

TANDEM DIABETES CARE INC
Form S-1
January 16, 2018

As filed with the Securities and Exchange Commission on January 16, 2018

Registration No. 333-

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

Delaware	3841	20-4327508
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

11075 Roselle Street

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.

David B. Berger, Esq.

Per B. Chilstrom, Esq.

Ryan C. Wilkins, Esq.

Executive Vice President, General Counsel

Clifford Chance US LLP

Stradling Yocca Carlson & Rauth, P.C.

and Secretary

31 West 52nd Street

660 Newport Center Drive, Suite 1600

Tandem Diabetes Care, Inc.

New York, New York 10019

Newport Beach, California 92660

11075 Roselle Street

(212) 878-8000

(949) 725-4000

San Diego, California 92121

(858) 366-6900

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.

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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 Common Stock, \$0.001 par value per share	Proposed Maximum Aggregate Offering Price ⁽¹⁾ \$40,000,000	Amount of Registration Fee ⁽²⁾ \$4,980
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- (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.

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.

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 16, 2018

Shares

TANDEM DIABETES CARE, INC.

Common Stock

\$ per share

We are offering _____ 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 11, 2018, the last reported sale price of our common stock on the NASDAQ Global Market was \$3.35 per share. The actual offering price per share will be as determined between us and the underwriters at the time of pricing.

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

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

	Per Share Total	
Public offering price	\$	\$
Underwriting discount ⁽¹⁾	\$	\$
Proceeds, before expenses, to us	\$	\$

⁽¹⁾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 _____ 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.

TABLE OF CONTENTS

<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	13
<u>CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	46
<u>USE OF PROCEEDS</u>	47
<u>PRICE RANGE OF OUR COMMON STOCK</u>	48
<u>DIVIDEND POLICY</u>	49
<u>CAPITALIZATION</u>	50
<u>DILUTION</u>	52
<u>SELECTED FINANCIAL DATA</u>	54
<u>MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	57
<u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u>	75
<u>BUSINESS</u>	76
<u>MANAGEMENT</u>	109
<u>EXECUTIVE COMPENSATION</u>	117
<u>CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS</u>	130
<u>DESCRIPTION OF CAPITAL STOCK</u>	132
<u>PRINCIPAL STOCKHOLDERS</u>	137
<u>SHARES ELIGIBLE FOR FUTURE SALE</u>	139
<u>CERTAIN U.S. FEDERAL TAX CONSIDERATIONS APPLICABLE TO HOLDERS OF COMMON STOCK</u>	141
<u>UNDERWRITING</u>	146
<u>LEGAL MATTERS</u>	151
<u>EXPERTS</u>	151

WHERE YOU CAN FIND ADDITIONAL INFORMATION

152

INDEX TO FINANCIAL STATEMENTS

F-1

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.

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.

PROSPECTUS SUMMARY

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

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

Overview

We are a medical device company with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. We believe 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 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.

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 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 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 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.

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;
- 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.

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, 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 a 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. 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 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 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

7

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 - \$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.

8

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 Medtronic's insulin pumps 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 our operating expenses to less than 10% annual growth.

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 the 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 operating and gross margins, and timeline to reach cash flow breakeven, are forward-looking statements that are subject to considerable risks and uncertainties. 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 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 for which we would be required to seek a waiver or an amendment of the Term Loan Agreement. We may not be able to obtain such a waiver or amendment on favorable terms or at all.

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;

9

- 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. 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.

The Offering

Issuer: Tandem Diabetes Care, Inc.

Common stock offered by us: shares

Common stock to be outstanding immediately after this offering: shares

Option to purchase additional shares: The underwriters have an option to purchase a maximum of 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 \$ million, or \$ million if the underwriters fully exercise their option to purchase additional shares, assuming an offering price of \$3.35, the last reported sale price of our common stock on the NASDAQ Global Market on January 11, 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. 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);

• 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

11

43 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.

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.

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;

13

- 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.

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;
- 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.

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.

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 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.

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

Another key element of our business strategy is utilizing market research to understand what people with diabetes are seeking to improve their diabetes therapy management. This strategy underlies our entire product design, marketing

and customer support approach and is the basis on which we developed our current products and are pursuing the development of new products. However, our market research is based on interviews, focus groups and online surveys involving people with insulin-dependent diabetes, their caregivers and healthcare providers that represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we received may not be reflective of the broader market and may not provide us accurate insight into the desires of people with insulin-dependent diabetes. In addition, understanding the meaning and significance of the responses received during our market research necessarily requires that analysis be conducted and conclusions be drawn. We may not be able perform an analysis that yields meaningful results, or the conclusions we draw from the analysis could be misleading 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.

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

21

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.

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 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.

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;
- 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;

24

- 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 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.

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 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.

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:

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