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.

Ryan C. Wilkins, Esq.

Stradling Yocca Carlson & Rauth, P.C.

660 Newport Center Drive, Suite 1600

Newport Beach, California 92660

(949) 725-4000

David B. Berger, Esq.

Executive Vice President, General Counsel and Secretary

Tandem Diabetes Care, Inc.

11075 Roselle Street

San Diego, California 92121

(858) 366-6900

Per B. Chilstrom, Esq.

Clifford Chance US LLP

31 West 52nd Street

New York, New York 10019

(212) 878-8000

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

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

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

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee(2)
Common Stock, $0.001 par value per share	$40,000,000	$4,980

(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

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

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.

- 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;

- 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

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

On January 1, 2018, the number of shares of common stock reserved for issuance under the 2013 Plan automatically increased by 404,776 additional shares pursuant to the terms of the 2013 Plan and the number of shares of common stock reserved for issuance under the ESPP automatically increased by 101,194 additional shares pursuant to the terms of the ESPP. These shares are not included in the number of shares of common stock to be outstanding after this offering.

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

- no exercise of the outstanding options and warrants described above; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

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;

- 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;