the development of products that achieve commercial success or result in positive financial results 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 have entered into multiple development agreements with Dexcom, which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. Our agreements with Dexcom currently run until June 2020 with automatic one-year renewals. Under certain circumstances, these agreements 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.

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***We operate our business in regions subject to natural disasters and other catastrophic events, and any disruption to our business resulting from natural disasters will adversely affect our revenue and results of operations.***

We operate our business in regions subject to natural disasters, including earthquakes, hurricanes, floods, fires and other catastrophic events. Any natural disaster could adversely affect our ability to conduct business and provide products and services to our customers, and the insurance we maintain may not be adequate to cover our losses resulting from any business interruption resulting from a natural disaster or other catastrophic events.

In the third quarter of 2017, Hurricane Irma and Hurricane Harvey adversely impacted our business operations in Texas, Florida and other nearby regions. These hurricanes directly and significantly affected our sales force, healthcare providers and potential customers, as well as distribution centers operated by certain of our independent distributors. Although our business operations have generally resumed in these areas, it is difficult to assess the impact these hurricanes had and will continue to have on our customers, the demand for our products in the affected areas, the effectiveness of our sales force, and the ability of our distributors to meet their obligations to us.

These and any future disruptions to our operations could have a material adverse impact on our financial condition and results of operations in future periods.

***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. These risks significantly increased after July 2016, when we received FDA clearance of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps. We may also face new risks relating to our information technology systems as we begin to commercialize our products outside the United States.

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 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.

***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, key members of our management have experience successfully scaling an

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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.

***We depend upon key employees in a competitive market, and if we are unable to provide meaningful equity incentives to retain key personnel, it could adversely affect our ability to execute our business strategy.***

We are highly dependent upon the members of our management team, as well as other key employees. Many of these individuals have been employed by us for many years, have played integral roles in the growth of our business, and will continue to provide value to us. In our industry, it is common to attract and retain executive talent and other employees with compensation packages that include a significant equity component. At this time, the vast majority of our outstanding equity awards, which generally are issued in the form of stock options, are significantly out of the money and unlikely to be exercised in the future. We have issued, and may continue to issue, additional equity incentives that we believe will enhance our ability to retain our current key employees and attract the necessary additional executive talent, although some or all of these awards may be subject to conditions including the requirement to obtain the consent of our stockholders to an increase in the number of shares reserved for issuance under our equity plan. However, even if we issue significant additional equity incentives, there can be no assurance that we will be able to attract and retain key executive talent. A loss of any of our key personnel, or our inability to hire new personnel, may have a material adverse effect on our ability to execute our business strategy.

***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 and security 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 privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. The privacy rule protects 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. The security rule protects protected health information, or PHI, stored electronically by requiring appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity and security of such PHI. If we, or any of our service providers, are found to be in violation of the promulgated privacy and security rules under HIPAA and HITECH, 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 also face new risks relating to security laws and privacy rights as we begin to commercialize our products outside the United States.



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*We are seeking approval to commercialize our products outside of the United States, which may result in a variety of risks associated with international operations that could materially adversely affect our business.*

We are planning to begin commercialization of the t:slim X2 in select geographies outside of the United States, including Canada, during 2018. We do not have experience in commercializing our products outside of the United States and expect that we will be subject to additional risks related to entering into international business markets, including:

different regulatory requirements for product approvals in foreign countries;

differing U.S. and foreign medical device import and export rules;

more restrictive privacy laws relating to personal information of end users and employees;

reduced protection for our intellectual property rights in foreign countries;

unexpected changes in tariffs, trade barriers and regulatory requirements;

different reimbursement systems;

economic weakness, including inflation, or political instability in particular foreign economies and markets;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad or with U.S. regulations that would apply to activities in such foreign jurisdictions, such as the Foreign Corrupt Practices Act;

foreign taxes, including withholding of payroll taxes;

foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and

business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters. In addition, entry into international markets may require significant financial resources and could divert management's attention from managing our core business. We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. Accordingly, if we are unable to expand internationally, manage the complexity of our global operations successfully or if we incur



unanticipated expenses, we may not achieve the expected benefits of this expansion and our financial condition and results of operations could be materially and adversely impacted.

***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 for the next twelve months.*

At December 31, 2017, we had approximately \$24.2 million in cash, cash equivalents and short-term investments, which included \$10.0 million of restricted cash. Our management believes that we do not have sufficient cash to fund our operations for the next twelve months 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 in this prospectus were issued. Moreover, the continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers and additional research and development activities, 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, infusion sets and insulin cartridges, and any other future products that we may develop and commercialize;

the gross profits and gross margin we realize from the sales we generate;

any proceeds we receive from the exercise of our outstanding warrants;

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

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;

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

the cost of obtaining and maintaining regulatory clearance or approval for our products and our manufacturing facilities;

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 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 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, elect to restructure or refinance our existing indebtedness or 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

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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 the Term Loan Agreement. 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 by us or our competitors. 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 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, including as a result of the transition to our new manufacturing facility;

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

seasonality and other factors affecting the timing of purchases of our products;

timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;

results of clinical research and trials on our existing and future products;

the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements;

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

the timing of revenue and expense recognition associated with our product sales pursuant to applicable accounting standards.

As a result of our recent and anticipated 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. For example, our recent commercial launch of t:slim X2 with G5, the FDA approval and launch of new products by one of our competitors, and the announcement by Johnson & Johnson that it is discontinuing the operations of Animas and exiting the insulin pump business, combine to make it more difficult for us to predict our operating results.

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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 for the next twelve months without additional financing and, therefore, there was substantial doubt about our ability to continue as a going concern within one year after October 26, 2017, which could have a material adverse impact on our business.***

At October 26, 2017, the date the most recent financial statements in this prospectus were issued, our management believed that we did not have sufficient cash to fund our operations for the next twelve months 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 most recent financial statements were issued. The financial statements included in this prospectus have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business.

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, our conclusion that there is substantial doubt about our ability to continue as a going concern may be viewed unfavorably by current and prospective investors, as well as by analysts and creditors. As a result, this conclusion may make it more difficult for us to raise the additional financing necessary to continue to operate our business. In addition, this conclusion 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 not be able to generate sufficient cash to service our indebtedness, which currently consists of our Term Loan Agreement with Capital Royalty Partners.***

At September 30, 2017, we had \$82.3 million of aggregate borrowings outstanding under the Term Loan Agreement with Capital Royalty Partners. Our ability to make scheduled payments or to restructure or 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

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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 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, in March 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 additional restrictive and financial covenants on us, which may increase our risk of triggering defaults under the Term Loan Agreement.

In the event of a future default triggered by any violations of the covenants in the Term Loan Agreement, including those 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 a waiver of any events of default, or an amendment 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, 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.





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### **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, 2017, our patent portfolio consisted of approximately 58 issued U.S. patents and 49 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2036. We also have and are seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we have 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.

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.

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***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.

***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.

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*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 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.

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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 Premarket Approval, or 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 and of our PMA supplement for t:slim X2 with G5 in August 2017. 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 products or product modifications in the future. If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our forecasts. 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;

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, delays by the FDA or other regulators in granting 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, lower than anticipated sales, and diversion of management time and resources, any of which could have a material adverse effect on our reputation, business, financial condition and operating results.

Further, we are evaluating international expansion opportunities for a potential launch in 2018. If we expand our operations outside of the United States, we will become subject to various additional regulatory and legal

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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 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. The FDA has broad discretion to require the recall of a product or to require that manufacturers alert customers of safety risks, and may do so even in circumstances where we do not believe our product poses an unacceptable risk to health. In addition, manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found or alert customers of unanticipated safety risks. 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 or notices relating to any products that we distribute would divert managerial and financial resources, 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

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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 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, with which the physician has a financial relationship;

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;

federal disclosure laws, such as the Physician Payments Sunshine Act, which require certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians;

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

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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 might challenge our current or future activities under these laws. Any of these challenges could have a material adverse effect on our reputation, business, financial condition and operating results. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

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

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

### ***Legislative or regulatory healthcare reforms may result in downward pressure on the price of and decrease reimbursement for our products, and uncertainty regarding the healthcare regulatory environment could have a material adverse effect on our business.***

The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to propose and pass new legislation and regulations designed to, among other things, expand healthcare coverage to more individuals, contain or reduce the cost of healthcare, and improve the quality of healthcare outcomes. This legislation and regulation may result in decreased reimbursement for medical devices, which may create additional pressure to

reduce the prices charged for medical devices. Reduced reimbursement rates could significantly decrease our revenue, which in turn would place significant downward pressure on our gross margins and impede our ability to become profitable.

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The PPACA substantially changed the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the medical device industry. However, a number of legislative changes have been proposed and adopted since the PPACA was enacted, and legislation has recently been proposed that could modify or repeal the PPACA. The uncertainties regarding the future of the PPACA, and other healthcare reform initiatives, may have an adverse effect on our customers' purchasing decisions regarding our products.

In the future, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. Cost control initiatives could decrease the price that we receive for our products. At this time, we cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they may have on the existing regulatory environment, or our ability to operate our business. Any of these factors could have a material adverse effect on our operating results and financial condition.

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

Beginning in 2013 through the end of 2015, the PPACA imposed, among other things, an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States. Congress imposed a moratorium on this tax on December 18, 2015, for sales of devices during the period January 1, 2016 through December 31, 2017. The moratorium expired on December 31, 2017. We do not believe that our products were subject to this tax (prior to the moratorium) based on the retail exemption under applicable Treasury Regulations. However, the availability of this exemption is subject to interpretation by the IRS, and the IRS may disagree with our analysis. Absent further legislative action, the medical device excise tax applies to sales of taxable medical devices beginning on January 1, 2018, and future products that we manufacture, produce or import may be subject to this tax (unless the retail exemption or other applicable exemption applies). The financial impact this tax may have on our business is unclear and there can be no assurance that our business will not be materially adversely affected by it.

## **Risks Related to our Common Stock and this Offering**

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

Based on an aggregate of 10,119,404 shares of our common stock outstanding as of December 31, 2017, our executive officers and directors, together with their respective affiliates, collectively owned approximately 13% of the voting power of our outstanding common stock. These persons, acting together, will have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets.

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

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

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



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

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

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

authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;

provide for the adoption of a staggered board of directors whereby the board is divided into three classes each of which has a different three-year term;

provide that the number of directors shall be fixed by the board;

prohibit our stockholders from filling board vacancies;

provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;

prohibit stockholders from calling special stockholder meetings;

prohibit stockholders from acting by written consent without holding a meeting of stockholders;

require the vote of at least two-thirds of the outstanding shares to approve amendments to the certificate of incorporation or bylaws; and

require advance written notice of stockholder proposals and director nominations.

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

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

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

***U.S. federal income tax reform could adversely affect us and our stockholders.***

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the TCJA, which significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a

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worldwide system of taxation to a territorial system. We do not expect tax reform to have a material impact on our projection of minimal cash taxes. Our net deferred tax assets and liabilities will be revalued at the newly-enacted U.S. corporate rate, and the impact will be recognized in our tax expense in the year of enactment. We continue to examine the impact that this tax reform legislation may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse. This prospectus does not discuss any such tax legislation or the manner in which it might affect investors in our common stock. We urge our stockholders, including investors in common stock in this offering, to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

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

As of December 31, 2016 we had federal net operating loss, or NOL, carryforwards of approximately \$283.5 million, not considering the limitation discussed below. The federal tax loss carryforwards begin to expire in 2026, unless previously utilized. In general, if there is an ownership change with respect to our company, as defined under Section 382 of the Code, the utilization of our NOL carryforwards may be subject to substantial limitations imposed by the Code, and similar state provisions. In general, an ownership change occurs whenever there is a shift in ownership of our company by more than 50% by one or more 5% stockholders over a specified time period.

Although we have not completed an update of our Section 382 analysis subsequent to December 31, 2016, the recent offerings of our securities, either separately or together with this offering, may have caused or could cause an ownership change or could increase the likelihood that we undergo an ownership change for purposes of Section 382 of the Code in the future. Limitations imposed on our ability to utilize NOL carryforwards could cause U.S. federal income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOL carryforwards to expire unused, in each case reducing or eliminating the benefit of such NOL carryforwards.

With respect to our NOLs generated in 2018 and thereafter, the TCJA may reduce the tax benefit of our NOLs. Under the TCJA, our ability to carry back NOLs incurred after December 31, 2017 to previous tax years is eliminated. Under prior law, we could carry back NOLs for two years and carry forward NOLs for 20 years. Under the TCJA, NOL carryforwards may be carried forward indefinitely. However, for NOLs arising after December 31, 2017, NOL carryforwards will be limited to 80% of our taxable income. Our NOLs generated in 2017 and in prior years will not be subject to the limitations under the TCJA.

***We do not intend to pay cash dividends.***

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

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

The SEC adopted a rule requiring disclosures by public companies of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured. The rule requires companies to perform due diligence, disclose and annually report to the SEC whether or not such minerals originate from the Democratic Republic of Congo or an adjoining country. The rule could affect sourcing at

competitive prices and availability in sufficient quantities of certain minerals used in the

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manufacture of our products, which could increase our expenses. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities.

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

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

not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act;

less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements; and

exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

***We are a smaller reporting company and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.***

We are a smaller reporting company under applicable SEC rules and regulations. Similar to an emerging growth company, a smaller reporting company is subject to scaled reporting and compliance obligations as compared to other public companies. Specifically, smaller reporting companies are able to provide simplified executive compensation disclosures in their filings, are exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and have certain other reduced disclosure obligations in their SEC filings. Reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our financial condition, operating results and prospects. If investors find our common stock less attractive as a result of our reduced disclosures, there may be a less active trading market for our common stock and our stock price may decline or be more volatile.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public

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accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act after we no longer qualify as an emerging growth company or a smaller reporting company, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

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

***The price of our common stock might fluctuate significantly.***

Our common stock is listed for trading on NASDAQ under the symbol TNDM. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

actual or anticipated fluctuations in our financial and operating results from period to period;

our actual or perceived need for additional capital to fund our operations, and perceptions about the dilutive impact of our recent or currently proposed financing transactions;

perceptions about our financial stability generally, and relative to our competitors, and our ability to sustain our business operations long term;

the reaction of investors to 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;

overall performance of the equity markets;

speculative trading practices of market participants;

perceptions about the market acceptance of our products and the recognition of our brand;

introduction of proposed products or technologies, or announcements of significant contracts, acquisitions or divestitures by us or our competitors, including the announcement that Johnson & Johnson intends to exit the



insulin pump business;

legislative, political or regulatory developments;

issuance of securities analysts' reports or recommendations;

additions or departures of key personnel;

threatened or actual litigation and government investigations;

sale of shares of our common stock by us or members of our management; and

general economic conditions.

These and other factors might cause the market price of our common stock to fluctuate substantially, which may negatively affect the liquidity of our common stock. For example, the implementation of our 1-for-10 reverse stock split in October 2017 may negatively impact the liquidity of our common stock, given the significantly reduced number of shares that are now issued and outstanding after the reverse stock split, and because our stock price did not increase commensurate with the ratio of the reverse stock split. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. The changes

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frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce the market price of our common stock.

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

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

Sales of our common stock, or the perception in the market that the holders of a large number of our shares intend to sell such shares, could reduce the market price of our common stock, which would impair our ability to raise future capital through the sale of additional equity securities. A substantial number of the outstanding shares of our common stock are, and the shares of common stock sold in this offering upon issuance will be, freely tradable without restriction or further registration under the Securities Act. As of December 31, 2017, we had outstanding 10,119,404 shares of common stock, of which approximately 1,323,680 shares are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act. In addition, as of December 31, 2017, we had outstanding warrants to purchase 9,552,753 shares of common stock and outstanding options to purchase 2,143,069 shares of common stock that, if exercised, will result in these additional shares becoming available for sale. These options included options to purchase up to 811,800 shares of our common stock under the terms of 2013 Stock Incentive Plan, or the 2013 Plan, that are subject to future stockholder approval of an increase to the share reserve under the 2013 Plan. As of December 31, 2017, no shares of our common stock were reserved for future grant or issuance under the 2013 Plan, but this number was automatically increased by an additional 404,776 shares of our common stock on January 1, 2018, in accordance with the terms of the 2013 Plan.

Upon the completion of this offering, approximately 1,322,790 shares of our outstanding common stock beneficially owned by our executive officers, directors and certain of our other existing stockholders will be subject to lock-up agreements with the underwriters of this offering that restrict the sale of shares of our common stock by those parties for a period of 90 days after the date of this prospectus. However, all of the shares sold in this offering and the remaining shares of our common stock outstanding prior to this offering (which include certain shares that are held by our affiliates) will not be subject to lock-up agreements with the underwriters and, except to the extent such shares are held by our affiliates, will be freely tradable without restriction under the Securities Act. In addition, following the expiration of the 90-day lock up period referenced above, certain holders of shares of our common stock will have the right, subject to various conditions and limitations, to include their shares in registration statements relating to our securities. In addition, these holders are entitled to piggyback registration rights with respect to the registration under the Securities Act of shares of our common stock. Shares of common stock registered under these registration statements can be freely sold in the public market. In the event registration rights are exercised and a large number of shares of common stock are sold in the public market, those sales could reduce the trading price of our common stock.

Certain of our existing stockholders and directors have indicated an interest in purchasing up to an aggregate of approximately \$ million in shares of our common stock in this offering at the public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters could determine to sell more, less or no shares to any of these potential investors and any of these potential investors could determine to purchase more, less or no shares in this offering.

In the future, we may issue additional securities if we need to raise more capital. In particular, 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

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guarantee that we will successfully raise all the funding we require in this offering. The number of new shares of our common stock issued in connection with raising additional capital, in this offering or otherwise, could constitute a material portion of the then-outstanding shares of our common stock.

***If we are unable to comply with certain continued listing requirements of NASDAQ, our common stock would be delisted from NASDAQ, which could adversely affect the market price of our common stock.***

Our common stock is currently listed on NASDAQ. In order to maintain this listing, we must satisfy minimum continued listing requirements and standards, including a minimum closing bid price requirement for our common stock. We have previously received a notice from NASDAQ indicating that we had failed to meet the minimum closing bid price requirement of \$1.00 per share for 30 consecutive business days, which subjected our common stock to potential delisting. While we regained compliance under the NASDAQ minimum continued listing requirements, due to the recent volatility of our stock price, which may be exacerbated as a result of this offering, we cannot assure you that we will continue to satisfy the NASDAQ continued listing requirements. If we cannot satisfy the continued listing standards going forward, NASDAQ may commence delisting procedures against us, which could result in our common stock being removed from listing on NASDAQ. If our common stock were to be delisted, the liquidity of our common stock could be adversely affected and the market price of our common stock could decrease.

***Our reverse stock split may have the effect of decreasing the liquidity of our common stock and result in higher transaction costs.***

The liquidity of our common stock may be negatively impacted by our implementation of a 1-for-10 reverse stock split in October 2017, given the significantly reduced number of shares that are now issued and outstanding after the reverse stock split, and because our stock price did not increase commensurate with the ratio of the reverse stock split. In addition, as a result of our reverse stock split, we now have a greater number of stockholders who own odd lots of fewer than 100 shares of our common stock. Brokerage commission and other costs of transactions for the sale of odd lots are generally higher than the costs of transactions of more than 100 shares of common stock.

***The effective increase in the authorized number of shares of our common stock as a result of our reverse stock split could have anti-takeover implications and result in further dilution to our existing stockholders.***

In connection with the implementation of our reverse stock split, we maintained the total number of authorized shares of our common stock. The combination of a reverse stock split of our issued and outstanding shares, and maintaining the number of our authorized shares, has significantly increased our authorized shares relative to our issued and outstanding shares. This effective increase in the number of authorized shares will allow us to sell additional shares of our common stock (or securities convertible or exchangeable for our common stock), which would result in further dilution of our current stockholders. In addition, the effective increase in the number of authorized shares could, under certain circumstances, have anti-takeover implications. For example, the additional shares of common stock that have become available for issuance could be used by us to oppose a hostile takeover attempt or to delay or prevent changes in control or our management. Although our reverse stock split was prompted by business and financial considerations and not by the threat of any hostile takeover attempt, stockholders should be aware that our reverse stock split could facilitate future efforts by us to deter or prevent changes in control, including transactions in which our stockholders might otherwise receive a premium for their shares over then-current market prices.

***We have broad discretion in the use of the net proceeds we receive from this offering, and may not use them in ways that improve our results of operations or enhance stockholder value.***

Although we currently intend to use the net proceeds from this offering in the manner described in the section of this prospectus entitled Use of Proceeds, our management will have broad discretion in the application of the

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net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of shares of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the market price of shares of our common stock to decline, delay the development of new products, and impede the execution of our strategic plans.

***If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.***

The assumed offering price of shares of our common stock is substantially higher than the pro forma net tangible book value per outstanding share of our common stock. You will incur immediate and substantial dilution of \$2.01 per share, representing the difference between the assumed public offering price and our pro forma net tangible book value per share as of September 30, 2017, based on the sale of 13,513,514 shares of common stock at an assumed public offering price per share of common stock of \$2.96, the last reported sale price of our common stock on NASDAQ on January 26, 2018, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of liquidation. Further, investors purchasing shares of our common stock in this offering will contribute approximately 9.2% of the total amount invested by stockholders since our inception, but will own, as a result of such investment, 57.2% of shares of our common stock outstanding immediately following this offering. In addition, if the underwriters exercise their over-allotment option, or outstanding options or warrants are exercised, you could experience further dilution. For more information on the dilution you may suffer as a result of investing in this offering, see the section of this prospectus entitled Dilution.

***We are at risk of securities class action litigation.***

In the past, securities class action litigation has been brought against companies following a decline in the market price of their securities. This risk is particularly relevant to medical device companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business, financial condition and results of operations.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our stock price and trading volume could decline.***

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. In addition, if our operating results fail to meet the forecasts of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

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**CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements within the meaning of the federal securities laws, which statements are subject to considerable risks and uncertainties. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this prospectus, other than statements of historical fact, are forward-looking statements. You can identify forward-looking statements by the use of words such as may, will, could, anticipate, expect, intend, believe, continue or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements. In particular, forward-looking statements contained in this prospectus may relate to, among other things, our estimated, future or assumed financial condition (including our ability to continue as a going concern), results of operations, liquidity, business forecasts and plans, research and product development plans, manufacturing plans, strategic plans and objectives, capital needs and financing plans, product launches, sales volumes, regulatory approvals, the impact of changes in the competitive environment, and the application of accounting guidance. For example, under Prospectus Summary Preliminary Fourth Quarter and Full Year 2017 Financial Results and Management's Discussion and Analysis of Financial Condition and Results of Operations Preliminary Fourth Quarter and Full Year 2017 Financial Results, we have included certain preliminary estimates of our financial results for the three months and full year ended December 31, 2017, and under Prospectus Summary Trends Impacting 2018 Financial Results and Management's Discussion and Analysis of Financial Condition and Results of Operations Trends Impacting Financial Results, we discuss certain expectations regarding our financial results for 2018. We caution you that the foregoing list may not include all of the forward-looking statements made in this prospectus.

Our forward-looking statements are based on our management's current assumptions and expectations about future events and trends, which affect or may affect our business, strategy, operations or financial performance. Although we believe that these forward-looking statements are based upon reasonable assumptions, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Our actual financial condition and results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in the sections entitled Risk Factors, Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this prospectus, as well as in the other reports we file with the SEC. You should read this prospectus completely and with the understanding that our actual future results may be materially different from and worse than what we expect.

Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for our management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Forward-looking statements speak only as of the date they were made, and, except to the extent required by law or the NASDAQ Listing Rules, we undertake no obligation to update or review any forward-looking statement because of new information, future events or other factors.

We qualify all of our forward-looking statements by these cautionary statements.

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**USE OF PROCEEDS**

We estimate that our net proceeds from the sale of 13,513,514 shares of our common stock in this offering will be approximately \$37.1 million, or \$42.7 million if the underwriters fully exercise their option to purchase 2,027,027 additional shares, after deducting the underwriting discount and estimated offering expenses payable by us, at an assumed offering price of \$2.96 per share of common stock, the last reported sales price of our common stock on January 26, 2018. The actual offering price per share will be as determined between us and the underwriters at the time of pricing, and may be at a discount to the current market price. Accordingly, the recent market price used throughout this prospectus may not be indicative of the actual public offering price.

A \$0.50 increase (decrease) in the assumed offering price of \$2.96 per share would increase (decrease) our expected net proceeds from this offering by approximately \$6.3 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us. We also may increase or decrease the number of shares we are offering. An increase of 1,000,000 shares in the number of shares offered by us would increase the net proceeds to us from this offering by approximately \$2.8 million after deducting the underwriting discount and estimated offering expenses payable by us, assuming the assumed offering price of \$2.96 per share remains the same. Conversely, a decrease of 1,000,000 shares in the number of shares offered by us would decrease the net proceeds to us from this offering by approximately \$2.8 million after deducting the underwriting discount and estimated offering expenses payable by us, assuming the assumed offering price of \$2.96 per share remains the same.

We intend to use the net proceeds from this offering for working capital and other general corporate purposes.

Our expected use of the net proceeds from this offering is based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of proceeds will vary depending on numerous factors, including the factors described in the section entitled **Risk Factors** beginning on page 13 of this prospectus. In general, our management will retain broad discretion over the allocation of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of the net proceeds.

Pending the use of the net proceeds of this offering, we intend to invest the net proceeds in high-quality, short-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government.



**Table of Contents****PRICE RANGE OF OUR COMMON STOCK****Market Information**

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

	<b>Price Range</b>	
	<b>High</b>	<b>Low</b>
<b><u>Year Ending December 31, 2018:</u></b>		
First Quarter (through January 26, 2018)	\$ 3.98	\$ 2.35
<b><u>Year Ended December 31, 2017:</u></b>		
First Quarter	\$ 30.00	\$ 11.00
Second Quarter	\$ 13.00	\$ 7.63
Third Quarter	\$ 12.20	\$ 3.90
Fourth Quarter	\$ 8.88	\$ 2.15
<b><u>Year Ended December 31, 2016:</u></b>		
First Quarter	\$ 118.00	\$ 65.90
Second Quarter	\$ 113.00	\$ 64.80
Third Quarter	\$ 88.10	\$ 60.40
Fourth Quarter	\$ 81.00	\$ 16.00

The last sale price for our common stock as reported by NASDAQ on January 26, 2018 was \$2.96 per share.

**Holder**

As of December 31, 2017, there were approximately 68 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

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**DIVIDEND POLICY**

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future decision to pay dividends will be made by our board of directors in its sole discretion and will depend upon our results of operations, financial condition, capital requirements and other factors that our board of directors deems relevant in its informed business judgment. In addition, the terms of the Term Loan Agreement restrict our ability to pay cash dividends.

Table of Contents**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and capitalization as of September 30, 2017:

on an actual basis;

on a pro forma basis to give effect to the sale of 4,630,000 shares of common stock (and accompanying warrants) by us at an offering price of \$3.50 per share in the October Financing; and

on a pro forma as adjusted basis to give effect to the sale in this offering of 13,513,514 shares of common stock by us at an assumed offering price of \$2.96 per share, the last reported sale price of our common stock on NASDAQ on January 26, 2018, after deducting the underwriting discount and estimated offering expenses payable by us.

The pro forma information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual offering price and other terms of this offering determined at the time of pricing. You should read this table in conjunction with the sections entitled "Use of Proceeds," "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.

	<b>As of September 30, 2017</b>		
	<b>Actual</b>	<b>Pro Forma</b>	<b>Adjusted</b>
	<b>(unaudited)</b>		
	<b>(dollar amounts in thousands, except par value)</b>		
Cash and cash equivalents	\$ 12,079	\$ 26,842	\$ 63,913
Debt, net of current portion	75,596	75,596	75,596
Common stock, par value \$0.001; 100,000,000 shares authorized, 5,487,001 shares issued and outstanding actual; 100,000,000 shares authorized, 10,117,001 shares issued and outstanding pro forma; 100,000,000 shares authorized, 23,630,515 shares issued and outstanding pro forma as adjusted	5	10	24
Additional paid-in capital	438,244	453,002	490,059
Accumulated other comprehensive loss			
Retained earnings	(466,207)	(466,207)	(466,207)
Total stockholders' equity (deficit)	(27,958)	(13,195)	23,876
Total capitalization	\$ 47,638	\$ 62,401	\$ 99,472

A \$0.50 increase (decrease) in the assumed offering price of \$2.96 per share would increase (decrease) our pro forma cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$6.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us. An increase of 1,000,000 shares in the number of shares offered by us would increase our pro forma cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$2.8 million, assuming the assumed offering price of \$2.96 per share remains the same. Conversely, a decrease of 1,000,000 shares in the number of shares offered by us would decrease our pro forma cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$2.8 million, assuming the assumed offering price of \$2.96 per share remains the same.

The number of shares of common stock outstanding in the table above excludes:

9,552,753 shares of common stock issuable upon exercise of outstanding warrants as of September 30, 2017, at a weighted average exercise price of \$4.63 per share, after giving effect to the warrants sold in the October Financing;

151,078 shares of common stock issuable upon exercise of outstanding options to purchase shares of common stock under the 2006 Stock Incentive Plan, or the 2006 Plan, as of September 30, 2017, at a

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weighted average exercise price of \$24.32 per share (of which options to acquire 151,087 shares of common stock are vested as of September 30, 2017);

781,755 shares of common stock issuable upon exercise of outstanding options to purchase shares of common stock under the 2013 Plan as of September 30, 2017, at a weighted average exercise price of \$75.64 per share (of which options to acquire 313,397 shares of common stock are vested as of September 30, 2017) and 38,656 shares that are reserved for future issuance under the 2013 Plan as of September 30, 2017; and

13 shares of common stock reserved for future grant or issuance under our 2013 Employee Stock Purchase Plan, or the ESPP, as of September 30, 2017.

Table of Contents**DILUTION**

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after giving effect to the shares sold in the October Financing and upon completion of this offering. Our historical net tangible book value (deficit) as of September 30, 2017 was \$(29.5) million, or \$(5.38) per share of our common stock. Historical net tangible book value (deficit) per share is determined by dividing the number of our outstanding shares of common stock by our total tangible assets (total assets less intangible assets) less total liabilities.

Investors purchasing in this offering will incur immediate and substantial dilution. After giving effect to (i) the shares sold in the October Financing and (ii) the sale of 13,513,514 shares of common stock offered in this offering assuming an offering price of \$2.96 per share, the last reported sale price of our common stock on NASDAQ on January 26, 2018, and after deducting the underwriting discount and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of September 30, 2017 would have been \$22.3 million, or \$0.95 per share of our common stock. This represents an immediate increase in net tangible book value of \$2.40 per share to existing stockholders, and an immediate dilution of \$2.01 per share to investors purchasing in this offering.

The following table illustrates this per share dilution:

Assumed offering price per share	\$ 2.96
Historical net tangible book value (deficit) per share as of September 30, 2017	\$ (5.38)
Increase in pro forma net tangible book value per share attributable to investors from the October Financing	\$ 3.92
Pro forma as adjusted net tangible book value (deficit) per share as of September 30, 2017	\$ (1.46)
Increase in net tangible book value per share attributable to investors purchasing in this offering	\$ 2.40
Pro forma as adjusted net tangible book value per share after this offering	\$ 0.95
Dilution per share to investors purchasing in this offering	\$ 2.01

The following table summarizes, on the pro forma basis described above as of September 30, 2017, the differences between the number of shares of common stock purchased from us, the total consideration paid and the average price per share paid by existing stockholders and by investors purchasing in this offering at an assumed offering price of \$2.96 per share, before deducting the underwriting discount and estimated offering expenses payable by us.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	10,117,001	42.8%	\$ 395,838,640	90.8%	\$ 39.13
Investors purchasing in this offering	13,513,514	57.2	40,000,001	9.2	\$ 2.96
Total	23,630,515	100.0%	\$ 435,838,641	100.0%	\$ 18.44

A \$0.50 increase or decrease in the offering price of \$2.96 per share would increase or decrease our pro forma net tangible book value per share by \$1.21 and the dilution per share to new investors in this offering by \$2.25, assuming the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same. An increase or decrease of 1,000,000 shares in the number of shares of common stock offered by us at the assumed public offering price would increase or decrease our pro forma net tangible book value per share after this offering by \$0.07 per share and the dilution per share to new investors in this offering by \$0.07.

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Except as otherwise indicated, the discussion and tables above assume no exercise of the underwriters' option to purchase additional shares and no exercise of any outstanding options or warrants. If the underwriters exercise their option to purchase additional shares in full, the number of shares of common stock held by existing stockholders will be reduced to 39.4% of the total number of shares of common stock to be outstanding upon consummation of this offering, and the number of shares of common stock held by investors purchasing in this offering will be increased to 15,540,541 shares or 60.6% of the total number of shares of common stock to be outstanding upon consummation of this offering.

The number of shares of common stock outstanding in the table excludes:

9,552,753 shares of common stock issuable upon exercise of outstanding warrants as of September 30, 2017, at a weighted average exercise price of \$4.63 per share, after giving effect to the warrants sold in the October Financing;

151,078 shares of common stock issuable upon exercise of outstanding options to purchase shares of common stock under the 2006 Plan as of September 30, 2017, at a weighted average exercise price of \$24.32 per share (of which options to acquire 151,087 shares of common stock are vested as of September 30, 2017);

781,755 shares of common stock issuable upon exercise of outstanding options to purchase shares of common stock under the 2013 Plan as of September 30, 2017, at a weighted average exercise price of \$75.64 per share (of which options to acquire 313,397 shares of common stock are vested as of September 30, 2017) and 38,656 shares that are reserved for future issuance under the 2013 Plan as of September 30, 2017; and

13 shares of common stock reserved for future grant or issuance under the ESPP as of September 30, 2017. We may issue shares of our common stock from time to time for a variety of corporate purposes, including in capital raising activities through future public offerings or private placements, in connection with the exercise of warrants, in connection with the exercise of options and any other issuances relating to our employee benefit plans, and as consideration for future acquisitions, collaborations, investments or other purposes. The number of shares of our common stock that we may issue may be significant, depending on the circumstances surrounding such issuances. In some cases, the shares we issue may be freely tradable without restriction or further registration under the Securities Act. In other cases, we may grant registration rights covering the shares issued in connection with these issuances, in which case the holders of the common stock will have the right, under certain circumstances, to cause us to register any resale of such shares to the public.



**Table of Contents****SELECTED FINANCIAL DATA**

The selected financial data presented below under the heading **Statement of Operations Data** for the nine months ended September 30, 2017 and 2016 and the selected financial data presented below under the heading **Balance Sheet Data** as of September 30, 2017 and 2016 have been derived from our unaudited financial statements included elsewhere in this prospectus. The selected 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 financial data presented below under the heading **Statement of Operations Data** for the years ended December 31, 2013 and 2012, and the selected financial data presented below under the heading **Balance Sheet Data** as of December 31, 2014, 2013 and 2012 are derived from our audited financial statements not included in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

You should read the selected financial data presented below in conjunction with the information included in the section of this prospectus entitled **Management's Discussion and Analysis of Financial Condition and Results of Operations** 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)	Nine Months Ended September 30						
	2017 (Unaudited)	2016	2016	2015	2014	2013	2012
Sales	\$ 67,306	\$ 55,336	\$ 84,248	\$ 72,850	\$ 49,722	\$ 29,007	\$ 2,475
Cost of sales	40,680	41,809	60,656	46,270	34,474	22,840	3,823
Gross profit (loss)	26,626	13,527	23,592	26,580	15,248	6,167	(1,348)
Operating expenses:							
Selling, general and administrative	65,077	63,768	82,834	78,621	75,121	44,522	22,691
Research and development	14,910	14,464	18,809	16,963	15,791	11,079	9,009
Total operating expenses	79,987	78,232	101,643	95,584	90,912	55,601	31,700
Operating loss	(53,361)	(64,705)	(78,051)	(69,004)	(75,664)	(49,434)	(33,048)
Total other income (expense), net	(8,266)	(3,919)	(5,411)	(3,404)	(3,789)	(13,705)	33
Net loss before taxes	\$ (61,627)	\$ (68,624)	\$ (83,462)	\$ (72,408)	\$ (79,453)	\$ (63,139)	\$ (33,015)
Provision for income tax (benefit) expense			(15)	10	71		
Net loss	\$ (61,627)	\$ (68,624)	\$ (83,447)	\$ (72,418)	\$ (79,524)	\$ (63,139)	\$ (33,015)

Net loss per share, basic and diluted	\$ (13.79)	\$ (22.52)	\$ (27)	\$ (25.04)	\$ (34.17)	\$ (214.60)	\$ (1758.80)
Weighted average shares used to compute basic and diluted net loss per share	4,468	3,047	3,057	2,892	2,327	294	19

**Table of Contents****Balance Sheet Data:**

(in thousands)	As of September 30, 2017      2016 (Unaudited)		As of December 31, 2016      2015      2014      2013      2012				
	Cash and cash equivalents	\$ 12,079	\$ 17,956	\$ 44,678	\$ 43,088	\$ 31,176	\$ 124,385
Short-term investments	\$ 459	\$ 16,122	\$ 8,860	\$ 28,018	\$ 36,106	\$ 5,095	\$
Working capital	\$ 26,581	\$ 36,166	\$ 60,616	\$ 80,464	\$ 72,657	\$ 134,390	\$ 10,762
Property and equipment, net	\$ 20,286	\$ 17,370	\$ 18,409	\$ 15,526	\$ 12,581	\$ 9,886	\$ 8,989
Total assets	\$ 87,977	\$ 90,334	\$ 112,392	\$ 124,725	\$ 106,464	\$ 162,215	\$ 39,817
Notes payable	\$ 75,596	\$ 44,681	\$ 78,960	\$ 29,275	\$ 29,440	\$ 29,397	\$ 4,203
Convertible preferred stock	\$	\$	\$	\$	\$	\$	\$ 124,638
Total stockholders' equity (deficit)	\$ (27,958)	\$ 5,197	\$ (5,927)	\$ 63,468	\$ 54,572	\$ 115,537	\$ (106,052)

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**MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes included elsewhere in this prospectus. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should review the section entitled Risk Factors beginning on page 13 of this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements. In addition, see the section of this prospectus entitled Cautionary Note Regarding Forward-Looking Statements.*

**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 our competitive advantage is rooted in our unique consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing and sales activities primarily focus on our flagship product, t:slim X2, which is based on our proprietary technology platform. The simple-to-use t:slim X2 is the smallest durable insulin pump available, and the only pump currently available in the United States that is capable of remote feature updates, which positions us well to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. By delivering innovative hardware and software solutions, as well as best-in-class customer support, we aim to improve and simplify the lives of people with diabetes and their healthcare providers.

We have commercially launched five insulin pumps in the past four years all of which have been developed using our proprietary technology platform. Two of these pumps have featured CGM. Since the launch of our first product in August 2012 through December 2017, we have shipped nearly 68,000 pumps to customers in the United States. In 2017, we announced plans to begin commercialization of t:slim X2 in select geographies outside the United States, including Canada, during 2018.

We began commercial sales of our first insulin pump, 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. In September 2017, we commenced commercial sales of t:slim X2 integrated with the Dexcom G5 Mobile CGM system and discontinued new sales of t:slim G4. In 2017, t:slim X2 represented approximately 95% of our new pump shipments.

Our insulin pump products are generally considered durable medical equipment, and have an expected lifespan of at least four years. In addition to selling insulin pumps, we sell disposable products that are used together with our pumps and replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. In September 2017, we commenced commercial sales of cartridge and infusion set products using t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to our cartridge. However, we continue to offer cartridges and infusion sets with a standard Luer-lok connector on a limited basis to facilitate customer transition to our new t:lock products.

Our insulin pumps are compatible with the Tandem Device Updater, a revolutionary new tool that allows pump users to update their pumps' software quickly and easily from a personal computer. The Tandem Device Updater provides our customers access to new and enhanced features and functionality faster than the industry has been able to in the past. The first use of our Tandem Device Updater was for deployment of the latest t:slim software to in-warranty t:slim pumps purchased before April 2015. In September 2017, we set a new standard of care in our industry by offering all existing t:slim X2 customers integration with the Dexcom G5 Mobile CGM system through a software

update using the Tandem Device Updater. Within the first 30 days following the FDA approval of this update, more than 30% of t:slim X2 customers who purchased their pump prior to its availability

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had updated their pump. By the end of 2017 more than 40% of t:slim X2 customers had updated their pump and now have access to Dexcom G5 Mobile CGM integration. In October 2017, we announced that, subject to FDA approval, we intend to make any new features approved by the FDA in 2018 available to all in-warranty users of t:slim X2 at no cost through the Tandem Device Updater. In the future, this tool has the potential to enable users to add other new features and functionality to their pumps, such as AID algorithms independent of the typical four-year insurance pump replacement cycle.

Between July 2016 and September 2017, we offered a Technology Upgrade Program to provide eligible customers a pathway to ownership of a t:slim X2. During the term of the Program, depending on the type of pump sold, we were required under accounting guidelines to defer some or all of the sales and cost of sales until a later date. This prevented us from recognizing up to 100% of the sales and cost of sales associated with the sale of our t:slim and t:slim G4 insulin pumps to eligible customers at the time of shipment. In general, the deferrals required by the Program had the effect of initially decreasing our GAAP sales, particularly in the second half of 2016, then benefiting our GAAP sales at the conclusion of the Program in the second half of 2017.

For the nine months ended September 30, 2017 and 2016 our sales were \$67.3 million and \$55.3 million, respectively. 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 nine months ended September 30, 2017 and 2016, our net loss was \$61.6 million and \$68.6 million, respectively. For the nine months ended September 30, 2017, this included incremental net sales of \$4.8 million with a corresponding increase of \$3.2 million in gross profit as a result of our Technology Upgrade Program, which we offered between July 2016 and September 2017 to provide eligible customers a pathway to ownership of a t:slim X2. For the nine months ended September 30, 2016, this included a deferral of sales of \$8.4 million with a corresponding deferral of \$1.4 million in cost of sales as a result of the Program. 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 September 30, 2017 and December 31, 2016 was \$466.2 million and \$404.6 million, respectively. Pump sales accounted for 65% and 74% of sales, respectively, for the nine months ended September 30, 2017 and 2016, while pump-related supplies primarily accounted for the remainder in each period. Pump sales accounted for 74%, 83% and 86% of sales, respectively, for the years ended December 31, 2016, 2015 and 2014, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in any of these periods.

We have rapidly increased sales since our commercial launch by expanding our sales, clinical and marketing infrastructure, by developing, commercializing and marketing multiple differentiated products that utilize our proprietary technology platform and consumer-focused approach, and by providing strong customer support. In our research, approximately 86% of healthcare providers surveyed believe that providing great customer support is the most important attribute in an insulin pump manufacturer. We believe that by demonstrating our product benefits and the shortcomings of existing insulin therapies, 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 and by offering customers a pathway to our future innovations through the Tandem Device Updater, as they are approved by the FDA. As we continue to develop differentiated products based on our proprietary technology platform, our strategy is to leverage a single sales, marketing and clinical organization, a shared manufacturing and supply chain infrastructure, and the expertise of our customer support services.

***Products under Development***

Our products under development support our strategy of focusing on both consumer and clinical needs, and include AID systems, a next-generation hardware platform, and connected (mobile) health offerings. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionalities that will allow us to target people in differentiated segments of the insulin-dependent diabetes market.

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Our current products under development include:

*t:slim X2 with Basal IQ* : Utilizes Dexcom G5 sensor values and a predictive low glucose suspend, or PLGS, algorithm to adjust the rate of insulin delivery to help minimize the frequency and/or duration of hypoglycemic events.

*t:slim X2 with Control IQ* : Our second generation AID system is expected to integrate the t:slim X2 pump with a combination of Dexcom's G6 sensor and AID technology that we licensed from TypeZero.

*t:sport Insulin Delivery System*: Expected to be half the size of t:slim and is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump.

*Connected (Mobile) Health Offerings*: A mobile application designed to utilize the capability of the Bluetooth low energy radio, or BLE, already built into our pumps to wirelessly upload pump data to t:connect, receive notification of pump alerts and alarms, integrate other health-related information from third party sources, and support future pump-control capabilities for our products under development.

For additional information, see the section of this prospectus entitled *Business*.

***Pump Shipments***

Since inception, we have derived nearly all of our sales from the shipment of insulin pumps and associated supplies in the United States. We consider the number of units shipped per quarter to be an important metric for managing our business. We have shipped more than nearly 68,000 insulin pumps since our initial launch in August 2012, of which over 60,000 pumps have been shipped within the four years ended December 31, 2017. Pump shipments are broken down by fiscal quarter as follows:

	<b>Pump Units Shipped for Each of the Three Months Ended in Respective Years<sup>(1)</sup></b>				
	<b>March 31</b>	<b>June 30</b>	<b>September 30</b>	<b>December 31</b>	<b>Total</b>
2012		9	204	844	1,057
2013	852	1,363	1,851	2,406	6,472
2014	1,723	2,235	2,935	3,929	10,822
2015	2,487	3,331	3,431	6,234	15,483
2016	4,042	4,582	3,896	4,418	16,938
2017	2,816	3,427	3,868	7,000	17,111

(1) This table does not reflect returns or exchanges of pump products that occur in the ordinary course of business, nor does it reflect 3,000 trade-ins fulfilled under the Technology Upgrade Program (discussed below) related to our commercial launch of t:slim X2.

***Technology Upgrade Program***



In the third quarter of 2016, we launched a Technology Upgrade Program that provided eligible t:slim and t:slim G4 customers a path towards ownership of t:slim X2 or, as of August 2017, t:slim X2 with G5, by offering customers the right to exchange their t:slim or t:slim G4 for t:slim X2 or t:slim X2 with G5, under a variable pricing structure.

While our Technology Upgrade Program expired on September 30, 2017, it resulted in a number of accounting complexities that will continue to make comparisons of our historical and future financial results more difficult. In particular, during the term of the Technology Upgrade Program, accounting guidelines prevented us from recognizing, at the time of sale, up to 100% of the sales and cost of sales associated with the sale of our insulin pumps to eligible customers. In general, the deferrals required by the Technology Upgrade Program had the effect of initially decreasing our GAAP sales, primarily in 2016, even when the number of our pump shipments increased.

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We recognized the deferred amount of sales and cost of sales at the earlier of when the obligations under the Technology Upgrade Program were satisfied or upon the expiration of the Program. If a customer elected to participate in the Technology Upgrade Program, we recognized any upgrade fees that we received and the associated costs at the time of fulfilling the given obligation. All deferred sales and cost of sales will be recognized by December 31, 2017 and we are no longer subject to these accounting deferrals.

***Historical Financial Results***

For the nine months ended September 30, 2017 and 2016, our sales were \$67.3 million and \$55.3 million, respectively. For the nine months ended September 30, 2017, this included incremental net sales of \$4.8 million with a corresponding increase of \$3.2 million in gross profit as a result of the Technology Upgrade Program. For the nine months ended September 30, 2016, this included a deferral of sales of \$8.4 million with a corresponding deferral of \$1.4 million in cost of sales as a result of the Technology Upgrade Program. For the nine months ended September 30, 2017 and 2016, our net loss was \$61.6 million and \$68.6 million, respectively. Our accumulated deficit as of September 30, 2017 was \$466.2 million.

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 year ended December 31, 2016, we recorded net sales deferrals of \$4.3 million and recognized net additional \$0.3 million in cost of sales as a result of the Technology Upgrade Program. 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. Our accumulated deficit as of December 31, 2016 was \$404.6 million.

***Preliminary Fourth Quarter and Full Year 2017 Financial Results***

Our financial statements for the fiscal quarter ended December 31, 2017, or the fourth quarter, and for the full year ended December 31, 2017, or the full year 2017, are not yet complete. We expect to report complete information for the fourth quarter and for the full year 2017 after the completion of this offering. Accordingly, we are presenting preliminary estimates of certain financial information related to our company, including our expected sales and cash, cash equivalents, short-term investments and restricted cash, that we expect to report for the fourth quarter and the full year 2017.

In the fourth quarter, we shipped an aggregate of approximately 7,000 pumps, of which more than 95% were t:slim X2. For the fourth quarter, we estimate our sales will be approximately \$39.0 million \$40.0 million, with no material impact from the Technology Upgrade Program. Pump sales accounted for approximately 68% of sales during the fourth quarter, while infusion sets accounted for approximately 20%, and cartridges accounted for the remainder of sales.

We believe our preliminary sales results for the fourth quarter were impacted by a number of factors, including:

We received FDA approval to market t:slim X2 with G5 on August 25, 2017 and discontinued new sales of t:slim G4. Following the launch, we experienced a meaningful increase in the demand for our insulin pumps. Pump shipments grew more than 80% to approximately 7,000 in the fourth quarter compared to 3,868 in the third quarter of 2017, which is the largest sequential quarterly increase since the fourth quarter of 2015 when we received approval and launched t:slim G4.

We began the transition of our customers to t:lock in the third quarter of 2017. This substantially increased our infusion set sales in the fourth quarter to an estimated \$8.0 million, compared to \$5.0 million in the third quarter of 2017 and \$3.9 million in the fourth quarter of 2016. Prior to announcing our plans to launch this product, only a small percentage of our customers and distributors purchased infusion sets from us as compared to purchases of our cartridges. In particular, the ratio of our sales volume of infusion sets relative to sales volume of cartridges during the third quarter was approximately 66%, as compared to 61% during the second quarter of 2017, 51% during the first quarter of 2017 and 31% for all of 2016. This ratio increased to approximately 88% in the fourth quarter of 2017, nearing 100% in December 2017.

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While the largest percentage of our new customers still report being new to pump therapy, with approximately half converting from MDI, we experienced an increase in the fourth quarter of 2017 in the percentage of sales to people who reported switching from an Animas pump following Johnson & Johnson's announcement that it intends to discontinue the operations of Animas and exit the insulin pump business.

We continue to be subject to negative perceptions regarding our financial stability relative to that of our competitors, including concerns among healthcare providers and potential customers regarding our ability to sustain our business operations on a long-term basis. In some cases, these perceptions and concerns have caused potential customers to delay the purchase of our products or purchase competitors' products and have negatively impacted the willingness of healthcare providers to recommend our products over those of our competitors.

We expect to continue to incur an operating loss for the fourth quarter and full year ended December 31, 2017.

In the full year 2017, we shipped an aggregate of approximately 17,100 pumps. For the full year 2017, we estimate our sales were approximately \$106.0 million to \$107.0 million, including approximately \$5.0 million of sales previously deferred in prior periods and upgrade fees received as a result of our Technology Upgrade Program. Pump sales accounted for approximately 65% of sales during the full year 2017, while pump-related supplies primarily accounted for the remainder of sales.

Our cash, cash equivalents, short-term investments and restricted cash as of December 31, 2017 was approximately \$24.2 million, of which \$10.0 million was restricted. Our cash balance reflects our completion of the October Financing of 4,630,000 shares of our common stock, Series A warrants to purchase up to 4,630,000 shares of our common stock and Series B warrants to purchase up to 4,630,000 shares of our common stock at a public offering price of \$3.50 per share and accompanying warrants. The gross proceeds were approximately \$16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

Our sales (including deferred sales and infusion set sales) and cash, cash equivalents, short-term investments and restricted cash estimates presented above, as well as our expectations regarding our operating loss, are preliminary and subject to revision based upon the completion of our year-end financial closing process and our financial statements. The estimated amounts are not intended to convey final results for the fourth quarter or the full year 2017. These preliminary estimates have been prepared by, and are the responsibility of, our management based upon the most current information available to them as of the date of this prospectus. Such preliminary estimates have not been subject to any audit procedures, review procedures, or any other procedures by our independent registered public accounting firm. In addition, these estimates and expectations are subject to risks and uncertainties. See the sections of this prospectus entitled *Risk Factors* and *Cautionary Note Regarding Forward-Looking Information*. Accordingly, following the completion of our year-end financial closing process, we may report financial results that could differ from these estimates. Factors that could cause the preliminary financial data and estimates to differ include, but are not limited to: (i) additional adjustments in the calculation of, or application of accounting principles, for the financial results; and (ii) discovery of new information that affects accounting estimates and management's judgment underlying these estimated results. The information presented herein should not be considered a substitute for the financial information to be filed with the SEC in our Annual Report on Form 10-K for the fiscal year ended December 31, 2017 once it becomes available. We have no intention or obligation to update the estimated financial results in this prospectus prior to filing our Annual Report on Form 10-K for the fiscal year ended December 31, 2017.

## ***Trends Impacting Financial Results***

Overall, we have experienced considerable sales growth since the commercial launch of t:slim in the third quarter of 2012, while incurring operating losses since our inception. Our operating results have historically fluctuated on a quarterly or annual basis, particularly in periods surrounding anticipated regulatory approvals, and the

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commercial launch of products by us and our competitors. In particular, customers may defer a purchasing decision if they believe that a new product may be launched in the near future. For example, we believe that our pump shipments were negatively impacted during the second half of 2016 and first half of 2017, as we announced the launches of t:slim X2 and the Technology Upgrade Program in the third quarter of 2016, and one of our competitors announced the future availability of two new products with financial incentives for adoption.

We believe that our business condition and financial results, as well as the decision-making process of our customers, has been and will continue to be impacted by a number of factors, including the following:

market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers;

the timing of the sale of our products;

seasonality associated with summer vacations, annual insurance deductibles, and coinsurance requirements associated with the medical insurance plans utilized by our customers and the customers of our distributors;

the buying patterns of our distributors and other customers;

the timing of the commercialization of new products by us or our competitors;

changes in the competitive landscape, including as a result of companies entering or exiting the diabetes therapy market;

access to adequate coverage and reimbursement for our current and future products by third-party payors, and reimbursement decisions by third-party payors;

the magnitude and timing of any changes to our facilities, manufacturing operations and other infrastructure; and

anticipated and actual regulatory approvals of our products and competitive products.

In particular, we believe the following trends could materially impact our financial results going forward:

continued increase in demand following the commercial launch of t:slim X2 with G5 and the demonstrated success of our Tandem Device Updater, which we expect will positively impact our sales;

the anticipated launch of t:slim X2 with Basal IQ in the summer of 2018, subject to the completion of our clinical trial with a satisfactory outcome, timely submission of our application for regulatory approval to the FDA and future FDA approval;

increased opportunity to achieve customer renewals as customers become eligible for insurance reimbursement to purchase a new insulin pump, which we expect will positively impact our sales. Customers are typically eligible for insurance reimbursement once every four years. 2017 was our first full year with customers eligible for renewal. In 2018, renewal opportunities exist for some portion of the 10,822 pumps we originally shipped in 2014, based on the typical four-year insurance reimbursement cycle for insulin pumps. This opportunity may be limited by many factors, such as the ability to obtain approval for reimbursement from insurance payors and the potential for customers to choose competitive products, to use their existing insulin pump on an out-of-warranty basis or to discontinue insulin pump therapy;

opportunity to attract Animas customers as their pumps come up for renewal, following the announcement by Johnson & Johnson that it intends to discontinue the operations of Animas and exit the insulin pump business entirely. We now offer the only alternative durable insulin pump to those sold by Medtronic in the United States. While it is too early to know how the announcement will influence our business or the competitive landscape in which we operate over the longer term, in the fourth quarter of 2017 we experienced an increase in our percentage of sales to people who reported switching from using an Animas pump;

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increased sales of infusion sets following the recent commercial launch of t:lock. In particular, the ratio of our sales volume of infusion sets relative to sales volume of cartridges during the third quarter was approximately 66%, as compared to 61% during the second quarter of 2017, 51% during the first quarter of 2017 and 31% for all of 2016. This ratio increased to approximately 87% in the fourth quarter of 2017, nearing 100% in December 2017. We expect to maintain a ratio of approximately 100% in the full year of 2018;

designation by UnitedHealthcare in July 2016 of 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 believe this decision has and will continue to prevent a majority of UnitedHealthcare members from purchasing an insulin pump from us for the foreseeable future. However, in most other circumstances in which we do not have contracts established with third-party payors, we utilize our network of national and regional distributors to service our customers;

international expansion in select geographies, including Canada, in the second half of 2018;

due to seasonality factors impacting annual insurance deductibles, and the historical buying patterns of our customers, our sales will continue to be heavily weighted towards the second half of the year and product shipments from the fourth quarter to the following first quarter will decrease significantly; and

we continue to be subject to negative perceptions regarding our financial stability relative to that of our competitors, including concerns among potential customers, healthcare providers, distributors and suppliers regarding our ability to sustain our business operations on a long-term basis. In some cases, we believe these perceptions have caused potential customers to delay the purchase of our products or purchase competitors products and have negatively impacted the willingness of healthcare providers to recommend our products over those of our competitors.

Even with our growth expectations, in 2018 we intend to leverage our existing infrastructure investments and realize additional manufacturing cost improvements to increase our operating margins. Our operating expense goal for 2018, including our international launch plans, is to manage annual growth of our operating expenses to less than 10%. We believe we can ultimately achieve profitability by driving incremental sales from these growth opportunities, achieving our pump renewal sales objectives, increasing gross profits from higher sales of infusion sets, maximizing manufacturing efficiencies on increased production volumes and leveraging the early investments made in our sales, clinical and marketing organization, as well as our customer support infrastructure.

***Additional Financing***

From inception through September 30, 2017, we have primarily financed our operations through sales of equity securities, and, to a lesser extent, debt financings. The continued growth of our business, including the expansion of our customer care infrastructure to support our growing base of customers, our plans to begin international sales activities in 2018 and additional research and development activities, will continue to increase our expenses and capital needs. Our goal is to reach the milestone of cash flow breakeven in the second half of 2019 when we expect to have an installed base of more than 80,000 customers and a gross margin of approximately 55%. We believe this will require us to raise \$50.0 million \$60.0 million through this offering and holders' exercise of our outstanding warrants. However, there can be no assurance that our warrants will be exercised.



On the date that our financial statements in this prospectus were issued, our management believed that we did not have sufficient cash to fund our operations for the next twelve months 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. We expect we will be required to raise additional capital through equity and debt financings in order to continue as a going concern, meet our minimum liquidity requirements, and execute on our business strategy. In particular, 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

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successfully raise all the funding we require in this offering. We may in the future seek additional capital from public or private offerings of our capital stock, elect to restructure or refinance our existing indebtedness, or borrow additional amounts under new credit lines or from other sources. We expect our ability to raise additional financing may be negatively impacted by a number of factors, including our recent and projected financial results, recent changes in and volatility of our stock price, perceptions about the dilutive impact of our recent financing transactions, concerns regarding our ability to maintain the continued listing of our common stock on NASDAQ, our current level of indebtedness and debt service costs, our conclusion that there is substantial doubt about our ability to continue as a going concern and the competitive environment in our industry.

### ***Term Loan Agreement***

We have entered into the Term Loan Agreement with Capital Royalty Partners. In the first quarter of 2016, we entered into Amendment No. 3 to Term Loan Agreement, or the Third Amendment, which granted us the right to borrow up to an additional \$50.0 million. We borrowed \$15.0 million of this amount in January 2016, and the remaining \$35.0 million in December 2016.

The terms of the Term Loan Agreement require that we deliver audited financial statements that include an unqualified audit report to Capital Royalty Partners. As a result, we entered into the Fourth Amendment in March 2017. The Fourth Amendment includes a limited waiver of a potential event of default that could have resulted from the inclusion of an explanatory paragraph in the audit report of our independent registered public accounting firm included in our Annual Report on Form 10-K for the year ended December 31, 2016 that describes conditions that raise substantial doubt about our ability to continue as a going concern. The Fourth Amendment also imposes additional restrictive and financial covenants on us, which may increase our risk of triggering defaults under the Term Loan Agreement.

In the event of a future breach of any of the covenants in the Term Loan Agreement, we will need to obtain additional waivers from Capital Royalty Partners to avoid being in default. For example, if the audit report and opinion of our independent registered public accounting firm contained in our financial statements for the year ended December 31, 2017 includes an explanatory paragraph that describes conditions that raise substantial doubt about our ability to continue as a going concern, it could constitute a potential event of default under the Term Loan Agreement. We will obtain a waiver of any such event of default under the Term Loan Agreement in connection with this offering.

At September 30, 2017, we had \$82.3 million in aggregate borrowings outstanding under the Term Loan Agreement.

For additional information about the Term Loan Agreement and Fourth Amendment, see the section entitled *Indebtedness* below.

## **Components of Results of Operations**

### ***Sales***

We offer products for people with insulin-dependent diabetes. We commenced commercial sales of our first insulin pump, t:slim, in the United States in the third quarter of 2012. We have launched four additional insulin pump products since that time. Our current pump product offering includes t:flex, which was launched in the second quarter of 2015, and t:slim X2 with G5, which was launched in the third quarter of 2017, as well as disposable cartridges and infusion sets. We also offer accessories including protective cases, belt clips and power adapters. Sales of accessories since commercial launch have not been significant.

We primarily sell our products through national and regional distributors on a non-exclusive basis. These distributors are generally providers of medical equipment and supplies to individuals with diabetes. Our primary end customers are people with insulin-dependent diabetes. Similar to other durable medical equipment, the

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primary payor is generally a third-party insurance carrier and the customer is usually responsible for any medical insurance plan copay or coinsurance requirements. We believe our existing sales, clinical and marketing infrastructure will allow us to continue to increase sales by allowing us to promote our products to a greater number of potential customers, caregivers and healthcare providers.

We expect that our sales will increase over time as we gain market acceptance for our current products and products under development. We believe that the factors discussed above under the heading Trends Impacting Financial Results have impacted and will continue to impact our product sales.

### ***Cost of Sales***

We manufacture our pumps and disposable cartridges at our manufacturing facilities in San Diego, California. Infusion sets and pump accessories are manufactured by third-party suppliers. Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs, reserves for expected warranty costs, scrap and inventory excess and obsolescence. Manufacturing overhead expenses include expenses relating to quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management. Historically, cost of sales has also included royalty costs associated with sales of t:slim G4. In August 2017, we commenced commercial sales of t:slim X2 with G5, which has no royalty obligation, and discontinued new sales of t:slim G4. We anticipate that our cost of sales will continue to increase as our products gain broader market acceptance and our product sales increase.

We expect our overall gross margin percentage, which for any given period is calculated as sales less cost of sales divided by sales, to improve over the long term, as our sales increase and we have more opportunities to spread our overhead costs over larger production volumes. We expect that we will be able to leverage our manufacturing cost structure across our products that utilize the same proprietary technology platform and manufacturing infrastructure, and will be able to further reduce costs with increased automation, process improvements and raw materials cost reductions. We also expect our warranty costs to decrease as we release product features and functionality utilizing the Tandem Device Updater.

In 2017, we transitioned our manufacturing operations to our Barnes Canyon facility, which we expect will double our previous manufacturing capacity for both insulin pumps and cartridges, and expand warehousing for additional infusion set supplies related to the launch of t:lock while maintaining approximately the same cost of facilities in manufacturing overhead. The transition to the new manufacturing facility took place primarily in the second half of 2017, during which time we experienced some temporary duplication of operations to support ongoing product requirements, as well as some incremental manufacturing costs.

We expect our overall gross margin to fluctuate in future quarterly periods due to fluctuating production volumes, as well as a result of numerous other factors. In general, we expect the gross margin on insulin pumps to be higher than the gross margin on pump-related supplies, which would be consistent with our historical experience. Other factors impacting our overall gross margin include the changing mix of products sold with different gross margins, the changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors, the timing and success of new regulatory approvals and product launches, warranty and training costs, and changes in our manufacturing processes, capacity, costs or output.

### ***Selling, General and Administrative***

Our selling, general and administrative, or SG&A, expenses primarily consist of salary, cash-based incentive compensation, fringe benefits and non-cash stock-based compensation for our executive, financial, marketing, sales,

clinical, customer care, technical services, insurance verification, regulatory affairs and administrative functions. In particular, our sales and clinical organization consisted of approximately 70 territories as of December 31, 2017. Territories are maintained by sales representatives and field clinical specialists, and

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supported by managed care liaisons, additional sales management and other customer support personnel. Other significant SG&A expenses include those incurred for product demonstration samples, commercialization activities associated with new product launches, travel, trade shows, outside legal fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs. Although we do not contemplate an increase in the number of sales territories in the near term or other significant infrastructure investments, we expect our SG&A expenses, including the cost of our customer care infrastructure, to moderately increase as our customer base grows and due to ordinary increases in employee compensation and benefits. Our SG&A expenses may also increase due to costs associated with additional compliance and regulatory reporting requirements, as well as in support of our planned international expansion in 2018.

### ***Research and Development***

Our research and development, or R&D, activities primarily consist of engineering and research programs associated with our products under development, as well as activities associated with our core technologies and processes. R&D expenses are primarily related to employee compensation, including salary, fringe benefits, non-cash stock-based compensation and temporary employee expenses. We also incur R&D expenses for supplies, development prototypes, outside design and testing services, depreciation, allocated facilities and information services, clinical trial costs, payments under our licensing, development and commercialization agreements and other indirect costs. Our R&D expenses, including clinical trial costs, may increase as we advance our products under development and develop new products and technologies and due to ordinary increases in employee compensation and benefits.

### ***Other Income and Expense***

Our other income and expense primarily consists of interest expense and amortization of debt discount and issuance costs associated with the Term Loan Agreement. At September 30, 2017, there was \$82.3 million of outstanding principal under the Term Loan Agreement, which accrues interest at a rate of 11.5% per annum as compared to \$45.8 million as of September 30, 2016, which resulted in a meaningful increase in interest expense over the comparable periods (see the section below entitled *Indebtedness* ).

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(in thousands, except percentages)	Nine Months Ended		Year Ended December 31,		
	2017	2016	2016	2015	2014
	September 30				
	(Unaudited)				
Sales	\$ 67,306	\$ 55,336	\$ 84,248	\$ 72,850	\$ 49,722
Cost of sales	40,680	41,809	60,656	46,270	34,474
Gross profit	26,626	13,527	23,592	26,580	15,248
Gross margin	40%	24%	28%	36%	31%
Operating expenses:					
Selling, general and administrative	65,077	63,768	82,834	78,621	75,121
Research and development	14,910	14,464	18,809	16,963	15,791
Total operating expenses	79,987	78,232	101,643	95,584	90,912
Operating loss	(53,361)	(64,705)	(78,051)	(69,004)	(75,664)
Other income (expense), net:					
Interest and other income	179	258	(5,351)	337	112
Interest and other expense	(8,445)	(4,177)	(60)	(3,741)	(3,901)
Total other expense, net	(8,266)	(3,919)	(5,411)	(3,404)	(3,789)
Net loss before taxes	(61,627)	\$ (68,624)	\$ (83,462)	\$ (72,408)	\$ (79,453)
Provision for income taxes (benefit)			(15)	10	71
Net loss	(61,627)	\$ (68,624)	\$ (83,447)	\$ (72,418)	\$ (79,524)

**Comparison of the Nine Months Ended September 30, 2017 and 2016**

*Sales.* For the nine months ended September 30, 2017, sales were \$67.3 million, including the recognition of \$4.8 million pump sales originally deferred in prior periods and upgrade fees received as a result of the Technology Upgrade Program. Sales were \$55.3 million for the same period in 2016, which reflect the deferral of \$8.4 million pump sales associated with the Technology Upgrade Program.

Sales of insulin pumps were \$43.9 million and \$41.2 million, respectively, for the nine months ended September 30, 2017 and 2016. For the nine months ended September 30, 2017, sales of pump-related supplies were \$23.0 million, of which \$9.7 million were sales of cartridges and \$13.0 million were sales of infusion sets. For the nine months ended September 30, 2016, sales of pump-related supplies were \$14.2 million, of which \$8.2 million were sales of cartridges and \$5.8 million were sales of infusion sets. The ratio of the number of infusion sets shipped to the number of cartridges shipped increased to 60% in the nine months ended September 30, 2017 from 25% in the same period in 2016. Sales of accessories were not significant in either of the reported periods.

Excluding the impact of the Technology Upgrade Program, the decrease in pump sales was primarily driven by a 19% decrease in aggregate pump shipments from 12,520 for the nine months ended September 30, 2016 to 10,111 for the

same period in 2017, which we believe was the result of a number of factors including the highly competitive market, the impact of the hurricanes in the Southeast region of the United States, the timing of FDA approval of t:slim X2 with G5 within the third quarter, and negative perceptions regarding our financial stability compared to that of our competitors. Additionally, the period ended June 30, 2016 represented the last period in which all UnitedHealthcare members had access to our products due to their decision to designate one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18, which was effective July 1, 2016. The decrease in pump sales was partially offset by an increase in sales of infusion sets to our distributors, as well as overall pump-related supplies to our growing customer base. Sales to distributors accounted for 73% and 74% of our total sales for the nine months ended September 30, 2017 and 2016, respectively.



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*Cost of Sales and Gross Profit.* Our cost of sales for the nine months ended September 30, 2017 was \$40.7 million, resulting in gross profit of \$26.6 million, compared to \$41.8 million cost of sales and gross profit of \$13.5 million in 2016. The gross margin for the nine months ended September 30, 2017 was 40% compared to 24% in the same period in 2016.

The increase in our gross profit for the nine months ended September 30, 2017 compared to the same period in 2016 was primarily the result of the Technology Upgrade Program. During the nine months ended September 30, 2017, our gross profit included \$3.5 million that had been deferred in prior periods, partially offset by \$0.3 million incurred for the fulfillment of upgrades. In the same period of 2016, our gross profit was reduced by a net deferral of \$7.0 million of pump sales eligible under the program. Additionally, we recorded a \$1.1 million charge in the nine months ended September 30, 2016 for inventory obsolescence as a result of the commercialization of the t:slim X2 Pump, launch of the Technology Upgrade Program and associated decrease in the overall demand for our t:slim G4 Pump.

Gross profit and gross margin also increased as a result of manufacturing cost improvements, including raw material cost reductions for our pumps and increased cartridge production volumes and cartridge labor and manufacturing efficiencies, as well as a decrease in warranty expense as a result of improvements in our warranty trends and warranty replacement costs.

The gross margin was also impacted by an increase in sales of pump-related supplies, which generally have lower gross margins than our insulin pumps.

*Selling, General and Administrative Expenses.* SG&A expenses increased 2% to \$65.1 million for the nine months ended September 30, 2017 from \$63.8 million for the same period in 2016.

Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. The increase in SG&A expenses was primarily the result of a \$1.1 million non-cash stock-based compensation charge associated with the suspension of our ESPP in 2017, as well as other net increases in employee expenses of \$0.9 million. Other SG&A expenses, including costs for outside services, marketing and promotional activities, tradeshow and travel, decreased \$0.7 million between periods.

*Research and Development Expenses.* R&D expenses increased 3% to \$14.9 million for the nine months ended September 30, 2017 from \$14.5 million for the same period in 2016. The increase in R&D expenses was the result of an increase of \$0.7 million of employee-related expenses, which includes a \$0.4 million non-cash stock-based compensation charge associated with the suspension of our ESPP in 2017. This increase was offset by a reduction in non-employee-related expenses, primarily consulting and supplies, for the advancement of our product pipeline.

*Other Income and Expense.* Other expense for the nine months ended September 30, 2017 and 2016 was \$8.4 million and \$4.2 million, respectively. Other expense for both periods was primarily comprised of interest expense associated with the Term Loan Agreement. The outstanding principal balances under the Term Loan Agreement were \$82.3 million and \$45.8 million as of September 30, 2017 and September 30, 2016, respectively. Other income for both periods presented was not significant.

## **Comparison of Years Ended December 31, 2016 and 2015**

*Sales.* For the year ended December 31, 2016, sales were \$84.2 million, net of \$4.3 million of deferred pump sales as a result of our Technology Upgrade Program, compared to \$72.9 million for the year ended December 31, 2015.

Sales of insulin pumps were \$62.4 million and \$60.8 million, respectively, for the years ended December 31, 2016 and 2015. For the year ended December 31, 2016, sales of pump-related supplies were \$21.4 million, of

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which \$11.7 million were sales of cartridges and \$9.7 million were sales of infusion sets. For the year ended December 31, 2015, sales of pump-related supplies were \$11.9 million, of which \$7.6 million were sales of cartridges and \$4.3 million were sales of infusion sets. Sales of accessories were not significant in either of the reported periods.

The growth in sales was driven by a 9% increase in pump shipments from 15,483 in 2015 to 16,938 in 2016, offset in part by our deferral of sales of eligible insulin pumps due to the Technology Upgrade Program. We also experienced an increase in sales of pump-related supplies from our growing customer base and as a result of an increase in our sales of infusion sets under contractual arrangements with various independent distributors during the second half of 2016.

Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor. Sales to distributors accounted for 74% and 77% of our total sales for the years ended December 31, 2016 and 2015, respectively. The percentage of sales to distributors decreased mainly due to UnitedHealthcare's decision to designate one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18, effective July 1, 2016. Previously, UnitedHealthcare's members accessed our products through one of our distributors.

*Cost of Sales and Gross Profit.* Our cost of sales in 2016 was \$60.7 million, resulting in gross profit of \$23.6 million, compared to \$46.3 million cost of sales and gross profit of \$26.6 million in 2015. The gross margin in 2016 was 28%, compared to 36% in 2015. The decrease in gross profit was primarily due to a net \$4.6 million reduction in gross profit as a result of the deferral of sales due to the Technology Upgrade Program.

During 2016, in conjunction with the Technology Upgrade Program, we recorded net sales deferrals of \$4.3 million, net deferrals of \$0.8 million in cost of sales and recognized \$1.1 million of incremental cost of sales for the upgrade of 1,413 pumps to t:slim X2. The net reduction of gross profit associated with the Technology Upgrade Program negatively affected our gross margin for 2016 by four percentage points. In addition, we recorded a \$2.8 million charge for inventory excess and obsolescence as the result of the commercialization of t:slim X2, the launch of the Technology Upgrade Program and the larger than anticipated decrease in t:slim G4 sales in the second half of the year. For the first and second quarters in the year ended December 31, 2016, t:slim G4 shipments as a percentage of total pump shipments were 60% and 57%, respectively. By comparison, in the third and fourth quarters of the same year t:slim G4 shipments as a percentage of total pump shipments decreased to 40% and 7%, respectively. This inventory excess and obsolescence charge negatively affected our gross margin for 2016 by three percentage points.

The remaining decrease in gross margin was primarily due to an increase in warranty and other non-manufacturing costs, such as freight, training, and royalty costs, as a percentage of sales. The gross margin was further impacted by an increase in sales of pump-related supplies, which generally have lower gross margins than our insulin pumps. However, we continue to experience improvement in the gross margin associated with our pump-related supplies, achieving a positive gross margin for the first time in the second half of 2016. This improvement was primarily the result of significantly lower per-unit manufacturing costs for cartridges, driven by increased production volumes and manufacturing efficiencies, as well as increases in the volume of infusion sets sold to distributors.

*Selling, General and Administrative Expenses.* SG&A expenses increased 5% to \$82.8 million in 2016 from \$78.6 million in 2015. The increase was primarily the result of the expansion of our commercial operations during 2016. In particular, we expanded the number of our sales territories from 60 to 72 in early 2016, and also increased our customer and technical support personnel throughout the year to service our growing customer base.

Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. These expenses increased \$4.4 million during 2016 compared to 2015, including an increase of \$7.6 million in salaries

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and fringe benefits, offset by a decrease in cash-based incentive compensation of \$2.1 million and stock-based compensation of \$1.2 million. We also experienced reduced costs for outside services, marketing and promotional activities, tradeshow and travel of \$0.1 million.

*Research and Development Expenses.* R&D expenses increased 11% to \$18.8 million in 2016 from \$17.0 million in 2015. This increase was primarily the result of an increase of \$2.3 million in clinical trial expenses, licensing fees, supplies and outside services, as well as an increase in employee-related expenses of \$0.5 million. The increase was offset in part by a \$1.0 million milestone payment made to Dexcom in 2015 that did not recur in 2016.

*Other Income (Expense).* Other expense in 2016 was \$5.4 million, compared to \$3.4 million in 2015. Other expense in 2016 and 2015 primarily consisted of interest expense associated with the Term Loan Agreement. We borrowed \$30.0 million under the agreement in January 2013, an additional \$15 million in January 2016, and the remaining \$35.0 million in December 2016. Other income for both periods presented was not significant.

**Comparison of Years Ended December 31, 2015 and 2014**

*Sales.* For the years ended December 31, 2015 and 2014, sales were \$72.9 million and \$49.7 million, respectively. Sales of insulin pumps were \$60.8 million and \$42.7 million, respectively, for the years ended December 31, 2015 and 2014. Pump sales accounted for 83% and 86% of sales, respectively, for the years ended December 31, 2015 and 2014, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in either year.

The growth in sales was primarily driven by a 43% increase in pump shipments from 10,822 in 2014 to 15,483 in 2015. This included shipments of 1,498 t:flex Pumps and 4,493 t:slim G4 Pumps during 2015 compared to none in 2014. Sales of t:flex Pumps and t:slim G4 Pumps began in May 2015 and September 2015, respectively.

Sales to distributors accounted for 77% and 75% of our total sales for the years ended December 31, 2015 and 2014, respectively.

*Cost of Sales and Gross Profit.* Our cost of sales in 2015 was \$46.3 million, resulting in gross profit of \$26.6 million, compared to \$34.5 million cost of sales and gross profit of \$15.2 million in 2014. The gross margin in 2015 was 36%, compared to 31% in 2014. The improvement in the gross margin was primarily a result of manufacturing efficiencies associated with an increase in production volume and improvement in our manufacturing processes. Our pump manufacturing overhead spending decreased 8% while our pump units produced increased 22% in 2015 compared to 2014, and our cartridge manufacturing overhead spending increased 28% while our cartridge units produced increased 78% in 2015 compared to 2014.

*Selling, General and Administrative Expenses.* SG&A expenses increased 5% to \$78.6 million in 2015 from \$75.1 million in 2014. The SG&A expenses increased at a slower rate as compared to our sales growth, as well as compared to our SG&A expense increase in 2014.

Employee-related expenses increased \$3.9 million during 2015 compared to 2014, including an increase of \$5.3 million in salaries, sales commission and bonus expenses offset by a decrease of \$1.4 million in stock-based compensation. The increase in employee-related expenses was offset by a decrease of \$0.3 million in travel expenses, supplies, and outside services as compared to the same period in 2014.

*Research and Development Expenses.* R&D expenses increased 7% to \$17.0 million in 2015 from \$15.8 million in 2014. The increase in R&D expenses in 2015 consisted primarily of an increase of \$1.0 million in employee-related

expenses. Included in R&D expenses were \$1.0 million milestone payments made to Dexcom, under the development and commercialization agreement, in each of the years ended December 31, 2015 and 2014.

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*Other Income (Expense).* Other expense in 2015 was \$3.4 million, compared to \$3.8 million in 2014. Other expense in 2015 and 2014 primarily consisted of interest expense as a result of the Term Loan Agreement.

## **Liquidity and Capital Resources**

At September 30, 2017, we had \$22.5 million in cash and cash equivalents and short-term investments, which included \$10.0 million of restricted cash as required by the Term Loan Agreement. At the date the most recent financial statements in this prospectus were issued, our management believed that we did not have sufficient cash to fund our operations for the next twelve months 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. The financial statements included in this prospectus have been prepared on a basis that assumes that we will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. This financial information and these financial statements do not include any adjustments that may result from the outcome of this uncertainty.

Historically, our principal sources of cash have included private placements and public offerings of equity securities, proceeds from borrowings under the Term Loan Agreement, and cash generated from product sales. Our historical cash outflows have primarily been associated with cash used for operating activities such as the expansion and support of our sales and marketing infrastructure, an increase in our research and development activities, expenditures related to the expansion of our manufacturing capacity and the improvement of our manufacturing efficiency, the acquisition of intellectual property and other working capital needs.

In November 2013, we completed an initial public offering of common stock that resulted in net proceeds of approximately \$125.0 million. In March 2015, we completed a public offering of common stock that resulted in net proceeds of approximately \$64.9 million. During 2017, we completed the following financings:

In March 2017, we completed a registered public offering of 1,850,000 shares of our common stock at a public offering price of \$12.50 per share. The gross proceeds to us from the offering were approximately \$23.1 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

During the three months ended September 30, 2017, we sold 464,108 shares of common stock under our at-the-market offering program at prices ranging from \$5.64 to \$10.54. The gross proceeds to us from the offering were \$4.3 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

On October 17, 2017, we completed the October Financing, pursuant to which we sold 4,630,000 shares of our common stock, Series A warrants to purchase up to 4,630,000 shares of our common stock and Series B warrants to purchase up to 4,630,000 shares of our common stock at a public offering price of \$3.50 per share and accompanying warrants. The gross proceeds to us from the October Financing were approximately \$16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. Each series of warrants, if exercised by all holders in full, may result in additional gross proceeds to us of \$16.2 million.

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. However, we expect our ability to raise additional financing may be negatively impacted by a number of factors, including our recent and projected financial results, recent changes in and volatility of our stock price, concerns regarding our ability to maintain the continued listing of our common stock on NASDAQ, perceptions about the dilutive impact of our financing transactions, our current level of indebtedness and debt service costs, our conclusion that there is substantial doubt about our ability to continue as a going concern, the competitive environment in our industry, and uncertainties regarding the regulatory environment. There can be no assurance that we will be able to complete any financing on acceptable terms or at all.



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We expect that, in addition to the outcome of any additional financing activities, our sales performance and the resulting operating income or loss, as well as the status of each of our new product development programs, will significantly impact our cash management decisions.

The following table shows a summary of our cash flows for the periods indicated:

(in thousands)	Nine Months Ended		Year Ended December 31,		
	September 30, 2017	2016	2016	2015	2014
	(Unaudited)				
Net cash provided by (used in):					
Operating activities	\$ (54,495)	(47,591)	\$ (61,186)	\$ (58,764)	\$ (61,378)
Investing activities	4,201	5,873	10,461	2,421	(35,470)
Financing activities	17,695	16,586	52,315	68,255	3,639
<b>Total</b>	<b>\$ (32,599)</b>	<b>(25,132)</b>	<b>\$ 1,590</b>	<b>\$ 11,912</b>	<b>\$ (93,209)</b>

*Operating activities.* Net cash used in operating activities was \$54.5 million for the nine months ended September 30, 2017, compared to \$47.6 million for the same period in 2016. The increase in net cash used in operating activities was primarily associated with changes in working capital, partially offset by a decrease in net loss. The changes in working capital were primarily due to decreases in deferred revenue and guarantee liabilities associated with the Technology Upgrade Program, lower cash collections from accounts receivable and increased inventory associated with the launch of t:lock, as well as other net changes associated with the timing of payments.

Net cash used in operating activities was \$61.2 million for the year ended December 31, 2016, compared to \$58.8 million and \$61.4 million for the same periods in 2015 and 2014, respectively. The increase in net cash used in operating activities for 2016 compared to 2015 was primarily associated with an increase in our operating loss, offset by changes in working capital. The changes in working capital were primarily due to greater cash collections from accounts receivable and an increase in deferred revenue and guarantee liability associated with the Technology Upgrade Program, offset by changes in employee-related liabilities, other current liabilities, accounts payable and an increase in inventory to meet higher production volumes, including those associated with new products, and an increase in prepaid expenses. The decrease in net cash used in operating activities for 2015 compared to 2014 was primarily associated with an improvement in operating margin, offset by changes in working capital. The change in working capital was primarily due to an increase in accounts receivable and increase in inventory to meet higher production volumes, including those associated with new products, offset by increase in accounts payable, employee-related liabilities and other current liabilities.

*Investing activities.* Net cash provided by investing activities was \$4.2 million for the nine months ended September 30, 2017, which was primarily related to sales and maturities of short-term investments of \$8.5 million, partially offset by the purchase of \$4.3 million of property and equipment. Net cash provided by investing activities was \$5.9 million for the nine months ended September 30, 2016, which was primarily related to the purchase of \$25.9 million of short-term investments and \$6.2 million of property and equipment, offset by proceeds from sales and maturities of short-term investments of \$38.0 million.

Net cash provided by investing activities was \$10.5 million for the year ended December 31, 2016, which was primarily related to proceeds from sales and maturities of short-term investments of \$50.0 million offset by the net

purchase of \$30.6 million in short-term investments and \$8.9 million in purchases of property and equipment. Net cash provided by investing activities was \$2.4 million for the year ended December 31, 2015, which was primarily related to proceeds from sales and maturities of short-term investments of \$88.5 million offset by the net purchase of \$80.2 million in short-term investments and \$5.8 million in purchases of property and equipment. Net cash used in investing activities was \$35.5 million for the year ended December 31, 2014, which was primarily related to the net purchase of \$67.1 million in short-term investments and \$4.4 million in purchases of property and equipment, offset by proceeds from sales and maturities of short-term investments of \$36.2 million.

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*Financing activities.* Net cash provided by financing activities was \$17.7 million for the nine months ended September 30, 2017, which was primarily the result of net proceeds of approximately \$25.7 million from the issuance of common stock, partially offset by an increase in our restricted cash balance of \$8.0 million as required by the Fourth Amendment to our Term Loan Agreement. Net cash provided by financing activities was \$16.6 million for the nine months ended September 30, 2016, which was primarily the result of net proceeds of \$15.0 million under the Term Loan Agreement and \$1.6 million in proceeds from the issuance of common stock associated with our ESPP, as well as the exercise of outstanding stock options and warrants.

Net cash provided by financing activities was \$52.3 million for the year ended December 31, 2016, which was primarily due to net proceeds from issuance of indebtedness under the Term Loan Agreement in the amount of \$50.0 million and \$2.3 million in proceeds from the exercise of outstanding stock options, and proceeds from employee contributions for the purchase of our common stock through our ESPP. Net cash provided by financing activities was \$68.3 million for the year ended December 31, 2015, which was primarily due to net proceeds from a public offering of our common stock in the amount of \$64.9 million and \$3.4 million in proceeds from the exercise of outstanding stock options and warrants, as well as proceeds from employee contributions for the purchase of our common stock through our ESPP. The net cash provided by financing activities was \$3.6 million for the year ended December 31, 2014, which was primarily related to \$3.7 million in net proceeds from the exercise of outstanding stock options and warrants, as well as proceeds from employee contributions for the purchase of our common stock through our ESPP.

Our liquidity position and capital requirements are subject to fluctuation based on a number of factors. In particular, our cash inflows and outflows are principally impacted by the following:

our ability to generate sales, the timing of those sales and the collection of receivables generated from those sales from period to period;

the timing and amount of any additional financings, including the proceeds raised in this offering and any exercise by holders of the warrants issued in the October Financing;

fluctuations in gross margins and operating margins; and

fluctuations in working capital.

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

support of our commercialization efforts related to our current and future products;

expansion of our manufacturing facilities and improvements in our manufacturing efficiency;

new research and product development efforts, including clinical trial costs;

payment of interest due under the Term Loan Agreement;

acquisition of equipment and other fixed assets; and

payments under our licensing, development and commercialization agreements.

Although we believe the foregoing items reflect our most likely uses of cash in the short-term, we cannot predict with certainty all of our particular short-term cash uses or the timing or amount of cash used. We expect we will need to raise additional funding in order to continue as a going concern, meet our minimum liquidity requirements, and execute on our business strategy. 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. We may also continue to seek additional capital from public or private offerings of our capital stock or we may elect to borrow additional amounts under new debt financing arrangements or from other sources.

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If we issue equity or convertible debt securities to raise additional funding, our existing stockholders may experience dilution, we may incur significant financing costs, and the new equity or convertible debt securities may have rights, preferences and privileges senior to those of our existing stockholders. If we issue debt securities to raise additional funding, we would incur additional debt service obligations, we could become subject to additional restrictions limiting our ability to operate our business, and we may be required to further encumber our assets. Our ability to continue as a going concern, meet our minimum liquidity requirements, satisfy the covenants under the Term Loan Agreement, and execute our business strategy is dependent on our ability to raise additional capital, of which there can be no assurance. If we cannot generate sufficient revenues from the sale of our products, are unable to complete this financing or are unable to secure additional financing on acceptable terms, we may be forced to significantly alter our business strategy, substantially curtail or modify our current operations, or cease operations altogether.

**Indebtedness*****Term Loan Agreement***

We had \$82.3 million and \$81.1 million of aggregate borrowings outstanding under the Term Loan Agreement at September 30, 2017 and December 31, 2016, respectively.

Under the Term Loan Agreement, interest is payable, at our option, (i) in cash at a rate of 11.5% per annum or (ii) at a rate of 9.5% of the 11.5% per annum in cash and 2.0% of the 11.5% per annum to be added to the principal of the loan and subject to accruing interest. Interest-only payments are due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period, which ends on December 31, 2019. The principal balance is due in full on the maturity date of the Term Loan Agreement, which is March 31, 2020. We had elected to pay interest in cash at a rate of 11.5% per annum through September 30, 2015. Beginning October 1, 2015, we elected to pay interest in cash at a rate of 9.5% per annum and to have 2.0% per annum added to the principal of the loan. As a result, \$2.3 million was added to the principal of the loan since October 1, 2015, which we refer to as PIK Loans.

The loan is collateralized by all of our assets. The principal financial covenants require that we attain minimum annual revenues of \$80.0 million in 2017 and \$95.0 million each year thereafter until the end of the term of the loan.

In connection with the Third Amendment, we previously agreed to pay, on the earlier of (i) the maturity date of the Term Loan Agreement, which is March 31, 2020, (ii) the date that the loan under the Term Loan Agreement becomes due, and (iii) the date on which we make a voluntary pre-payment of the loan, a financing fee equal to 3.0% of the sum of (x) the aggregate amount drawn under the Third Amendment, and (y) any PIK Loans issued in relation to the Third Amendment, which we refer to as the Back End Financing Fee.

The audit report and opinion of our independent registered public accounting firm contained in our Annual Report on Form 10-K for the fiscal 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 constitutes a potential event of default under the Term Loan Agreement. On March 7, 2017, we entered into the Fourth Amendment, which included a limited waiver of the potential event of default. In consideration for the waiver, we agreed to: (i) issue Capital Royalty Partners ten-year warrants to purchase an aggregate of 1,937,890 shares of our common stock at an exercise price equal to \$23.50 per share, the closing price of our common stock on NASDAQ on the date of the Fourth Amendment, which we refer to as the Capital Royalty Warrant, (ii) increase our restricted cash balance from \$2.0 million to \$10.0 million, (iii) provide Capital Royalty Partners the same information we make available to our board of directors, subject to limited exceptions, and (iv) not incur additional third party indebtedness secured solely by accounts receivable, inventory and cash. In addition, the Fourth Amendment includes a covenant requiring us to complete financings in which our gross proceeds from the sale of equity securities is at least

\$30.0 million, no later than January 15, 2018. While we have satisfied our obligations pursuant to this equity financing covenant, we remain subject to additional covenants.

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Pursuant to the Fourth Amendment, we also agreed to increase the Back End Financing Fee to 5.0% of the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued, under the Term Loan Agreement. The Back End Financing Fee is payable at maturity of our loans and on the principal amount of any loans for which we make an optional prepayment, and may be payable in connection with asset sales not permitted under the Term Loan Agreement or in connection with a change of control. As of September 30, 2017, we had accrued \$4.1 million for the Back End Financing Fee.

## **Critical Accounting Policies Involving Management Estimates and Assumptions**

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

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

### ***Revenue Recognition***

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

Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred and title passed, the price is fixed or determinable, and collectability is reasonably assured.

### ***Trade-In Rights***

We launched a Technology Upgrade Program in 2016, which expired September 30, 2017. The trade-in rights associated with the program were accounted for as guarantees or rights to return based on specific factors and circumstances, including the period of time the trade-in rights were exercisable, the likelihood that the trade-in rights would be exercised, and the amount of the specified-price trade-in value.

We determined that trade-in rights for t:slim G4 Pump customers were generally guarantees. We accounted for the guarantees under applicable accounting standards, which require a guarantor to recognize, at the inception of the guarantees, a liability for the estimated fair value of the obligation undertaken in issuing the guarantees. Subsequently, the initial liability recognized for the guarantees was reduced as we were released from the risk under the guarantees, which was when the trade-in right was exercised or the right expired. The guarantees were accounted for as an element of a multiple element arrangement. The estimated fair value of the guarantees was based on various economic and customer behavioral assumptions, including the probability that a trade-in right would be exercised, the specified trade-in amount, the expected fair value of the used t:slim G4 Pump at trade-in and the expected sales price of a t:slim X2 pump. Upon expiration of the Technology Upgrade Program at September 30, 2017, the remaining guarantee liabilities of \$1.1 million were recognized as sales compared to \$1.1 million recorded as guarantee liabilities in other

current liabilities on the balance sheets included elsewhere in this prospectus, as of September 30, 2017 and December 31, 2016, respectively.



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We determined that t:slim pump trade-in rights were in-substance rights to return products. Such rights to return were accounted for pursuant to the right of return accounting guidance. As we did not have sufficient history to reasonably estimate returns associated with trade-in rights, all eligible t:slim pump sales between July 2016 and October 2016, which is when we discontinued new shipments of t:slim, were recorded as deferred revenue until the trade-in right was exercised or the right expired. Despite expiration of the program at September 30, 2017, we recorded \$0.2 million for upgrades requested but not yet fulfilled compared to \$3.2 million as trade-in rights reserve in deferred revenue on the balance sheets included elsewhere in this prospectus as of September 30, 2017 and December 31, 2016, respectively.

*Revenue Recognition for Arrangements with Multiple Deliverables*

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

We offer a cloud-based data management application, t:connect, which is made available to customers upon purchase of any of our insulin pumps. In July 2016, we received clearance from the FDA to begin offering the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of Tandem insulin pump software. Utilizing Tandem Device Updater, we may from time to time provide future unspecified software upgrades to the insulin pump's essential software. The t:connect service and the embedded right included with qualifying insulin pumps to receive, on a when-and-if-available basis, future unspecified software upgrades relating to the product's essential software are deemed undelivered elements at the time of the insulin pump sale. Because we have neither VSOE nor TPE for these deliverables, the allocation of revenue is based on our ESP. We establish our ESP based on the estimated cost to provide such services, including consideration for a reasonable profit margin, which is then corroborated by comparable market data. We allocate fair value based on management's ESP to these elements at the time of sale and recognize the revenue over a four-year period, which is the hosting period for t:connect and the period that software upgrades are expected to be provided. At September 30, 2017 and December 31, 2016, \$1.8 million and \$1.6 million, respectively, were recorded as deferred revenue for these undelivered elements. All other undelivered elements at the time of sale are deemed inconsequential or perfunctory.

*Product Returns*

We offer a 30-day right of return to our customers from the date of shipment of any of our insulin pumps, provided a physician's confirmation of the medical reason for the return is received. Estimated allowances for sales returns are based on historical returned quantities as compared to pump shipments in those same periods of return. The return rate is then applied to the sales of the current period to establish a reserve at the end of the period. The return rates used in the reserve are adjusted for known or expected changes in the marketplace when appropriate. The allowance for product returns is recorded as a reduction of revenue and accounts receivable in the period in which the related sale is recorded. The amount recorded on our balance sheets for product return allowance was \$0.2 million and \$0.2 million at September 30, 2017 and December 31, 2016, respectively. Actual product returns have not differed materially from estimated amounts reserved in the accompanying condensed financial statements.



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***Warranty Reserve***

We generally provide a four-year warranty on our insulin pumps to end user customers and may replace any pumps that do not function in accordance with the product specifications. Insulin pumps returned to us may be refurbished and redeployed. Additionally, we offer a six-month warranty on disposable cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. Warranty costs are estimated based on the current expected product replacement cost and expected replacement rates based on historical experience. We evaluate the reserve quarterly and make adjustments when appropriate. Changes to the actual replacement rates or the expected product replacement cost could have a material impact on our warranty reserve. At September 30, 2017 and December 31, 2016, the warranty reserve was \$4.8 million and \$5.7 million, respectively.

**Off-Balance Sheet Arrangements**

As of September 30, 2017, we did not have any off-balance sheet arrangements.

**JumpStart Our Business Startups Act of 2012 (JOBS Act)**

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

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**QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK**

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

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

Because of the short-term maturities of our financial instruments, we do not believe that an increase or decrease in market interest rates would have any significant impact on the realized value of our investment portfolio. If a 10% change in interest rates were to have occurred on September 30, 2017, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

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

Our operations are located in the United States, and nearly all of our sales since inception have been made in U.S. dollars. Although we are evaluating international expansion opportunities for a potential launch in 2018, we do not currently have any material exposure to foreign currency rate fluctuations. From time to time, we may have foreign currency exchange risk associated with currency exposure related to existing assets and liabilities, committed transactions and forecasted future cash flows. In certain circumstances, we may seek to manage such foreign exchange risk by using derivative instruments such as foreign exchange forward contracts to hedge our risks. In general, we may hedge material foreign exchange exposures up to 12 months in advance. However, we may choose not to hedge some exposures for a variety of reasons including prohibitive economic costs.

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**Table of Contents****BUSINESS****Overview**

We are a medical device company with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. We believe our competitive advantage is rooted in our unique consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing and sales activities primarily focus on our flagship product, the t:slim X2 Insulin Delivery System, or t:slim X2, which is based on our proprietary technology platform. The simple-to-use t:slim X2 is the smallest durable insulin pump available, and the only pump currently available that is capable of remote feature updates, which positions us well to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. By delivering innovative hardware and software solutions, as well as best-in-class customer support, we aim to improve and simplify the lives of people with diabetes and their healthcare providers.

We have commercially launched five insulin pumps in the past four years, all of which have been developed using our proprietary technology platform. Two of these pumps have featured CGM. Since the launch of our first product in August 2012, through December 2017, we have shipped nearly 68,000 pumps to customers in the United States. In 2017, we announced plans to begin commercialization of t:slim X2 in select geographies outside the United States, including Canada, during 2018.

We began commercial sales of our first insulin pump, 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. In September 2017, we commenced commercial sales of t:slim X2 integrated with the Dexcom G5 Mobile CGM system, which is manufactured by Dexcom, and discontinued new sales of t:slim G4. In 2017, t:slim X2 represented approximately 95% of our new pump shipments. In September 2017, we also commenced commercial sales of cartridge and infusion set products using our custom t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to our cartridge.

All people with type 1 diabetes require daily rapid-acting insulin, but only a subset of people with type 2 diabetes require daily rapid-acting insulin, as a majority manage their therapy through improvements in diet and exercise, oral medications, or injectable therapies such as long acting insulin. According to the Centers for Disease Control and Prevention, or CDC, 2017 National Diabetes Statistics Report, approximately 23 million people in the United States had diagnosed diabetes, of which type 1 diabetes accounts for approximately 5% to 10%, or approximately 1.2 to 2.3 million people. Of people with type 2 diabetes in the United States, the CDC reports that approximately 14%, or 3.2 million people, manage their diabetes with insulin only. The International Diabetes Federation estimates that in 2017 approximately 425 million people had diabetes worldwide, of which approximately 10%, or 42.5 million, had type 1. Our target market consists of people in the United States, and select geographies worldwide beginning in 2018, who require daily rapid-acting insulin.

Our insulin pump products are generally considered durable medical equipment, and have an expected lifespan of at least four years. In addition to selling insulin pumps, we sell disposable products that are used together with our pumps and replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body. In September 2017, we commenced commercial sales of cartridge and infusion set products using t:lock, which replaces the standard Luer-lok connector that historically joined an infusion set to our cartridge. However, we continue to offer cartridges and infusion sets with a standard Luer-lok connector on a limited basis to facilitate customer transition to our new t:lock products.

Each of our insulin pump products is compatible with the Tandem Device Updater, a unique tool that allows our pump users to update their pumps' software quickly and easily from a personal computer. The Tandem Device Updater provides our customers access to new and enhanced features and functionality faster than the industry.

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has been able to in the past. Its first cleared use by the FDA was to update t:slim pumps purchased before April 2015 to the latest software. In September 2017, we set a new standard of care in our industry by offering all existing t:slim X2 customers integration with the Dexcom G5 Mobile CGM system through a software update using the Tandem Device Updater. Within the first 30 days following the FDA approval of this update, more than 30% of t:slim X2 customers who purchased their pump prior to its availability had updated their pump. By the end of 2017 more than 40% of t:slim X2 customers had updated their pump and now have access to Dexcom G5 Mobile CGM integration. In October 2017, we announced that, subject to FDA approval, we intend to make any new features approved by the FDA in 2018 available to all in-warranty users of t:slim X2 at no cost through the Tandem Device Updater. In the future, this tool has the potential to enable users to add other new features and functionality to their pumps, such as automated insulin delivery algorithms, or AID algorithms, independent of the typical four-year insurance pump replacement cycle.

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. By doing so, we seek to optimize our products, which allows for them to be successfully operated by users in their intended environment.

We have developed our products to provide the specific features that people with insulin-dependent diabetes and healthcare providers seek in a next-generation insulin pump. Our use of modern consumer technologies, and a proprietary pumping technology, has allowed us to design the slimmest and smallest durable insulin pump on the market, without sacrificing insulin capacity. t:slim X2 features our patented Micro-Delivery technology, a miniaturized pumping mechanism that draws insulin from a flexible bag within the pump's cartridge, rather than relying on a lead screw driven syringe mechanism. It also features an easy-to-navigate software architecture, a vivid color touchscreen, an advanced Bluetooth radio capable of communicating with multiple compatible devices, such as a CGM sensor, blood glucose meter or mobile applications, and a micro-USB connection that supports a rechargeable battery, software updates through the Tandem Device Updater, as well as uploads to the t:connect Diabetes Management Application, or t:connect. t:connect is our custom cloud-based data management application that provides our customers and healthcare providers a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters.

Based on customer surveys, approximately half of our customers are new to insulin pump therapy, and the average age of our existing customers is 31 years old, with relatively equal distribution between men and women. Of the customers who converted from another manufacturer's pump, the greatest percent converted from Medtronic, followed by Animas. However, in the fourth quarter of 2017, we did see a meaningful increase in our sales to former Animas pump users.

Between July 2016 and September 2017, we offered a Technology Upgrade Program to provide eligible customers a pathway to ownership of a t:slim X2. During the term of the Program, depending on the type of pump sold, we were required under accounting guidelines to defer some or all of the sales and cost of sales until a later date. This prevented us from recognizing up to 100% of the sales and cost of sales associated with the sale of our t:slim and t:slim G4 insulin pumps to eligible customers at the time of shipment. In general, the deferrals required by the Program had the effect of initially decreasing our GAAP sales, particularly in the second half of 2016, then benefiting our GAAP sales at the conclusion of the Program in the second half of 2017.

For the nine months ended September 30, 2017 and 2016 our sales were \$67.3 million and \$55.3 million, respectively. 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 nine months ended September 30, 2017 and 2016, our net loss was \$61.6 million and \$68.6 million, respectively. For the nine months ended September 30, 2017, this included incremental net sales of \$4.8 million with a corresponding increase of \$3.2 million in gross profit as a result of our Technology Upgrade Program, which we offered between July 2016 and September 2017 to provide eligible



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customers a pathway to ownership of a t:slim X2. For the nine months ended September 30, 2016, this included a deferral of sales of \$8.4 million with a corresponding deferral of \$1.4 million in cost of sales as a result of the Program. 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 September 30, 2017 and December 31, 2016 was \$466.2 million and \$404.6 million, respectively. Pump sales accounted for 65% and 74% of sales, respectively, for the nine months ended September 30, 2017 and 2016, while pump-related supplies primarily accounted for the remainder in each period. Pump sales accounted for 74%, 83% and 86% of sales, respectively, for the years ended December 31, 2016, 2015 and 2014, while pump-related supplies primarily accounted for the remainder in each year. Sales of accessories were not material in any of these periods.

In January 2018, we announced our preliminary, unaudited financial results for the fourth quarter of 2017, and 2017 full year results. For the fourth quarter of 2017, we estimate our sales were \$39.0 million to \$40.0 million, compared to \$28.9 million in the fourth quarter of 2016. For the year ended December 31, 2017, we estimate our sales were \$106.0 million to \$107.0 million, which includes approximately \$5.0 million that we recognized during the period as a result of the conclusion of our Technology Upgrade Program. We estimate that pump sales accounted for approximately 68% of sales during the fourth quarter of 2017, while infusion sets accounted for approximately 20% and cartridges accounted for the remainder of sales. We began the transition of our customers to t:lock in the third quarter of 2017, which substantially increased our infusion set sales in the fourth quarter on 2017. Sales of accessories were not material in any of these periods. Pump shipments grew more than 80% to approximately 7,000 in the fourth quarter compared to 3,868 in the third quarter of 2017, which is the largest sequential quarterly increase since the fourth quarter of 2015 when we launched t:slim G4. While the largest percentage of our new customers during the fourth quarter of 2017 still report being new to pump therapy, we experienced an increase in the percentage of new pump sales to people who reported switching from an Animas pump. We estimate that our cash, cash equivalents and restricted cash as of December 31, 2017 was approximately \$24.2 million.

We began the transition of our customers to our proprietary t:lock in the third quarter of 2017. This substantially increased our infusion set sales in the fourth quarter to an estimated \$8.0 million, compared to \$5.0 million in the third quarter of 2017 and \$3.9 million in the fourth quarter of 2016. Prior to announcing our plans to launch this product, only a small percentage of our customers and distributors purchased infusion sets from us as compared to purchases of our cartridges. In particular, the ratio of our sales volume of infusion sets relative to sales volume of cartridges during the third quarter was approximately 66%, as compared to 61% during the second quarter of 2017, 51% during the first quarter of 2017 and 31% for all of 2016. This ratio increased to approximately 87% in the fourth quarter of 2017, and nearly reached 100% in December 2017.

We have rapidly increased sales since our commercial launch by expanding our sales, clinical and marketing infrastructure, by developing, commercializing and marketing multiple differentiated products that utilize our proprietary technology platform and consumer-focused approach, and by providing strong customer support. In our research, approximately 86% of healthcare providers surveyed believe that providing great customer support is the most important attribute in an insulin pump manufacturer. We believe that by demonstrating our product benefits and the shortcomings of existing insulin therapies, 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 and by offering customers a pathway to our future innovations through the Tandem Device Updater, as they are approved by the FDA. As we continue to develop differentiated products based on our proprietary technology platform, our strategy is to leverage a single sales, marketing and clinical organization, a shared manufacturing and supply chain infrastructure, and the expertise of our customer support services.

Our headquarters and our manufacturing facility are located in San Diego, California and we employed 574 full-time employees as of December 31, 2017.

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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 IDF estimates that in 2017, approximately 425 million people had diabetes worldwide and that by 2045, this number will increase to 629 million people worldwide. According to the CDC, approximately 23 million people in the United States have diagnosed diabetes.

There are two primary types of diabetes:

The IDF estimates that people with type 1 diabetes represent approximately 10% of the diabetes population worldwide, or approximately 42.5 million people. Similarly, the CDC estimates that people with type 1 diabetes represent approximately 5% to 10% of individuals with diagnosed diabetes in the United States, or approximately 1.2 to 2.3 million people.

The IDF estimates that people with type 2 diabetes represent approximately 90% of the diabetes population worldwide, or approximately 382.5 million people. Similarly, the CDC estimates that people with type 2 diabetes represent approximately 90% to 95% of individuals with diagnosed diabetes in the United States, or approximately 20.7 to 21.8 million people. Initially, many people with type 2 diabetes attempt to manage their diabetes with improvements in diet, exercise and oral medications. However, as their diabetes advances, some patients progress to requiring injectable therapies, such as long-acting insulin, and a subset of this population will require daily rapid-acting insulin therapy. Approximately 14% of people with type 2 diabetes in the United States, or 3.2 million people, manage their diabetes with insulin only.

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.

People with insulin-dependent diabetes require intensive insulin therapy to manage their blood glucose levels within a healthy range, which is typically between 70-120 milligrams per deciliter, or mg/dL. Blood glucose levels can be affected by many factors, such as type or quantity of food eaten, illness, stress and exercise. Hypoglycemia, or low blood glucose levels, can cause a variety of long-term effects or complications, including damage to various tissues and organs, seizures, coma or death. Hyperglycemia, or high blood glucose levels, can also cause a variety of long-term effects or complications, including cardiovascular disease and damage to various tissues and organs. It can also cause the emergency condition ketoacidosis, which can result in vomiting, shortness of breath, coma or death. According to the CDC, in 2014 there were approximately 245,000 emergency department visits for adults with hypoglycemia, and approximately 207,000 visits for hyperglycemic crisis in the United States.

There are two primary therapies used 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 MDI and involve the use of syringes or insulin pens to inject insulin into the person's body. Insulin pumps are used to perform what is often referred to as continuous subcutaneous insulin infusion, or insulin

pump therapy, and typically use a programmable device and an infusion set to administer insulin into the person's body.

MDI therapy involves the administration of a rapid-acting insulin before meals, or bolus insulin, to bring blood glucose levels down into the healthy range. MDI therapy may also require a separate injection of a long-acting

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insulin, or basal insulin, to control glucose levels between meals; this type of insulin is typically taken once or twice per day. Insulin pump therapy, by comparison, uses only rapid-acting insulin to fulfill both mealtime (bolus) and background (basal) requirements. Insulin pump therapy allows a person to customize their bolus and basal insulin doses to meet their insulin needs throughout the day, and is intended to more closely resemble the physiologic function of a healthy pancreas.

Insulin pump therapy has been shown to provide people with insulin-dependent diabetes with numerous advantages relative to MDI therapy. The following chart illustrates some of the key advantages and disadvantages of using MDI therapy versus insulin pump therapy:

**Comparison of MDI Therapy vs. Insulin Pump Therapy**

<b>Therapy</b>	<b>Advantages</b>	<b>Disadvantages</b>
Multiple Daily Injection, or MDI	<p>Less training and shorter time to educate</p> <p>Less cost</p> <p>Lower risk of technological malfunction</p>	<p>Requires injections up to seven times per day</p> <p>Delivers insulin less accurately than insulin pumps</p> <p>Results in greater variability in blood glucose levels or less accurate glycemic control</p> <p>Requires more planning around and restrictions regarding meals and exercise</p>
Insulin Pump	<p>Eliminates individual insulin injections</p> <p>Delivers insulin more accurately and precisely than injections</p> <p>Often improves HbA1c, a common measure of blood glucose levels over time</p>	<p>Requires intensive education on insulin pump therapy and management</p> <p>Wearing a pump can be bothersome</p> <p>More costly</p>

Fewer large swings in blood glucose levels      Risk of diabetic ketoacidosis if the catheter comes out and insulin infusion is interrupted

Provides greater flexibility with meals, exercise and daily schedules

Can improve quality of life

Reduces severe low blood glucose episodes

Eliminates unpredictable effects of intermediate or long-acting insulin

Allows exercise without having to eat large amounts of carbohydrates, as insulin delivery can be adjusted

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According to the American Diabetes Association, it is estimated that between 750,000 and 1 million people worldwide used an insulin pump. Domestically, we estimate that 550,000 people in the United States use an insulin pump, of which approximately 80% have type 1 diabetes.

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. In addition, SAPs may feature an 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. We further believe that recent and ongoing developments in the use of CGM technology and AID algorithms in conjunction with insulin pump therapy will continue to provide people with insulin-dependent diabetes benefits that will make insulin pump therapy an even more attractive treatment alternative.

### **The Opportunity**

The foundation of our consumer-focused approach is market research, through which we seek to better understand the opportunity within the insulin-dependent diabetes market. This opportunity includes both the introduction of the benefits of pump therapy to people using MDI and the introduction of the features and benefits of our pumps to people who use traditional pumps. We have conducted extensive research obtained from interviews, focus groups and online surveys to understand what people with diabetes, their caregivers and healthcare providers are seeking to improve in diabetes therapy management, as we believe the user is the primary decision-maker when purchasing an insulin pump. 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. Because an insulin pump must be used multiple times throughout the day, often in social settings, its style and appearance are important to users. Our market research has shown that traditional insulin pump users frequently report being embarrassed by the style of their traditional pump. For current MDI users, the style of traditional pumps is often cited as a reason for not adopting pump therapy.

***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 this is due to hardware and user interface limitations that prevent traditional pumps from being easily updatable to provide new feature offerings. As a result, consumers have had limited product choices from pump manufacturers, and healthcare providers are required to learn a greater number of user interfaces. 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. This complaint,



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along with concerns relating to how and where the pump can be utilized due to its size and shape, is frequently cited among users of traditional pumps. For current MDI users, the size of traditional pumps is often communicated as a reason for not adopting pump therapy.

***Difficult to learn and teach.*** Traditional pumps often rely on complicated and outdated technology and are not intuitive to operate. Our research has shown that it can take several days to competently learn how to use traditional pumps, leading to frustration, frequent mistakes and additional training, each of which may discourage adoption. We believe difficult-to-use traditional pumps result in a higher frequency of calls by the user to the pump manufacturer or their healthcare provider for support, adding both frustration and cost to the learning process. We also believe that the complicated functionality of traditional pumps significantly limits the willingness of healthcare providers to recommend insulin pump therapy to many patients, and limits the number of patients they consider as candidates for insulin pump therapy.

***Complicated to use.*** Traditional pumps are designed with linear software menus, which require the user to follow display screens sequentially, limiting their ability to access information within workflows or easily return to the starting point. Most traditional pumps require users to scroll through numerous menus and input multiple commands to make selections. This process, which must be performed multiple times per day, can be frustrating and time-consuming. 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 pump features, or even discourage use entirely.

***Pump mechanism limitations.*** Traditional pumps utilize a mechanism in which a lead screw drives a plunger to deliver insulin. This design limits the ability to reduce the size of the pump due to the length and diameter of the syringe and lead screw.

### **Traditional Pump Mechanism**

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

### **Our Solution**

We develop our insulin pump technology and related product offerings using a consumer-focused approach. We initially rely on extensive market research to ascertain what people with insulin-dependent diabetes require and

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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 features and functionality they seek and in a manner that makes the features usable and intuitive. We believe this approach is fundamentally different from the historical approach applied to the traditional medical device development process. All of our insulin pump products were developed using this approach, as were our related product offerings, including the Tandem Device Updater, t:connect and t:lock. We expect to continue to utilize this approach as we develop new product offerings and innovations.

Our flagship t:slim X2 platform, which we believe addresses the shortcomings of currently available traditional pumps, features:

***Contemporary style.*** t:slim X2, as well as our products under development, has the look and feel of a modern consumer electronic device, such as a smartphone. Relying on extensive consumer input and feedback received during the development process, we believe the modern and innovative 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 t:slim X2 unique in the insulin pump market.

### **Our t:slim X2 Insulin Pump Form Factor (Actual Size)**

***Adaptable platform.*** The t:slim X2 platform is highly adaptable as a result of a number of features that are inherent within our proprietary technology, including our easy-to-navigate software architecture and touchscreen user interface. t:slim X2 is also compatible with the Tandem Device Updater, which is a tool that allows pump users to update their pumps software quickly and easily from a personal computer. This tool uniquely positions us to bring new features and benefits, such as CGM integration or AID algorithms, to customers within their typical four-year insurance pump replacement cycle. 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, t:slim X2 can easily and discreetly fit into a pocket. t:slim X2 is the slimmest and smallest durable insulin pump on the market, while still offering a cartridge with 300 units of insulin. More specifically, t:slim X2 is at least 25% smaller than all other durable insulin pumps available in the United States, and 38% smaller than the newest insulin pump form factor offered by one of our leading competitors. t:flex offers a similar sleek pump form factor, while utilizing a cartridge with 480 units of insulin, providing enhanced flexibility to people with greater insulin needs. 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

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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.

**t:slim X2 Profile (Actual Size)**

***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 pumps 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 these features also allow healthcare providers to more efficiently train people to use our pump and have a higher degree of confidence that users can successfully operate our pump, including its more advanced features. Our touchscreen technology also allows us to offer our t:simulator App, which permits anyone to experience our easy-to-navigate software for any of our pumps free of charge on a mobile device. We believe the ease with which our pump can be learned and taught, and the accessibility of our t:simulator App that broadly demonstrates our software technology, will help attract consumers who may have been frustrated or intimidated by traditional pumps.

**t:simulator App Accessible Through Mobile Device**

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***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. These features were designed to enable users to operate their pump more efficiently and with greater confidence, and to expand the set of therapy features they regularly utilize. Users can also execute most tasks in fewer steps than traditional pumps, which we believe further encourages people to use more advanced pump features. We believe these features also allow users to more efficiently manage their diabetes without fear or frustration.

### **Easy-to-Navigate Pump Software Architecture**

***Innovative technology.*** Our Micro-Delivery technology is unique compared to traditional pumps. Its miniaturized pumping mechanism draws insulin from a flexible bag within the pump's cartridge rather than relying on a mechanical syringe and lead screw mechanism. Our technology was tested under both typical and extreme operating conditions and is designed to last for at least the anticipated four-year warranty of the pump. Our technology allows us to reduce the size of the device as compared to traditional pumps, making t:slim X2 the slimmest and smallest durable insulin pump on the market. In addition, our technology is capable of delivering the smallest increment of insulin compared to any pump currently available, which allows insulin therapy to be individualized for each user.

### **Quick Access to Pump History**

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### **Our Insulin Pump Mechanism**

Our insulin pumps feature a micro-USB connection that supports a rapid rechargeable battery and uploads to t:connect, both of which can be performed without disconnecting or interrupting insulin delivery. This connection also supports software updates through the Tandem Device Updater.

We believe the t:slim X2 platform will allow us to further penetrate and expand the insulin pump therapy market by addressing the specific product and technology limitations associated with traditional pumps that have been raised by people with diabetes, their caregivers and healthcare providers. We also believe our technology under development provides us with the opportunity to address unmet needs in the insulin-dependent diabetes market, including advancements in AID and the potential for further device miniaturization.

### **Our Strategy**

Our goal is to expand significantly 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 offering an adaptable insulin pump that can provide features and functionality to respond to evolving needs and preferences, we believe we are uniquely positioned to address differentiated segments of the insulin-dependent diabetes market. At the same time, by rapidly innovating and offering new product features and benefits through the t:slim X2 platform, and Tandem Device Updater, we are also able to leverage a single sales, marketing and clinical organization, a shared manufacturing and supply chain infrastructure, and the expertise of our customer support services.

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

***Drive adoption of our products through our sales, marketing and clinical infrastructure.*** We have achieved commercial success by investing in the development of our sales, marketing and clinical infrastructure. With this base infrastructure, we believe we are well-positioned to introduce our products to more people with insulin-dependent diabetes, their caregivers and healthcare providers, while continuing to provide the highest level of customer service. For example, we are leveraging our infrastructure by marketing our new products, including t:slim X2 with Dexcom G5 Mobile CGM integration, to primarily the same healthcare providers as our previous pump products, thereby increasing our efficiency. We are also leveraging our infrastructure to launch reusable supplies that utilize the t:lock, which has substantially increased our sales of infusion sets over the past year. We believe our early investments in this infrastructure, when combined with the launch and marketing of new products, will drive continued adoption of our products, while efficiently increasing our revenues over the long-term.

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***Promote awareness of our products to consumers, their caregivers and healthcare providers.*** Our products were specifically designed to address the shortcomings of currently available technologies that we believe have limited the adoption of insulin pump therapy. We intend to continue our direct-to-consumer marketing to promote the insulin therapy features and functionalities offered by our products through our website, the use of social media and online advertising tools, our t:simulator App and motivational spokespeople at industry forums and events. We also expect to leverage our sales and marketing force, together with our clinical specialists, to cultivate relationships with diabetes clinics, insulin-prescribing healthcare professionals and other key opinion leaders. By promoting awareness of our products, we believe we will be able to attract users of our competitors' insulin pump products, as well 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.*** Data analyzed from t:connect suggests that use of our pump products may provide users with improved clinical outcomes. For example, in a recent study, we compared retrospective user data from our t:slim G4 SAP and a leading competitor's SAP. Our SAP demonstrated statistically significant clinical advantages, including reduced hypoglycemia, increased time in range, and improved overall glycemic control, despite approximately half of our competitors' SAP users actively using a feature that suspends insulin delivery if blood glucose levels fall below a preset threshold. This study suggests that our simple-to-use touchscreen interface may translate to improved clinical outcomes for people with insulin-dependent diabetes. Another recent study demonstrated a reduced risk of hypoglycemia associated with use of our pumps compared to other methods of diabetes therapy, as well as a statistically significant reduction in ambulance rides due to severe hypoglycemia and in days spent at the hospital due to severe hypoglycemia. In addition, we are actively involved in multiple clinical trials supporting the use of our AID products in development, which were designed to demonstrate the clinical benefits associated with our products under development. We plan to continue to invest in clinical activities intended to demonstrate that the use of our products contributes to improved clinical outcomes combined with the data collected from our t:connect platform.

***Continue to innovate to provide products that address the unmet needs of people in the insulin-dependent diabetes market.*** We believe that the t:slim X2 platform allows us to provide the most sophisticated and intuitive insulin pump therapy on the market. In addition, our Tandem Device Updater is designed to allow pump users to quickly and easily update their pumps' software from a personal computer. We successfully demonstrated the utility of this tool in the third quarter of 2017 when, following FDA approval, we simultaneously offered Dexcom G5 Mobile CGM integration to both existing and new t:slim X2 users. Subject to obtaining future FDA approvals, we intend to leverage the t:slim X2 platform to allow users to update their pumps' software to include AID algorithms, which also eliminates the need for disruptive and costly trade-in programs to upgrade hardware to newer platforms. We also intend to leverage the t:slim X2 platform to continue to pursue advances in AID, including through strategic agreements and commercial product development efforts. As examples of these efforts, we have entered into development agreements with Dexcom to allow the integration of our insulin pumps with Dexcom's CGM systems, and a license agreement with TypeZero Technologies, LLC, or TypeZero, to allow the integration of TypeZero's inControl AID algorithms. In addition, we intend to continue to explore additional features, functionality and mobile applications for the t:slim X2 platform, as well as a next generation pump platform, in order to address differentiated segments of the insulin-dependent diabetes market.

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

throughout our business.

***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

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therapy. We also believe that customer and healthcare provider interest in our products is an important factor that enhances our prospect of contracting with third-party payors. 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 facilities located in San Diego, California. We utilize a semi-automated manufacturing process for our pump products and disposable cartridges. We have significantly increased our manufacturing output since we began commercialization of our products. During 2017, we relocated our manufacturing operations to our new, 50,000 square foot Barnes Canyon facility, which became fully operational at the beginning of 2018. This facility doubles our previous manufacturing capacity for both insulin pumps and cartridges and expands warehousing for additional infusion set supplies related to the launch of our t:lock. The facility is also designed to maximize efficiencies in our manufacturing processes and workflows, and allow us to further expand our production capacity by replicating our production lines, without increasing the cost of overhead from our facilities. As demand for our products increase, we intend to drive operational efficiencies by leveraging our manufacturing infrastructure, which we expect will result in improvements in gross margin over the long-term. In addition, because the t:slim X2 platform is highly adaptable and can provide new features and functionality through remote software updates, our current systems will not need to change to support new features as they are approved by the FDA, which we expect will create additional manufacturing efficiencies.

**Our Technology Platform**

We have developed an innovative technology platform that we believe is fundamental to the ease-of-use and functionality of t:slim X2, and will provide the foundation for the development of our future products. The key elements of our current technology platform are:

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

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

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



***Lithium-polymer rechargeable battery technology.*** Our products are the first and only insulin pumps to use a rechargeable battery, unlike traditional pumps that rely on expensive disposable batteries. By using a built-in rechargeable battery, we eliminate the risk of losing personal settings associated with replacing batteries. Our

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lithium-polymer rechargeable battery charges rapidly with a standard micro-USB connection, and a full charge lasts for five to seven days depending on CGM use. Users report that they keep their battery powered by charging it for just 10 to 15 minutes each day, often while showering or commuting with the use of the car charger we provide with the pump. Our battery allows for accessible monitoring of the current charge level on the device's Home Screen. Our battery has also been tested to last for at least the four-year warranty life of the pump.

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

## **Our Products**

We have commercially launched five insulin pumps in the past four years all of which have been developed using our proprietary technology platform. We began commercial sales of our first insulin pump, t:slim, in 2012. During 2015, we commenced commercial sales of t:flex and t:slim G4. In 2016, we commenced commercial sales of t:slim X2 and discontinued new sales of t:slim. In September 2017, we commenced commercial sales of t:slim X2 integrated with the Dexcom G5 Mobile CGM system and discontinued new sales of t:slim G4.

## ***Commercial Products***

### ***Our Insulin Pump Products***

Since the launch of our first product in August 2012, through December 2017, we have shipped nearly 68,000 pumps to customers in the United States. Today, our commercial efforts primarily focus on the manufacturing and sale of t:slim X2, although we continue to offer t:flex for people with greater insulin needs. Our insulin pumps feature a vivid, full color touchscreen made of high-grade, shatter-resistant glass that provides users the ability to enter numbers and access features directly, rather than scrolling through a list of numbers and screens. We designed the streamlined, user-friendly interface of our products to facilitate rapid access to the features people use most, such as delivering a bolus, viewing remaining insulin on board, viewing insulin cartridge volume and monitoring current pump status and settings. The interface also includes an Options Menu that provides quick and intuitive navigation to key insulin management features, pump settings, cartridge loading and use history. Our insulin pumps also feature a Home Screen button that immediately returns the user to the Home Screen where important administrative features are displayed, including the current battery charge level, a time and date display, and an LED indicator for alerts, alarms and reminders.

In addition, our insulin pumps allow for the creation of multiple customizable Personal Profiles, each supporting up to 16 timed insulin delivery settings. This feature allows users to manage their day-to-day insulin therapy with less effort and interruption. Users can quickly and easily adjust insulin settings based on a number of key factors, including basal rate, correction factor, insulin-to-carbohydrate ratio and target blood glucose levels.

Furthermore, our insulin pumps share important common features, including a black aluminum case and chrome trim, that give them the look and feel of a modern consumer electronic device, such as a smartphone. Our insulin pumps are also watertight, with an IPX7 rating, eliminating concerns about accidentally getting it wet. Each device also features a micro-USB connection that supports charging the lithium-polymer battery, software updates through the Tandem Device Updater, and rapid data uploads to t:connect.

*t:slim X2 Insulin Delivery System*

Our next-generation flagship product, the t:slim X2 Insulin Delivery System, is comprised of a t:slim X2 pump, its 300-unit disposable insulin cartridge and an infusion set. We began commercial sales of t:slim X2 in the

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United States in the fourth quarter of 2016. Measuring 2.0 x 3.1 x 0.6 inches, t:slim X2 is the slimmest and smallest durable insulin pump on the market. t:slim X2 features new hardware advancements, including a two-way Bluetooth wireless technology radio for communicating with more than one external device at a time.

**300-unit Insulin Cartridge being inserted into t:slim X2 Pump**

We have a development and commercialization agreement with Dexcom, which provides us a non-exclusive license to integrate our product platform with the Dexcom G5 Mobile CGM System. CGM is a therapy that provides users with real-time access to their glucose levels as well as trend information. Following approval by the FDA, we began offering Dexcom G5 Mobile CGM integration on the t:slim X2 platform in the third quarter of 2017, at which point we ceased sales of t:slim G4. t:slim X2 with G5 incorporates the same pump technology and user interface as t:slim X2, but also provides the added convenience of allowing CGM information to be displayed on the pump, thereby eliminating the need to carry an additional device. Based on this information, users are able to utilize the pump to take direct action with their insulin pump therapy.

t:slim X2 with G5 is the only insulin pump available with Dexcom G5 Mobile CGM integration and is the first SAP approved to let users make treatment decisions without pricking their finger. We believe that these advancements, together with future anticipated applications of the Tandem Device Updater, have the potential to enable users to add new features and functionality, such as AID algorithms, to their pumps independent of their typical four-year insurance pump replacement cycle.

*t:flex Insulin Delivery System*

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

**t:flex Insulin Pump**

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People with insulin-dependent diabetes require different amounts of insulin based on their level of insulin sensitivity, which can vary significantly from person to person. t:flex is designed for individuals who require more than 100 units of U-100 insulin per day on MDI or more than 80 units per day using a pump, such as teenagers with type 1 diabetes and many people with type 2 diabetes. t:flex incorporates the same technology platform as the original t:slim, but offers a 480-unit insulin reservoir, the largest capacity currently approved in the United States. This provides users the benefits of pump therapy without the frequent cartridge changes required by 200- and 300-unit capacity pumps. The insulin cartridge used in t:flex extends out slightly on one side to accommodate the extra volume while maintaining all of the other benefits of t:slim, including its slim and sleek appearance.

In our market research, two-thirds of endocrinologists cited limited volume capacity as the number one barrier to pump adoption for their patients with type 2 diabetes who use daily rapid-acting insulin. Our research also has shown that the appearance and bulky size of traditional pumps is a deterrent to pump adoption for people with greater insulin needs. We believe that offering a 480-unit cartridge, combined with the other features and benefits offered by our technology platform, addresses many of the common barriers to pump therapy for a person with type 2 diabetes who is insulin-dependent.

### ***Our Complementary Products***

#### *Tandem Device Updater*

Our insulin pumps are compatible with the Tandem Device Updater, a revolutionary new tool that allows pump users to update their pumps' software quickly and easily from a personal computer. The Tandem Device Updater was cleared by the FDA in the third quarter of 2016 and is PC- and Mac- compatible. It works with our insulin pumps in a manner similar to software updates on a smartphone. Because remote updatability for insulin pump software is a unique feature not available in competitive pump offerings, the Tandem Device Updater provides our customers with the capability to access new and enhanced features and functionality faster than the industry has been able to in the past. We are uniquely positioned to offer this capability due to the intuitive software architecture and convenient micro-USB connection included within our pump products.

The first use of our Tandem Device Updater was for deployment of the latest t:slim software to in-warranty t:slim pumps. The first use of our Tandem Device Updater was for deployment of the latest t:slim software to in-warranty t:slim pumps purchased before April 2015. In September 2017, we set a new standard of care in our industry by offering all existing t:slim X2 customers integration with the Dexcom G5 Mobile CGM system through a software update using the Tandem Device Updater. Within the first 30 days following the FDA approval of this update, more than 30% of t:slim X2 customers who purchased their pump prior to its availability had updated their pump. By the end of 2017 more than 40% of t:slim X2 customers had updated their pump and now have access to Dexcom G5 Mobile CGM integration.

In October 2017, we announced that, subject to FDA approval, we intend to make any new features approved by the FDA in 2018 available to all in-warranty users of t:slim X2 at no cost through the Tandem Device Updater. In the future, this tool has the potential to enable users to add other new features and functionality to their pumps, such as AID algorithms, independent of the typical four-year insurance pump replacement cycle. We expect that future software upgrades will be implemented through our Tandem Device Updater as we obtain regulatory approval for their commercialization.

#### *t:connect Diabetes Management Application*

We commercially introduced the t:connect Diabetes Management Application, or t:connect, our cloud-based data management application, in the first quarter of 2013. It provides users, their caregivers and their healthcare providers a fast, easy and visual way to display therapy management data from our pumps and supported blood glucose meters. This application empowers people with diabetes, as well as their caregivers and healthcare

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providers, to quickly and easily identify meaningful insights and trends, allowing them to refine therapy and lifestyle choices for better management of their diabetes. It also provides us with valuable data that we can analyze computationally to reveal patterns, trends and associations that can be used in continuous product improvements, and identification of clinical outcomes data for marketing purposes and to payors. We also believe that t:connect can serve as a key component of mobile health applications that are currently under development.

We developed t:connect to be intuitive, with the same consumer-focused approach utilized in the development of our insulin pumps. It features built-in smart logic that manages duplicate blood glucose readings from a user's pump and blood glucose meter to ensure report accuracy. t:connect can also generate color-coded graphs and interactive, multi-dimensional reports that make it easy to identify therapy management trends, problems and successes. While our insulin pumps hold the data generated over a period of up to 90 days, once a user uploads their therapy management information to t:connect, the information is retained in their account. t:connect maintains the highest standards of patient data privacy and is hosted on secure servers that are compliant with HIPAA.

In 2017, we launched an enhanced version of t:connect that we expect will simplify the ability of pump users to share t:connect data with their healthcare providers, which we refer to as t:connect HCP. This application allows a healthcare provider to establish a separate account that centralizes t:connect data from all of their enrolled patients.

### **t:connect Diabetes Management Application**

#### *Infusion Sets*

In September 2017, we began replacing the standard Luer-lok connector that previously joined an infusion set to our cartridge with a custom connector, the t:lock Connector. Our t:lock was designed to address the most requested improvement to our products that we have received from customers. It is similar in its design to that of a standard Luer connector, but on average, reduces the time required to fill tubing by more than 30 seconds and reduces the amount of insulin used in the process by 4.5 units. It also reduces the possibility of air bubbles being trapped in the connector. We are offering our customers the same choice in infusion set configurations as they were able to purchase from us previously, but with the added benefits associated with our t:lock. We continue to offer both the original Luer-lok connector and our t:lock concurrently for a period of time to facilitate the transition, and by the end of 2017 our infusion sets and cartridges were being sold on a one-to-one basis. The transition to our t:lock resulted in a substantial increase in our sales of infusion sets in 2017, particularly in the third and fourth quarters, which we anticipate will continue in 2018. We intend to continue to invest in the development of enhancements to our infusion set products to address the perceived shortcomings of existing products on the market.

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### *Pump Accessories*

We offer our customers a broad range of accessories for their pumps, allowing users to customize their device to their individual lifestyle and sense of style. We believe our accessories increase user flexibility and willingness to use and carry their insulin pump.

### *Products under Development*

Our products under development support our strategy of focusing on both consumer and clinical needs, and include: AID systems, a next-generation hardware platform, and connected (mobile) health offerings. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionalities that will allow us to target people in differentiated segments of the insulin-dependent diabetes market.

#### *Automated Insulin Delivery Systems*

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

We have supported leading researchers at facilities such as the University of Virginia, Boston University, Massachusetts General Hospital and Stanford University by providing pump hardware and software to advance development of AID solutions. More recently, we commenced clinical trials of our own products under development with embedded AID systems.

#### *t:slim X2 with Basal IQ*

The t:slim X2 with Basal IQ is designed to utilize Dexcom G5 sensor values to adjust the rate of insulin delivery to help minimize the frequency and/or duration of hypoglycemic events. The algorithm was developed internally in consultation with clinical thought leaders in AID research. In our market research, a predictive low glucose suspend, or PLGS, algorithm was reported as the most valuable AID feature among people with insulin-dependent diabetes and their healthcare providers.

### **t:slim X2 with Basal IQ**

We previously referred to this system under its development name, the t:slim X2 with PLGS and, following FDA approval, intend to market this product under the name t:slim X2 with Basal IQ. During 2016, we completed a feasibility study of our PLGS algorithm. The data from this feasibility study was used in an IDE submission for a pivotal study, which was approved by the FDA in May 2017. We commenced a pivotal study for our t:slim X2



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with Basal IQ in the third quarter of 2017 and anticipate that it will conclude in January 2018. Subject to the completion of the trial with a satisfactory outcome, we intend to use the results of this pivotal study in a PMA submission with the FDA. Based on our current pivotal study timing, and subject to future FDA approval, our goal is to launch the t:slim X2 with Basal IQ in the summer of 2018.

*t:slim X2 with Control IQ*

Our second generation AID system is expected to integrate the t:slim X2 pump with a combination of Dexcom's G6 sensor and AID technology that we licensed from TypeZero. TypeZero's technology includes a series of algorithms developed from research initially conducted at the University of Virginia. To date, this technology has been used in more than 30 clinical studies including more than 450 participants and the data has been referenced in a number of journal articles.

We previously referred to this system under its development name, the t:slim X2 with TypeZero and, following FDA approval, intend to market the product under the name t:slim X2 with Control IQ. This hybrid closed loop product will be differentiated from competing products, as we expect it will provide automated correction boluses, which we believe will bring additional benefits to our customers. In our market research, people with insulin-dependent diabetes and their healthcare providers reported a strong preference for t:slim X2 with Control IQ as compared to a competitive AID system.

**t:slim X2 with Control IQ**

In November 2016, we announced that we are working with Dexcom and TypeZero on the integration of our technologies into the IDCL Trial. We anticipate that a portion of the trial will utilize a t:slim X2 integrated with TypeZero's inControl AID algorithms, which is designed to automatically adjust a person's insulin based on information from a Dexcom G6 sensor. We intend to use the results from this portion of the trial in a PMA submission with the FDA. We also anticipate conducting one or more targeted pediatric studies in a summer or winter camp setting for a future regulatory submission. Subject to both the timely completion of the IDCL Trial with a satisfactory outcome and future FDA approval, our goal is to launch this product in the first half of 2019.

*t:sport Insulin Delivery System: Our Next-generation Hardware Platform*

Our next generation hardware platform is referred to under its development name, the t:sport Insulin Delivery System, or t:sport. This product is expected to be half the size of t:slim and is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. We anticipate that t:sport will feature a low-cost 200-unit cartridge, an on-pump bolus button, a rechargeable battery, an AID algorithm, and a Bluetooth radio. t:sport is being designed for use with leading U-100 insulins, and we plan to conduct research on the use of insulin concentrates to provide people with greater insulin needs an alternative to t:flex. We are also evaluating offering a 300-unit cartridge alternative. We anticipate that t:sport will utilize a pumping mechanism

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that differs from our current Micro-Delivery technology and will be controlled through a separate controller or mobile device application.

**t:sport shown with touchscreen controller**

In 2016, we began discussions with the FDA on the t:sport controller, and whether it can be implemented as a mobile device application or will need to be a separate device. Based on their feedback and concerns regarding the use of unrestricted mobile phones, we believe that controlling a pump via an unrestricted mobile device will be a longer path to market, and as a result, we are designing the product so that it will have the technical capability to be controlled using either a dedicated controller or a mobile device. Because of the nature of our touchscreen user interface, we are well positioned to pursue either option.

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### *Connected (Mobile) Health Offerings*

We are currently developing a mobile application designed to utilize the capability of the Bluetooth radio, which is already built into our pumps, to wirelessly upload pump data to t:connect, receive notification of pump alerts and alarms, integrate other health-related information from third party sources, and support future pump-control capabilities for our products under development. We intend to launch the first generation of our mobile application in mid-2018, with a subset of these features.

## **Mobile Application**

### **Sales and Marketing**

Our sales and marketing objectives are to:

generate demand and acceptance for our current product offerings and future products developed with our technology platform among people with insulin-dependent diabetes; and

promote advocacy and support for our products and brands with healthcare providers.

As of December 31, 2017, we had approximately 70 territories in our U.S. sales organization, with approximately 200 full-time employees on our sales, clinical and marketing team. The vast majority of territories are supported by a territory manager and a clinical diabetes specialist who, as a team, call on endocrinologists, nurse practitioners, primary care physicians, certified diabetes educators and potential customers. Where appropriate, some territories are supported by multiple clinical diabetes specialists. Our sales team is augmented by individuals in our internal customer sales support organization, who follow up on leads generated through promotional activities and educate people on the benefits of our proprietary technology and products.

Our internal, San Diego-based customer sales support organization also contacts existing customers who are approaching their insurance renewal date to aid in the renewal process. Our goal is for at least 70% of our existing customers to purchase a new pump from us when making a new pump purchasing decision. Typically, customers are eligible for insurance reimbursement to purchase a new insulin pump once every four years, however some plans may be limited to once every five years or have additional restrictions or requirements. 2017

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was our first full year with customers eligible for renewal. Trend data suggests that we will achieve our renewal rate goal in the longer term, based on renewal purchases by our earliest customers. However, factors such as the timing of competitive launches, regulatory approvals and other market dynamics may impact the rate of renewal purchases.

As our market penetration continues to build momentum, and as we launch new products into the market, we may consider further expanding our sales, clinical and marketing infrastructure in the United States; however, no territory expansions are anticipated in 2018. We plan to begin commercialization of t:slim X2 outside the United States in select geographies, including Canada, during 2018. Unlike our approach domestically, with the exception of Canada, we currently plan to partner with distributors who will carry out the selling efforts, as well as the service and support of customers in geographies outside the United States. Currently, we anticipate having a direct sales and clinical infrastructure in Canada beginning in 2018, with customer support and services shared with our domestic organization.

For the nine months ended September 30, 2017, we made sales to approximately 35 independent distributors, with sales to Edgepark Medical Supplies, Inc., and Byram Healthcare accounting for 19.8%, and 13.8% of our sales, respectively. For the year ended December 31, 2016, Edgepark Medical Supplies, Inc., and Byram Healthcare accounted for 18.7%, and 14.0% of our sales, respectively. None of our independent distributors have been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements generally have one-year initial terms with automatic one-year renewal terms, and are terminable in connection with a party's material breach.

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

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

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

- our Demonstration Unit Program, through which we provide healthcare professionals with our products, or a mobile device that operates our t:simulator App, for pump demonstrations to their patients; and

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

***Consumer-focused initiatives.*** We sell our products directly to consumers through referrals from healthcare providers and through leads generated through our promotional activities. Our direct-to-consumer marketing efforts focus on positioning our products as innovative, consumer-focused insulin pumps with a unique Micro-Delivery technology, slim touchscreen design, and an intuitive user interface designed to meet different needs in the diabetes community. In connection with the launch of t:slim X2 with G5 Mobile CGM, our marketing also emphasizes the greater accuracy of

the Dexcom G5 Mobile CGM over competitive products. Some of our recent consumer-focused marketing initiatives include:

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

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

promotion of our t:simulator App, which allows anyone to explore the key features of our pump products for free using their mobile device;

corporate sponsorships of organizations focused on people with diabetes, including JDRF, TCOYD and College Diabetes Network; and

community diabetes fundraising and awareness events.

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

### **Animas will Discontinue the Manufacture and Sale of Insulin Pumps**

In October 2017, Johnson & Johnson announced that it intends to discontinue the operations of Animas, and exit the insulin pump business entirely, and, in connection with these activities, designated Medtronic as a preferred partner to facilitate the transition of Animas insulin pump customers. As part of this transition, Medtronic is offering a portion of Animas customers the option of acquiring a prior-generation Medtronic insulin pump, the 630G, at no charge. As a result of this change in the insulin pump market, we now offer the only alternative durable insulin pump to those sold by Medtronic in the United States. While this announcement represents a significant change within our industry, it is too early to know how it will influence our business or the competitive landscape in which we operate over the longer term. More recently, in the fourth quarter of 2017 we experienced an increase in our percentage of sales to people who reported switching from using an Animas pump. However, the largest percentage of our new customers still report being new to pump therapy, with approximately half converting from MDI, followed by customers who reported converting from either a Medtronic or Animas pump. The potential impact on our business of this announcement is uncertain, although we expect it may be dependent on one or more of the following factors:

The offer to Animas customers for a free Medtronic 630G pump is currently limited to customers with a warranty expiration date later than September 30, 2019, and the offer is not available until May 2018. It remains uncertain how many Animas customers will avail themselves of this offer.

While Medtronic will have direct access to all Animas customers during the transition period, as those customers' pumps come up for renewal and they make new pump purchasing decisions, they may consider alternative pump options. According to recent surveys from dQ&A, when making renewal decisions, Animas customers have historically chosen their pump or a Tandem pump rather than a Medtronic offering.

Recent surveys from dQ&A have also shown that only 5% of patients acquiring a Medtronic pump during the past six quarters were previous Animas customers, and 80% of new purchasers of Medtronic pumps were customers who upgraded from a current Medtronic pump rather than switching from an alternative brand. For these reasons, and based on our own customer data that shows a high number of customers switching to our products from an Animas pump, we believe our pumps are an attractive alternative to both Animas and Medtronic pumps.

We believe one of the product features that have made Animas pumps attractive to their customers is the integration of the Animas Vibe with Dexcom's CGM technology. We now provide the only commercially available pump that is integrated with Dexcom's technology.

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

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

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

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

For our customers who have purchased t:slim X2 with G5, we offer online training on the use of the CGM components of the system. Customers can access one or more modules of the training system at their own pace and at their preferred location, which offers them a convenient method to access the latest training available. We anticipate using similar online training modules for t:slim X2 with Basal IQ. In the fourth quarter of 2017, we presented research demonstrating the ease-of-use and effectiveness of computer-based training from the human factors study for t:slim X2 with Basal IQ. The study demonstrated a 99% success rate among study participants who performed a series of critical tasks using the system after initial training. Out of 530 tasks performed, only seven task failures were observed, none of which related to safety. We believe the ease of training on our AID systems will be a competitive advantage compared to currently-available AID systems.

**Technical Services.** We believe that a difficult-to-use pump will result in users making more frequent calls to the pump manufacturer or their healthcare provider for support in using the device. This can be frustrating for the customer and costly for the pump manufacturer as well as for the healthcare provider. In general, we expect the intuitive nature of our products to result in fewer calls from users requesting support from our technical services team or their healthcare provider. However, because of the significant percentage of our customers who are new to pump therapy, we also anticipate receiving high call volume from customers who are still becoming familiar with the fundamentals of insulin pump therapy. In addition, we have experienced increases to our call volume as our existing



customers begin to utilize CGM integration with their t:slim X2, and we may see similar trends as we launch our new AID systems in the future.

Our customer-focused technical services team provides support seven days a week, 24 hours a day by answering questions, troubleshooting and addressing issues or concerns for both the pump and CGM components of our

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systems. Our insulin pump products are typically covered by a four-year warranty. The warranty includes our product replacement program, which allows our technical services team members to provide a customer with a replacement device within as little as 24 hours, to minimize the interruption of his or her therapy. We also coordinate product replacements of CGM components where appropriate.

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

Following communication of a person's estimated financial responsibility, final confirmation of their desire to purchase the device and method of fulfillment, the customer's order is typically shipped to their home. The initial order generally contains their insulin pump as well as a 90-day supply of infusion sets and cartridges. For customers that we service on a direct basis, a member of our internal team then contacts the customer prior to the end of their 90-day supply to re-verify their insurance benefits and assist in reordering supplies. For customers who purchase our insulin pump through one of our authorized distributors, ongoing supplies are typically also arranged through the distributor.

## **Third-Party Reimbursement**

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

We are accredited by the Community Health Accreditation Program and are an approved Medicare provider. We currently bill for all of our insulin pump products and associated supplies using existing Healthcare Common Procedure Coding System codes for which Medicare reimbursement is well established. However, pump eligibility criteria for people with type 2 diabetes can be different and often requires additional documentation and laboratory testing to gain in-network insurance reimbursement benefits.

Over the last ten years, Medicare reimbursement rates for insulin pumps and disposable cartridges have remained relatively unchanged. However, Medicare periodically reviews its reimbursement practices for diabetes-related products. Medicare implemented a competitive bidding process for blood glucose strip reimbursement, which resulted in a significant reduction in the reimbursement rate for those products. More recently, in 2017, Medicare announced, and then shortly thereafter suspended, a competitive bidding process for insulin pumps. As a result, there is some uncertainty as to the future Medicare reimbursement rate for our current and future products.

As of December 31, 2017, we had entered into commercial contracts with approximately 176 national and regional third-party payors to establish reimbursement for our insulin pump products, disposable cartridges and other related supplies. We employ a team of managed care managers who are responsible for negotiating and securing contracts with third-party payors throughout the United States. For the nine months ended September 30, 2017, approximately 27% of our sales were generated through our direct third-party payor contracts.

If we are not contracted with a person's third-party payor and in-network status cannot be otherwise obtained, then to the extent possible we utilize distribution channels so our customers' orders can be serviced. As of December 31, 2017, we had executed distributor agreements with approximately 35 independent distributors. In some cases, but not all, this network of distributors allows us to access people who are covered by commercial payors with whom we are not contracted, at in-network rates that are generally more affordable for our customers. However, 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

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18. We expect this decision will prevent a majority of UnitedHealthcare members from purchasing our insulin pump for the foreseeable future, whether directly from us or through our network of distributors.

### **Manufacturing and Quality Assurance**

We currently manufacture our products at our facilities in San Diego, California. In 2017, we transitioned our manufacturing operations to a new facility located on Barnes Canyon Road in San Diego, California, which became fully operational at the beginning of 2018. We expect that this facility will double our manufacturing capacity for insulin pumps and cartridges, provide additional production capacity for new products in development and expand warehousing for additional infusion set supplies related to the launch of our t:lock, without increasing the cost of overhead associated with our manufacturing our facilities.

The Barnes Canyon facility is designed to optimize our manufacturing processes and allow for greater operational efficiencies, which we believe positions us well to achieve our long-term gross margin targets. By maintaining close proximity to our other business functions, we believe we will enhance our ability to monitor and manage our manufacturing processes, and to adjust manufacturing operations quickly in response to our business needs. The transition to the new manufacturing facility took place primarily in the second half of 2017, during which time we experienced some temporary duplication of operations to support ongoing product requirements, as well as some incremental manufacturing costs. In 2018, we do not expect significant capital expenditures in our manufacturing operations.

Site inspections of the Barnes Canyon facility by the FDA and the California State Food and Drug Branch were completed in 2017. Following the FDA inspection, we received a Form 483, List of Inspectional Observations, containing two observations. Following our receipt of the Form 483, we began implementing corrective and preventive actions to fully address the FDA observations, and in October 2017, we provided a written response to the FDA. In December 2017, we received a letter from the FDA stating that our initial written response did not fully address the FDA observations, and that the FDA would review the observations during its next regularly scheduled inspection of our facilities. It is possible that the FDA will conclude that our corrective and preventive actions are inadequate.

We currently utilize a semi-automated manufacturing process for our pump products and disposable cartridges. The pump production line requires approximately 20 manufacturing assemblers and limited support staff to run the line, and reaches a maximum output of approximately 30,000 pumps per year on a single shift. Disposable cartridges are manufactured on a production line that requires 12 manufacturing operators and limited support staff, and reaches a maximum output of approximately 1.0 million cartridges per year on a single shift. We continue to improve the efficiency of our disposable cartridge manufacturing process. For instance, in 2017, we began manufacturing t:flex cartridges primarily using the same semi-automated manufacturing equipment used in the manufacture of t:slim X2 cartridges, and reduced the number of operators required to operate a production line.

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

Outside suppliers are the source for most of the components and some sub-assemblies in the production of our insulin pumps. Any sole and single source supplier is managed through our supplier management program that is focused on reducing supply chain risk. Key aspects of this program include managing component inventory in house and at the

supplier, contractual requirements for last time buy opportunities and second sourcing approaches for specific suppliers. Typically, our outside vendors produce components to our specifications and in many instances to our designs.

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Our suppliers are evaluated, approved and monitored periodically by our quality department to ensure conformity with the specifications, policies and procedures for our devices. Members of our quality department also inspect our devices at various steps during the manufacturing cycle to facilitate compliance with our devices' stringent specifications.

We have received certification from BSI Group, a Notified Body to the International Standards Organization, or ISO, of our quality system. This ISO 13485 certification now extends to our new manufacturing facility on Barnes Canyon Road. Certain processes utilized in the manufacturing and testing of our devices have been verified and validated as required by the FDA and other regulatory bodies. As a medical device manufacturer, our manufacturing facility and the facilities of our sterilization and other critical suppliers are subject to periodic inspection by the FDA and certain corresponding state agencies.

## **Research and Development**

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

In June 2015, we entered into non-exclusive agreements with Dexcom to allow the integration of our insulin pump products with the Dexcom G5 and G6 CGM systems worldwide. Each agreement has an initial term of five years, and thereafter renew automatically for additional one-year terms unless either party provides advance notice to the other party that they do not wish to extend the agreement. The agreements do not require any licensing fees, milestone payments or royalty obligations to Dexcom. The agreements contain customary provisions for termination in the event of an uncured material breach or in the event of a dissolution of the other party, and prohibit our assignment of the agreements to a Dexcom competitor without Dexcom's prior consent.

In 2016, we entered into a worldwide, non-exclusive, royalty-bearing license agreement with TypeZero to allow the integration of our insulin pump products with TypeZero's inControl AID technology. The agreement also provides us access to TypeZero's future AID innovations for five years following the date of the agreement. In addition, the license agreement contemplates that our insulin pump products will be used alongside TypeZero's AID technology in the IDCL Trial. The agreement is effective until the patents covered by the agreement have expired, but also contains customary provisions for termination in the event of an uncured material breach.

Research and development costs were \$14.9 million and \$14.5 million for the nine months ended September 30, 2017 and 2016, respectively. Research and development costs were \$18.8 million, \$17.0 million, and \$15.8 million for the years ended 2016, 2015 and 2014, respectively.

## **Intellectual Property**

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

As of December 31, 2017 our patent portfolio consisted of approximately 58 issued U.S. patents and 49 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2036. We are also seeking patent protection for our proprietary technology in other countries throughout the world. In addition, we also have 23 trademark registrations, including 10 U.S. trademark registrations and 13 foreign trademark registrations.

In July 2012, we entered into an agreement with Smiths Medical pursuant to which we were granted, through certain assignments and certain non-exclusive and exclusive, worldwide, fully paid-up, royalty-free licenses,

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certain rights to patents and patent applications related to ambulatory infusion pumps and related software and accessories for the treatment of diabetes. We agreed to pay \$5.0 million in license fees and to share equally any associated sublicense revenues we may receive. As of December 31, 2017, we had paid the initial license fees in full and have not entered into any sublicense agreements.

## **Competition**

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 market activities of industry participants. We compete with a number of companies that manufacture insulin delivery devices, such as Medtronic MiniMed, a division of Medtronic, 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. In October 2017, Johnson & Johnson announced that it intends to discontinue the operations of Animas and exit the insulin pump business entirely, and that it has designated Medtronic as a preferred partner to facilitate the transition of Animas insulin pump customers. Most recently, in late 2017, Eli Lilly & Co. announced that it is developing an insulin pump with AID technology that it intends to launch in the next two to three years. However, it is difficult to predict the potential impact of these changes on our competitive landscape.

Our current primary competitors are either publicly traded companies or divisions or subsidiaries of publicly traded companies. These companies have several competitive advantages over us, including greater financial resources for sales and marketing and product development, established relationships with healthcare providers and third-party payors, and larger and more established distribution networks. In some instances, our competitors also offer products that include features that we do not currently offer. For instance, Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set, and Medtronic offers a traditional insulin pump that is integrated with a CGM system featuring a hybrid closed-loop AID algorithm.

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

For additional information, see the section of this prospectus entitled **Risk Factors**.

## **Government Regulation**

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

product design and development;

pre-clinical and clinical testing;

establishment registration and product listing;



product manufacturing;

labeling and storage;

pre-market clearance or approval; advertising and promotion;

product sales and distribution;

recalls and field safety corrective actions; and

servicing and post-market surveillance.

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

The FDA classifies medical devices into one of three classes. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are subject to general controls such as labeling, pre-market notification and adherence to the FDA's Quality System Regulation, or QSR, which cover manufacturers methods and documentation of the design, testing, production, control quality assurance, labeling, packaging, sterilization, storage and shipping of products. Class II devices are subject to special controls such as performance standards, post-market surveillance, FDA guidelines, or particularized labeling, as well as general controls. Some Class I and Class II devices are exempted by regulation from the 510(k) clearance requirement, and the requirement of compliance with substantially all of the QSR. t:slim, t:flex, t:slim X2 and t:connect received FDA clearance as Class II devices. However, t:connect was subsequently down-classified to a Class I device. A PMA application is required for devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices, or those that are not substantially equivalent either to a device previously cleared through the 510(k) process or to a preamendment Class III device in commercial distribution before May 28, 1976 when PMA applications were not required. t:slim G4 and t:slim X2 with Dexcom's G5 sensor integration received FDA approval as a Class III device.

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

We obtained 510(k) clearance for t:connect in February 2013 and for t:flex in January 2015. In September 2015, we received approval of our PMA for t:slim G4. In July 2016, we received FDA clearance for the Tandem Device Updater. Also in 2016, we received FDA clearance for an expanded pediatric indication for t:slim and t:slim X2, lowering its use to children ages six and older from children ages 12 and older.

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

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

systems may not be safe or effective to the FDA's satisfaction;

the data from pre-clinical studies and clinical trials may be insufficient to support approval;

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the manufacturing process or facilities may not meet applicable requirements; and

changes in FDA approval policies or adoption of new regulations may require additional data.

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

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

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

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

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

patients do not comply with trial protocols;

patient follow-up is not at the rate expected;

patients experience adverse side effects;

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

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

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

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

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

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

changes in governmental regulations or administrative actions;

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

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

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

establishment registration and device listing;

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

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

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

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

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

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

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

warning letters or untitled letters that require corrective action;

finances and civil penalties;

unanticipated expenditures;

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delays in approving or refusal to approve future products;

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

suspension or withdrawal of FDA clearance or approval;

product recall or seizure;

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

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

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

***Fraud and Abuse Laws.*** There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Our relationships with healthcare providers and other



third parties are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

***Federal Anti-Kickback and Self-Referral Laws.*** The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The definition of remuneration has been broadly interpreted to include anything of value, including such items as gifts, discounts, the furnishing of supplies or equipment, credit arrangements, waiver of payments and providing anything at less than its fair market value. HHS has issued regulations, commonly known as safe harbors, that set

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forth certain provisions which, if fully met, will result in the transaction or arrangement being exempt from scrutiny under the federal Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued, but that the facts and circumstances of such arrangement or transaction may be reviewed on a case by case basis to determine if an intent to violate the Anti-Kickback Statute is present. Thus, arrangements and transactions that do not fully satisfy each element of an applicable safe harbor carry an increased risk of scrutiny by government enforcement authorities such as the HHS Office of Inspector General or the Department of Justice.

The penalties for violating the federal Anti-Kickback Statute include imprisonment for up to five years, criminal fines of up to \$25,000 per violation, civil fine of up to \$50,000 per violation, and possible exclusion from federal healthcare programs such as Medicare and Medicaid. Many states have adopted prohibitions similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not only by the Medicare, Medicaid and other federal healthcare programs. Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or PPACA, amends the intent requirement of the federal Anti-Kickback Statute and certain other criminal healthcare fraud statutes. An individual or entity no longer is required to have actual knowledge of a particular statute or specific intent to violate it. PPACA also provides that claims submitted in violation of the Anti-Kickback Statute automatically constitute false claims for purposes of the False Claims Act.

We provide the initial training to customers necessary for appropriate use of our products either through our own diabetes educators or by contracting with outside diabetes educators who have completed a Tandem pump-training course. Outside diabetes educators are reimbursed for their services at fair market value. Although we believe that these arrangements do not violate the law, regulatory authorities may determine otherwise, especially as enforcement of this law historically has been a high priority for the federal government. Noncompliance with the federal Anti-Kickback Statute could result in our exclusion from Medicare, Medicaid or other governmental programs (which could adversely affect our revenues to a material extent), restrictions on our ability to operate in certain jurisdictions, and civil and criminal penalties.

Federal law also includes a statute commonly known as the Stark Law, which prohibits a physician from referring Medicare or Medicaid patients to an entity providing designated health services, including a company that furnishes durable medical equipment, if the physician has a financial relationship with the company. The term financial relationship is very broadly defined to include ownership or investments interests, as well as compensation arrangements. CMS has issued numerous exceptions to the Stark Law. The prohibition on referrals of designated health services does not apply when the financial relationship created by an arrangement or transaction meets all of the requirements of an applicable exception. Many states have also enacted statutes similar to the federal Stark Law. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these arrangements may not expressly meet the requirements for applicable exception from the law.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. As a result, our provider and training arrangements may ultimately be found to not comply with applicable federal law.

***Federal False Claims Act.*** The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private

parties to bring qui tam whistleblower lawsuits under the Federal False Claims Act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines and/or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

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On November 2, 2015, President Obama signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, which provides for adjustments to civil money penalties. In particular, the 2015 legislation provided for an initial catch up adjustment, followed by annual adjustments thereafter. For violations of the False Claims Act that occurred on or before November 2, 2015, and for violations of the False Claims Act occurring after November 2, 2015 for which civil money penalties were assessed prior to August 1, 2016, penalties include fines ranging from \$5,500 to \$11,000 for each false claim, plus three times the amount of damages that the federal government sustained because of the false claim. For civil money penalties assessed after August 1, 2016, and on or before February 3, 2017, for violations of the False Claims Act occurring after November 2, 2015, penalties include fines ranging from \$10,781 to \$21,563 per claim, plus three times the amount of damages that the federal government sustains because of the false claim. Finally, for civil money penalties assessed after February 3, 2017 for violations of the False Claims Act that occurred after November 2, 2015, penalties include fines ranging from \$10,957 to \$21,916.

We submit reimbursement claims to federal healthcare programs, and we also may provide some coding and billing information to purchasers of our devices. These activities, if inappropriate, could result in liability under the False Claims Act. Further, claims arising from relationships which violate the Anti-Kickback Statute are considered to be false claims under the False Claims Act. Liability under the False Claims Act may also attach to claims arising from financial relationships which violate the Stark Law. We believe that we currently are in compliance with the federal government's laws and regulations concerning the submission of claims and the provision of coding and billing information. However, because we cannot guarantee that the government or qui tam relators will regard any billing errors that may be made as inadvertent, or our provider relationships as compliant, we may have exposure under the False Claims Act.

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

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

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

HIPAA, as amended by HITECH, also set forth privacy and security rules. The privacy rules protect medical records and other personal health information (known as protected health information or PHI) by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own PHI and limiting most use and disclosures of PHI to the minimum amount reasonably necessary to accomplish the intended purpose. The security rule protects PHI by requiring appropriate administrative, physical and technical safeguards to ensure the

confidentiality, integrity and security of such PHI. If we, or any of our service providers,

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are found to be in violation of the privacy and security rules under HIPAA and HITECH, 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 believe we are in substantial compliance with the privacy and security rules under HIPAA. However, even HIPAA compliant entities can have security breaches resulting in potential liability under HIPAA.

***Physician Payments Sunshine Act.*** The Physician Payments Sunshine Act requires certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians. Manufacturers may be subject audit for their compliance with this law. Failure to submit the required data in an accurate and timely manner may result in the imposition of civil monetary penalties. We believe we are in substantial compliance with the Physician Payments Sunshine Act.

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

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

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

During the fourth quarter of 2017 we completed both the self-assessment and the third-party assessment of our operations by a Notified Body. Based on the outcome of those assessments, we anticipate receiving CE marking of our existing products in the first half of 2018, and beginning the commercialization of products outside the United States in the second half of 2018. The timing of our international launch will remain dependent on other activities, including our completion of appropriate translations for our products and associated materials, software updates to our pump products to allow for alternative units of measurement and a 24 hour clock, our ability to commence manufacturing of our products for use outside the United States, and our entering into distribution agreements with third party distributors in the relevant geographies. During 2018 we also intend to begin direct commercial activities in Canada. Marketing our products in Canada requires regulatory approval of our products from Health Canada. We intend to file for regulatory approval of our products in Canada during the first half of 2018, subject to our completion

of software updates to our pump products to allow for alternative units of measurement.

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**Employees**

As of December 31, 2017, we had 574 full-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

**Additional Information**

We were incorporated in Colorado in January 2006 and reincorporated in Delaware in January 2008. Our website address is [www.tandemdiabetes.com](http://www.tandemdiabetes.com). We post links on our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, information statements, beneficial ownership reports and any amendments to those reports or statements filed or furnished pursuant to Sections 13(a), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act. All such filings are available through our website free of charge. However, 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.

Our filings may also be read and copied at the SEC's public reference room located at 100 F Street, N.E., Washington, D.C. 20549-1004. The public may obtain information on the operation of the public reference room by calling the SEC at 1-800-SEC-0330. Our filings with the SEC are also available on the SEC's website at <http://www.sec.gov>, which contains registration statements, reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.



**Table of Contents****MANAGEMENT****Executive Officers and Directors**

The following table sets forth information concerning our executive officers and directors as of December 31, 2017:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Kim D. Blickenstaff	65	President, Chief Executive Officer and Director
Leigh A. Vosseller	45	Senior Vice President, Chief Financial Officer and Treasurer
John F. Sheridan	62	Executive Vice President and Chief Operating Officer
Brian B. Hansen	50	Executive Vice President and Chief Commercial Officer
David B. Berger	48	Executive Vice President, General Counsel and Secretary
Susan M. Morrison	38	Executive Vice President and Chief Administrative Officer
Dick P. Allen <sup>(1)</sup>	73	Director, Chairman of the Board
Edward L. Cahill <sup>(1)</sup>	64	Director
Fred E. Cohen, M.D., D.Phil., F.A.C.P. <sup>(3)</sup>	61	Director
Howard E. Greene, Jr. <sup>(2)</sup>	75	Director
Douglas A. Roeder <sup>(2)(3)</sup>	47	Director
Christopher J. Twomey <sup>(1)</sup>	58	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

The following are biographical summaries of the experience of our executive officers and directors:

***Executive Officers***

*Kim D. Blickenstaff* has served as our President and Chief Executive Officer and as one of our directors since September 2007. Prior to joining our company, Mr. Blickenstaff served as Chairman and Chief Executive Officer of Biosite Incorporated, or Biosite, a provider of medical diagnostic products, from 1988 until its acquisition by Inverness Medical Innovations, Inc. in June 2007. Mr. Blickenstaff previously served as a director of Medivation, Inc. (NASDAQ: MDVN) from 2005 to 2016, until its acquisition by Pfizer, during the majority of which time he served as the chairman of the board, and as a director of Dexcom (NASDAQ: DXCM), a provider of glucose monitoring systems, from June 2001 to September 2007. Mr. Blickenstaff was formerly a certified public accountant and has more than 20 years of experience overseeing the preparation of financial statements. He received a B.A. in Political Science from Loyola University, Chicago, and an M.B.A. from the Graduate School of Business, Loyola University, Chicago.

*Leigh A. Vosseller* has served as our Senior Vice President, Chief Financial Officer and Treasurer since January 1, 2018. She joined us as Vice President of Finance in September 2013 and was promoted to Senior Vice President in August 2017. Prior to joining our company, she served as Vice President and Chief Financial Officer at Genoptix, Inc. (a Novartis company) beginning in 2011, after initially joining the company in 2008. Prior to that, she held a senior finance position at Biosite, where she played a key role in developing the financial and administrative infrastructure for international expansion. Ms. Vosseller is a certified public accountant (inactive) and holds a B.A. in accounting

from Missouri State University.

*John F. Sheridan* has served as our Executive Vice President and Chief Operating Officer since April 2013. Prior to joining our company, Mr. Sheridan served as Chief Operating Officer of Rapiscan Systems, Inc., a provider of security equipment and systems, from March 2012 to February 2013. Mr. Sheridan served as Executive Vice President of Research and Development and Operations for Volcano Corporation, a medical technology

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company, from November 2004 to March 2010. From May 2002 to May 2004, Mr. Sheridan served as Executive Vice President of Operations at CardioNet, Inc., a medical technology company, now operating as BioTelemetry, Inc. (NASDAQ: BEAT). From March 1998 to May 2002, he served as Vice President of Operations at Digirad Corporation, a medical imaging company. Mr. Sheridan holds a B.S. in Chemistry from the University of West Florida and an M.B.A. from Boston University.