**UNITED STATES**
**SECURITIES AND EXCHANGE COMMISSION**
**WASHINGTON, D.C. 20549**

**FORM 10-K**

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

**For the fiscal year ended December 31, 2020**
**or**

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

**For the transition period from _____ to _____**
**Commission File Number 001-36189**

# Tandem Diabetes Care, Inc.

**(Exact name of registrant as specified in its charter)**

| | |
|---|---|
| **Delaware** | **20-4327508** |
| **(State or other jurisdiction of incorporation or organization)** | **(I.R.S. Employer Identification No.)** |
| **11075 Roselle Street** | **92121** |
| **San Diego California** | **(Zip Code)** |
| **(Address of principal executive offices)** | |

**(858) 366-6900**
**Registrant's telephone number, including area code**
**Securities registered pursuant to Section 12(b) of the Act:**

| Title of Each Class | Trading Symbol(s) | Name of Each Exchange on Which Registered |
|---|---|---|
| **Common Stock, par value $0.001 per share** | **TNDM** | **Nasdaq Global Market** |

**Securities registered pursuant to Section 12(g) of the Act:**
**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐
Indicate by check if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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 | x | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | 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 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒
As of June 30, 2020, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $5.8 billion based on the closing price for the common stock of $98.92 on that date. Shares of common stock held by each executive officer, director, and their affiliated stockholders have been excluded from this calculation as such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.
As of February 19, 2021, there were 62,504,754 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement for the 2021 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III, Items 10-14 of this Form 10-K. Except for the portions of the Proxy Statement specifically incorporated by reference in this Form 10-K, the Proxy Statement shall not be deemed to be filed as part hereof.

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This Annual Report on Form 10-K for the fiscal year ended December 31, 2020, or this Annual Report, contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to considerable risks and uncertainties. These forward-looking statements are intended to qualify for the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. All statements included or incorporated by reference in this Annual Report, other than statements of historical fact, are forward-looking statements. You can identify forward-looking statements by the use of words such as "may," "will," "could," "anticipate," "expect," "intend," "believe," "continue" or the negative of such terms, or other comparable terminology. Forward-looking statements also include the assumptions underlying or relating to such statements. In particular, forward-looking statements contained in this Annual Report relate to, among other things, our future or assumed financial condition, results of operations, liquidity, trends impacting our financial results, business forecasts and plans, research and product development plans, manufacturing plans, strategic plans and objectives, capital needs and financing plans, product launches, regulatory approvals, the impact of changes in the competitive environment, and the application of accounting guidance. We caution you that the foregoing list may not include all of the forward-looking statements made in this Annual Report.*

*Our forward-looking statements are based on our management's current assumptions and expectations about future events and trends, which affect or may affect our business, strategy, operations or financial performance. Although we believe that these forward-looking statements are based upon reasonable assumptions, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Our actual financial condition and results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption "Risk Factors" in Part I, Item 1A and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7, and elsewhere in this Annual Report, as well as in the other reports we file with the Securities and Exchange Commission, or the SEC. You should read this Annual Report with the understanding that our actual future results may be materially different from and worse than what we expect.*

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

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

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

## PART I

### Item 1. Business

### Overview

We are a medical device company with a positively different approach to the design, development and commercialization of products for people with insulin-dependent diabetes. Diabetes management can vary greatly person-to-person, creating multiple market segments based on clinical needs and personal preferences. We aim to improve and simplify the lives of all people living with insulin-dependent diabetes and those of their healthcare providers, by delivering innovative hardware and software solutions, as well as best-in-class customer support. Our goal is to lead in insulin therapy management by building a robust ecosystem and portfolio of data-driven products and services around our flagship insulin pumps. We believe our competitive advantage is rooted in our consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing, sales and support activities principally focus on our flagship pump platform, the t:slim X2 Insulin Delivery System (t:slim X2), and our complementary product offerings.

Since our initial commercial launch, we have been able to rapidly innovate and bring more products to market than our competitors. We have commercially launched seven insulin pump configurations in the United States since 2012 and three insulin pump configurations outside the United States since 2018. Today, our software-updatable t:slim X2 hardware platform represents 100% of our new pump shipments.

Our simple-to-use t:slim X2 is based on our proprietary technology platform and is the smallest durable insulin pump available. We have commercially offered our pump technology integrated with three generations of Dexcom's continuous glucose monitoring (CGM) sensors. The t:slim X2 is the only pump on which remote software updates have been commercially available in the United States. This experience, which offers and supports different software updates, provides us with a unique competitive advantage. Two of our updates provided our users access to our automated insulin delivery (AID) algorithms, Basal-IQ technology and Control-IQ technology. Basal-IQ technology launched in August 2018 and is a predictive low glucose suspend feature that is designed to temporarily suspend insulin delivery to help reduce the frequency and duration of hypoglycemic events. Control-IQ technology launched in January 2020 and is an advanced hybrid-closed loop feature, designed to help increase a user's time in targeted glycemic range. It is the first and only system cleared by the United States Food and Drug Administration (FDA) to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. Outside the United States we began selling efforts with t:slim X2 with Dexcom G5 integration in the third quarter of 2018, offering no-cost software updates for Basal-IQ technology in the third quarter of 2019 and for Control-IQ technology beginning in the third quarter of 2020. We intend to complete our scaled launch of Control-IQ technology outside the United States in the first half of 2021, subject to securing necessary regulatory clearances or approvals. We continue to offer both AID algorithms on the market to support the varying needs of people living with diabetes.

In support of our digital health strategy, we also offer t:connect, a web based data management application that provides users, their caregivers and their healthcare providers with a fast, easy and visual way to display diabetes therapy management data from our pumps, integrated CGMs and supported blood glucose meters. In the first quarter of 2020, we began a limited launch in the United States of our first-generation t:connect mobile application, followed by general availability in July 2020. The t:connect mobile application features wireless upload of pump data to t:connect, allows the user to receive notification of pump alerts and alarms, and provides a discrete, secondary display of glucose and insulin data. In addition, in the second quarter of 2020, we acquired Sugarmate, a popular app designed to help people visualize diabetes therapy data in innovative ways that also connects with many other popular, consumer-friendly devices.

Our insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, we sell disposable products that are used together with our pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body, as well as a variety of accessories designed for enhanced usability.

In the four-year period ended December 31, 2020, we shipped more than 215,000 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. More than 170,000 of these pumps were shipped to customers in the United States and nearly 45,000 were shipped to international markets.

Our primary research and development and administrative headquarters are located in San Diego, California. We also operate a manufacturing facility and a warehousing facility in San Diego. In addition, we maintain offices in Boise, Idaho and in Markham, Ontario, Canada. We employed approximately 1,500 regular full-time employees as of December 31, 2020.

**Diabetes and the Insulin Therapy Management 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. 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.

Diabetes is typically classified as either type 1 or type 2:

- Type 1 diabetes is characterized by the body's nearly complete inability to produce insulin. It is frequently diagnosed during childhood or adolescence. Individuals with type 1 diabetes require daily insulin therapy to survive.
- Type 2 diabetes represents 90% to 95% of all individuals diagnosed with diabetes and is characterized by the body's inability to either properly utilize insulin or produce enough insulin. Initially, many people with type 2 diabetes often attempt to manage their diabetes with improvements in diet and exercise, and with oral medications. However, as their diabetes advances, many patients progress to requiring injectable therapies, such as long-acting insulin, and a subset of this population require daily rapid-acting insulin therapy.

The International Diabetes Federation estimates that, in 2019, approximately 231 million adults age 20-79 years worldwide had diagnosed type 1 or 2 diabetes worldwide. In addition, approximately 1.1 million children and adolescents had type 1 diabetes, and nearly 130,000 people under age 20 are estimated to be diagnosed annually. In the United States, the Centers for Disease Control and Prevention estimates that in 2020 approximately 34 million people were living with diabetes of which approximately 27 million had diagnosed diabetes. We consider our addressable market to be people diagnosed with diabetes who are living with either type 1 diabetes, or with type 2 diabetes who require daily rapid acting insulin. Throughout this Annual Report, we refer to these individuals as people with insulin-dependent diabetes.

**Estimated Diagnosed Diabetes Prevalence[(1)]**

| | Worldwide | Domestic |
|---|---|---|
| Type 1 | 24.2 million | 1.6 million |
| Type 2 (all therapies) | 206.8 million | 25.4 million |
| *Type 2 (insulin only)* | *5 million* | *1.5 million* |

(1) Internal estimates based on data from the International Diabetes Federation and the Centers for Disease Control and Prevention (CDC)

*Diabetes Management Challenges*

Diabetes can be difficult for patients to manage. Unlike most therapies, daily insulin requirements can vary greatly and can be affected by many factors, such as type or quantity of food eaten, illness, stress and exercise. People with diabetes have to be diligent in working to prevent their blood glucose from fluctuating outside of a targeted range. Hypoglycemia, or low blood glucose levels, can cause a variety of long-term effects or complications, including damage to various tissues and organs, seizures, coma or death. Hyperglycemia, or high blood glucose levels, can also cause a variety of long-term effects or complications, including cardiovascular disease and damage to various tissues and organs. Preventing and managing fluctuations in blood glucose levels, particularly when someone is outside their target blood glucose range is often time consuming and stressful to people with diabetes and their loved ones.

*Insulin Therapy Management*

There are two primary therapies used by people with insulin-dependent diabetes, insulin injections and insulin pumps. The use of insulin injections is often referred to as Multiple Daily Injection (MDI) therapy. Insulin pumps are intended to more closely resemble the physiologic function of a healthy pancreas and use rapid-acting insulin to fulfill both mealtime (bolus) and background (basal) requirements. Insulin pump systems are most commonly comprised of a programmable hardware device, a cartridge filled with insulin by the user, and an infusion set to administer insulin into the person's body. This system is known as a durable pump. By comparison, patch insulin pumps are disposable and adhere to the body without an infusion set.

Insulin pump therapy can provide benefit to a person with insulin-dependent diabetes when used independently or in conjunction with CGM, which is a therapy that provides users with real-time access to their glucose levels as well as trend information. In addition, insulin pumps may feature an AID algorithm that is designed to automatically adjust a person's insulin delivery based on their CGM trends and other factors to help minimize the frequency and/or duration of hypoglycemia and/or hyperglycemic events. Insulin pumps may also feature connectivity with mobile apps and data management applications, which are used by the pump user, their caregivers and their healthcare providers, to quickly and easily identify meaningful insights and trends, allowing them to refine therapy and lifestyle choices for better management of their diabetes.

The American Diabetes Association estimated that in 2015, between 750,000 and 1 million people worldwide used an insulin pump. Domestically, we estimate that 600,000 people in the United States use an insulin pump. There are a variety of insulin pump manufacturers worldwide, while domestically, we are currently one of only two commercial durable insulin pump manufacturers and there is one programmable commercial patch insulin pump manufacturer.

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 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.

**Our Technology: Improving the Lives of People with Diabetes**

We develop our insulin pump technology and related product offerings using a consumer-focused approach. We initially rely on the use of behavioral sciences, including extensive 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 the specific demands of people with diabetes. 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.

Since our initial commercial launch, we have been able to rapidly innovate and bring more products to market than our competitors. We have commercially launched seven insulin pump configurations since inception, all of which have been developed using our proprietary technology platform. The following table provides information regarding the commercial availability of our insulin pump products:

| Product | U.S. Commercial Availability | Outside U.S. Commercial Availability |
|---|---|---|
| t:slim | August 2012 - October 2016 | N/A |
| t:flex | May 2015 - June 2018 | N/A |
| t:slim G4 | September 2015 - August 2017 | N/A |
| t:slim X2 | October 2016 - September 2017 | N/A |
| t:slim X2 with G5 | September 2017 - August 2018 | September 2018 - present (varies by geography) |
| t:slim X2 with Basal-IQ technology | August 2018 - present | September 2019 - present (varies by geography) |
| t:slim X2 with Control-IQ technology | January 2020 - present | Scaling launch began July 2020 (to vary by geography)* |

*Subject to regulatory approvals and other factors

Today, our commercial efforts exclusively focus on the manufacturing, sale and support of our flagship pump platform, the t:slim X2 insulin delivery system, but we continue to provide ongoing service and support to existing t:slim, t:slim G4 and t:flex customers. The t:slim X2 insulin delivery system is comprised of a t:slim X2 pump, its 300-unit disposable insulin cartridge and an infusion set. It is also the only commercially available insulin pump featuring optional integration with Dexcom's CGM.


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

*t:slim X2 Insulin Pump*: Our t:slim X2 was designed to offer greater ease of use and look more like other modern consumer technology, such as a smart phone, as compared to other traditional insulin pumps. Key features include:

- Color touchscreen - The large color touchscreen is easy to read, simple to learn, and intuitive to use for anyone familiar with a smartphone or tablet.
- Small and discreet - The t:slim X2 pump is up to 38% smaller than other pumps, yet the device can hold up to 300-units of insulin.

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

- Flexible technology - The device can be used with or without AID or CGM. When advanced features are turned off, the t:slim X2 pump removes the CGM chart from the screen and puts the Bolus and Option buttons front and center for easy access.
- AID features (availability varies by geography) - We have commercially launched two AID algorithms on our t:slim X2 platform: Basal-IQ technology and Control-IQ technology.
    - Basal-IQ technology: This predictive low glucose suspend feature is designed to temporarily suspend insulin delivery to help reduce the frequency and duration of hypoglycemic events. With Dexcom G6 CGM integration, this feature works with no fingersticks required for mealtime dosing or calibration.
    - Control-IQ technology: This advanced hybrid-closed loop feature is designed to help increase a user's time in targeted glycemic range (70-180 mg/dL). It is the first and only system cleared to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. Control-IQ technology is integrated with Dexcom’s G6 CGM and offers optional settings for sleep and exercise that change the treatment values to better match the different physiological needs during these activities. Results from two independent pivotal studies using Control-IQ technology were published in the New England Journal of Medicine in October 2019 and August 2020.
- Connectivity - The t:slim X2 features a two-way Bluetooth wireless technology radio for communicating with more than one external device at a time. It also features a micro-USB connection that supports charging the lithium-polymer battery, software updates and optional rapid data uploads.

*Tandem Device Updater*: A revolutionary tool that allows pump users to update their pumps' software quickly and easily from a personal computer. It is PC- and Mac- compatible and designed to work with the t:slim X2 in a manner similar to software updates on a smartphone. It was cleared by the FDA in the third quarter of 2016 and launched outside the United States in the third quarter of 2019. We have used this technology to offer in-warranty t:slim customers in the United States four different software updates for no-cost, including Basal-IQ technology, and most recently Control-IQ technology. Outside the United States we began offering no-cost software updates for Basal-IQ technology in the third quarter of 2019 and Control-IQ technology updates in the third quarter of 2020. Subject to regulatory approvals and other factors, we intend to complete our scaled launch of Control-IQ technology outside the United States in the first half of 2021.

*t:connect*: Our web-based data management application provides users, their caregivers and their healthcare providers with a fast, easy and visual way to display diabetes therapy management data from our pumps, integrated CGMs and supported blood glucose meters. This application empowers people with diabetes, as well as their caregivers and healthcare providers, to quickly and easily identify meaningful insights and trends, allowing them to refine therapy and lifestyle choices for better management of their diabetes. It also provides us with valuable data that we can analyze computationally to reveal patterns, trends and associations that can be used in continuous product improvements, and identification of clinical outcomes data. t:connect launched in the United States in the third quarter of 2013. In 2017, we launched t:connect HCP, which is an enhanced version of t:connect designed to simplify the ability of pump users to share t:connect data with their healthcare providers. In the third quarter of 2020, we launched a new t:connect mobile application that features the wireless upload of pump data to t:connect, allows the user to receive notification of pump alerts and alarms, and provide a discrete, secondary display of glucose and insulin data. The t:connect mobile application is compatible with multiple versions of iOS and Android operating systems, and at the end of 2020, more than 80,000 customers had downloaded our mobile app. We believe t:connect can serve as a key component of additional mobile health applications that are currently under development.

*Sugarmate*: During the second quarter of 2020, we acquired Sugarmate, Inc. (Sugarmate), the developer of a popular mobile app for people with diabetes who use insulin. The Sugarmate app is designed to help people with diabetes visualize diabetes therapy data in innovative ways. It allows users to log glucose data and health and nutrition information, and can provide notifications and alerts to users, their family, and their caregivers. Sugarmate became a wholly owned subsidiary of Tandem, and is continuing to be led by its founder, who joined our Company.

**Our Strategy**

Enabled by our singular focus on diabetes management, our goal is to lead in insulin therapy management by building a robust ecosystem and portfolio of data-driven products and services around our flagship insulin pumps. We believe that our positively different approach uniquely positions us to significantly expand and further penetrate the varying segments of the insulin-dependent diabetes market by focusing on the needs of our customers and their caregivers, and by supporting healthcare providers and payors with real world insights.
To achieve our goal, we intend to pursue the following business strategies:

- drive worldwide adoption of our products by offering the best insulin delivery systems;
- deliver a portfolio of therapy management solutions designed to improve patient outcomes;
- expand the value provided by our portfolio through an ecosystem approach to diabetes management;
- build deeper relationships with all stakeholders across multiple channels, including virtual and telehealth platforms;
- leverage our manufacturing operations to achieve cost and production efficiencies;
- use data in new ways that deliver real-world insights and that promote better outcomes; and
- identify new offerings that support our mission to improve the lives of people with diabetes.

**Products Under Development**

Our products under development support our strategy of focusing on both consumer and clinical needs, which can vary greatly person-to-person. We will be furthering our efforts to improve and simplify the lives of people living with type 1 diabetes, in addition to expanding our longer-term initiatives in support of people living with type 2 diabetes.

Our product development efforts are designed to support different segments of the diabetes market by offering options that can be flexible, personalized, and used by themselves or in combination with other devices, and include:

- creating new hardware platform options;
- continuing AID system evolution;
- expanding connected (mobile) health offerings; and
- adding and enhancing system components.

*New Hardware Platform Options*

Preference in the size, shape, and mode of operation that comprise an insulin pump's hardware often impact a person's pump purchasing decision and overall user experience. We are expanding our development efforts to offer a family of pump hardware options to provide people with greater choice in the form factor that best fits their personal needs. Our new hardware platforms are being designed to be CGM integrated and compatible with our AID algorithms.

The next new hardware platform that we expect to offer in addition to the t:slim X2 is referred to under its development name, the t:sport Insulin Delivery System, (t:sport). The t:sport pump is half the size of t:slim X2 and is expected to be controlled using our mobile device application. It is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. We anticipate that t:sport will feature a 200-unit cartridge, an on-pump bolus button, a rechargeable battery, an AID algorithm, a Bluetooth radio, and a dedicated controller option. t:sport is being designed for use with leading U-100 insulins, and we are evaluating the use of insulin concentrates for people with greater insulin needs. The t:sport pumping mechanism differs from our current micro-delivery technology used in the t:slim pump platform.


**t:sport Shown with Mobile App Controller**

*AID System Evolution*

We are evolving our AID technology to provide users greater clinical benefit, with fewer direct interactions required on a pathway to a fully closed-loop AID system. We are building upon our Control-IQ technology, the most advanced commercially available AID system, and intend to deliver new features and benefits to our customers on a regular basis. In addition to algorithm enhancements intended to improve clinical outcomes, we are also developing new features for greater personalization and refinements to the overall system usability.

*Digital Health Offerings*

Our digital health offerings are being developed to enhance our ecosystem of products and services, and integrate our insulin therapy management systems with consumer electronics technology. Today, we offer individual applications through the web, such as our t:connect patient and HCP portals, through mobile via our t:connect and Sugarmate apps, and through the PC with the Tandem Device Updater. In the fourth quarter of 2020, we submitted a 510(k) application to the FDA for use of our mobile app in the remote delivery of bolus insulin and are preparing for launch in the United States in the first half of 2021. Future updates of our mobile application are planned to include additional pump control features and integrate other health-related information from third-party sources.

We plan to transition several of our discrete digital offerings to a single, global digital platform, which is intended to provide all users, including pump users, caregivers and healthcare providers, with a simplified and tailored user experience. This platform is being developed to support pump viewing, control, and reporting, as well as a mobile store through which users can learn about and shop for our products, and in the future we hope to include new customer onboarding, training and support. The platform is also being designed to enhance the user experience, streamline the pump and supplies purchasing process, and provide internal efficiencies. Data from our centralized system will be used for new product development, continuous product improvement, and for the generation of health economic outcomes data, and may ultimately support artificial intelligence and patient monitoring services.

We intend to launch the first element of this new platform under the name Tandem Source. Tandem Source is our second generation data management application that we intend to first offer outside the United States. It is a customizable dashboard designed to deliver the data and insights needed to expertly manage diabetes. With Tandem Source, healthcare providers and people living with diabetes have a trusted and reliable destination to review and analyze pump performance over time. Tandem Source's data visualization and customization options will offer healthcare providers better tools to identify trends that can help them make educated, data-driven decisions. We intend to commence a scaled launch of Tandem Source in select countries outside the United States beginning in the second half of 2021, and once globally available, it will ultimately replace t:connect.

*Adding and Enhancing System Components*

Building a robust ecosystem and portfolio around our flagship insulin pumps requires product development efforts to integrate, add and enhance complimentary system components. This includes integration with CGM, expansion of insulin administration and infusion set technology, and the use of alternative insulins.

In November 2020, we entered into an agreement with Dexcom to extend our current collaboration to include integration with their future G7 CGM technology. Following integrated product development work, and required regulatory clearances or approvals, this will be the fourth generation of Dexcom CGM that we intend to integrate with our devices.

In June 2020, we announced an agreement with Abbott Laboratories (Abbott) to develop and commercialize integrated diabetes solutions that combine Abbott's CGM technology with our insulin delivery systems. Following the completion of our integrated product development work, and after obtaining required regulatory clearances or approvals, we intend to focus our initial commercial activities on integrated products in the U.S. and Canada, with additional geographies considered in the future.

**Sales, Marketing and Customer Care**

In 2020, our U.S. sales organization was comprised of approximately 90 territories. The vast majority of these territories are supported by a sales representative and a clinical diabetes specialist who, as a team, call on domestic endocrinologists, nurse practitioners, primary care physicians, certified diabetes educators and potential customers. Where appropriate, some territories are supported by multiple clinical diabetes specialists. Our U.S. sales team is augmented by individuals in our internal customer sales support organization, who follow up on leads generated through promotional activities and educate people on the benefits of our proprietary technology and products.

Our internal customer sales support organization also contacts existing customers who are approaching their insurance renewal date to aid in the renewal process. Our goal is for at least 70% of our existing customers to purchase a new pump from us when making their next pump purchasing decision. Typically, domestic customers are eligible for insurance reimbursement to purchase a new insulin pump once every four years; however, some plans may be limited to once every five years or have additional restrictions or requirements. Insurance reimbursement processes outside the United States vary by geography. As our market penetration continues to build momentum, and as we launch new products into the market, we plan to further expand our sales, clinical and marketing infrastructure in the United States. However, only modest territory optimizations and expansions are planned in 2021.

In Canada, we established a small direct sales and clinical infrastructure in 2018, and since that time have secured reimbursement in the majority of Canadian provinces. Following Health Canada approval, we commenced marketing and sales efforts of the t:slim X2 with G5 integration in October 2018, and for the t:slim X2 with Basal-IQ technology in November 2019. In December 2020, Health Canada approved the t:slim X2 with Control-IQ technology, which we anticipate commercializing in the first quarter of 2021.

In other select geographies outside the United States, our initial efforts focused on the identification and contracting of distributors in areas where we believe there is a meaningful opportunity to achieve market acceptance of our t:slim X2 insulin pump. We began our scaled launch in the third quarter of 2018 after obtaining the right to affix the CE Mark to the t:slim X2 with G5 integration and following the completion of pre-launch activities, such as translating our pump software and user manual, and completing distributor sales and customer service trainings. Unlike our domestic operations, our international distributors (other than in Canada) have substantially greater responsibility for sales, marketing and customer support efforts. As of the end of 2020, our international distributors covered nearly 20 countries. In 2021, we anticipate our international distributor coverage will expand to approximately 25 countries.

***Revenue Concentrations and Significant Customers.*** A small number of independent domestic distributors have historically accounted for a significant portion of our revenues. During the year ended December 31, 2020, we made sales to approximately 43 independent distributors in the United States, and 12 independent distributors internationally. During the year ended December 31, 2020, sales to our two largest distributors accounted for 15.9% and 12.9% of consolidated sales, respectively. During the year ended December 31, 2019, sales to our two largest distributors accounted for 14.8% and 15.4% of consolidated sales, respectively. None of our independent distributors in the United States are required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements in the United States generally have one-year initial terms with automatic one-year renewal terms and are terminable in connection with a party's material breach. Our distributor agreements outside the United States generally have longer initial terms and, in addition to being terminable in connection with a party's material breach, include provisions that allow us to terminate those agreements prior to their ordinary expiration in exceptional circumstances. We believe our domestic distributors carry minimal inventory at any given time. Internationally, there may be variability in inventory levels among our distributors, particularly when they first commence product sales or surrounding the launch of new products.

***Animas.*** In October 2017, Johnson & Johnson announced that it was discontinuing the operations of Animas, and exiting the insulin pump business entirely, and, in connection with these activities, designated Medtronic as a preferred partner to facilitate the transition of Animas insulin pump customers. Throughout 2018 and 2019 we experienced an increase in our percentage of sales to people who reported converting from using an Animas pump. Animas pump supplies were no longer available for customers to purchase after September 2019. Accordingly, we believe that the vast majority of Animas pump users transitioned to an alternative pump by the end of 2019.

Outside the United States, many of our international distributors had existing relationships with Animas customers and were motivated to keep those individuals as existing customers by replacing Animas pumps with our t:slim X2 as opportunities arose. We believe the benefit from the Animas opportunity outside the U.S. was substantially realized by end of the second quarter of 2019.

***Training and Customer Care***. Our customer care infrastructure, which services the United States and Canada, consists of individuals focused on training, insurance verification and 24/7 technical services. Our goal is to offer best-in-class customer support and services as these offerings are often viewed by people with diabetes and their healthcare providers equally as important as the products we offer. In 2019, we opened a facility in Boise, Idaho to begin scaling our customer care organization outside of San Diego. This has allowed us to hire talented service employees more quickly than we would have been able to in San Diego at a lower cost of operations, which provides further leverage to our infrastructure. During 2021 we expect to further expand our customer care infrastructure, including investments in technology and personnel, to meet the needs of our larger base of in-warranty customers. We also provide training to our distribution partners who fulfill their customer care responsibilities outside the United States.

**Third-Party Reimbursement**

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

We are accredited by the Community Health Accreditation Program and are an approved Medicare provider. Over the last ten years, Medicare reimbursement rates for insulin pumps and disposable cartridges have remained relatively unchanged. Domestically, we primarily bill for our insulin pump products and associated supplies using existing Healthcare Common Procedure Coding System codes for which Medicare reimbursement is well established. However, pump eligibility criteria for people with type 2 diabetes can be different and may require additional documentation and laboratory testing to gain in-network insurance reimbursement benefits.

We enter into contracts with national and regional third-party payors to establish reimbursement for our insulin pump products, disposable cartridges and other related supplies. We employ a team of managed care managers who are responsible for negotiating and securing contracts with third-party payors throughout the United States. In July 2020, we were named as a network provider by UnitedHealthcare. From July 2016 to June 2020, only a small subset of UnitedHealthcare's members were able to obtain reimbursement for our products, primarily select pediatric and government plan members. For the year ended December 31, 2020, approximately 30% of our sales in the United States were generated through our direct third-party payor contracts, compared to approximately 27% for the same period of 2019.

If we are not contracted with a person's third-party payor and in-network status cannot be otherwise obtained, then to the extent possible we utilize distribution channels so our customers' orders can be serviced. As of December 31, 2020, we had executed distributor agreements with approximately 43 independent distributors in the United States. In most cases, but not all, this network of distributors allows us to access people who are covered by commercial payors with whom we are not contracted, at in-network rates that are generally more affordable for our customers.

Our distribution partners outside the United States and Canada are responsible for all reimbursement, tender application and fulfillment activities.

**Manufacturing and Quality Assurance**

Historically, we have manufactured our pump and disposable cartridge products at our Barnes Canyon facility in San Diego, California. In 2020, we began outsourcing a portion of our cartridge manufacturing to an experienced third-party contract manufacturer to provide us additional flexibility in scaling our business while creating additional leverage. In 2019, we made capital expenditure investments for the expansion of warehousing capacity and ordered additional manufacturing equipment that was implemented in 2020. These investments allowed us to double our cartridge manufacturing capacity from 2019 to 2020, without meaningfully increasing the cost of overhead associated with our manufacturing facilities. We believe these investments position us well to achieve our long-term gross margin targets.

We currently utilize a semi-automated manufacturing process for our pump products and disposable cartridges. A single pump production line reaches a maximum output of approximately 30,000 pumps per year on a single shift and we currently have the capacity to produce approximately 180,000 pumps annually. Disposable cartridges are manufactured on a production line that reaches a maximum output of approximately one million cartridges per year on a single standard eight-hour shift. Throughout 2020, we scaled our cartridge capacity at our third-party manufacturing location and now have capacity to produce up to approximately 33 million cartridges annually to support an installed base of more than 275,000 customers.

Outside suppliers are the source for most of the components and some sub-assemblies in the production of our insulin pumps. Any sole and single source supplier is managed through our supplier management program that is focused on reducing supply chain risk. Our suppliers are evaluated, approved and monitored periodically by our quality department to ensure conformity with the specifications, policies and procedures applicable to our devices. Members of our quality department also inspect our devices at various steps during the manufacturing cycle to facilitate compliance with our devices' stringent specifications.

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

**Research and Development**

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

In June 2015, we entered into non-exclusive agreements with DexCom to allow the integration of our insulin pump products with the DexCom G5 and G6 CGM systems worldwide. In November 2020, we entered into non-exclusive agreements with DexCom to continue the development and collaboration activities that enable the integration of the Company's insulin pump products with DexCom's CGM devices, including current and future generation insulin pump products with DexCom's G6 and G7 CGM devices. The 2015 agreements have an initial term of five years, and thereafter renew automatically for additional one-year terms unless either party provides advance notice to the other party that they do not wish to extend the agreements. The 2020 agreements have an initial term of five years and thereafter renew automatically for additional successive two-year periods unless either party provides advance notice of non-renewal. The agreements do not require any licensing fees, milestone payments or royalty obligations to DexCom. The agreements contain customary provisions for termination in the event of an uncured material breach or in the event of a dissolution of the other party, and prohibit our assignment of the agreements to a DexCom competitor without DexCom's prior consent.

In 2016, we entered into a worldwide, non-exclusive, royalty-bearing license agreement with TypeZero to allow the integration of our insulin pump products with TypeZero's inControl AID technology. The agreement also provides us access to TypeZero's future AID innovations for five years following the date of the agreement. In addition, the license agreement contemplated that our insulin pump products would be used alongside TypeZero's AID technology in certain studies under the International Diabetes Closed Loop (IDCL) Trial, which are now completed. In August 2018, TypeZero was acquired by Dexcom. Nevertheless, the terms of our agreement with TypeZero remain effective until the patents covered by the agreement have expired, subject to customary provisions for termination in the event of an uncured material breach.

In June 2020 we announced an agreement with Abbott to develop and commercialize integrated diabetes solutions that combine Abbott's CGM technology with our insulin delivery systems to provide more options for people to manage their diabetes. Following the completion of our integrated product development work, and after obtaining required regulatory clearances or approvals, we intend to focus our initial commercial activities on integrated products in the U.S. and Canada, and consider additional geographies in the future.

**Intellectual Property**

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

As of December 31, 2020, our patent portfolio consisted of approximately 103 issued U.S. patents and 69 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2038. We are also seeking patent protection for our proprietary technology in other countries throughout the world. In addition, we also have 81 trademark registrations, including 19 U.S. trademark registrations and 62 foreign trademark registrations.

In July 2012, we entered into an agreement with Smiths Medical, Inc. pursuant to which we were granted, through certain assignments and certain non-exclusive and exclusive, worldwide, fully paid-up, royalty-free licenses, certain rights to patents and patent applications related to ambulatory infusion pumps and related software and accessories for the treatment of diabetes. We agreed to pay $5.0 million in license fees and to share equally any associated sublicense revenues we may receive. As of December 31, 2020, we had paid the initial license fees in full and have not entered into any sublicense agreements.

In July 2020, we entered into a non-exclusive patent cross-license agreement for certain technologies in the field of diabetes with Medtronic plc. With certain exclusions, the agreement applies to the companies' existing products, as well as new products for at least the next five years, and includes a provision that prohibits the parties from cloning one another's products.

**Competition**

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, or other market activities of industry participants. We compete in domestic and international markets with a number of companies that manufacture insulin delivery devices, such as Medtronic MiniMed, a division of Medtronic, and Insulet Corporation. In addition, Eli Lilly & Co. has announced a collaboration to commercialize a version of Ypsomed AG's existing insulin pump as part of a to-be-developed system. There are also a number of other companies developing and marketing their own insulin delivery systems and/or related software applications for launch in the U.S. market, including insulin pumps and Bluetooth-enabled insulin pens to support MDI therapy. Additionally, several other companies currently market insulin pump products in international markets. In addition, we face competition from a number of companies, medical researchers and existing pharmaceutical companies that are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs and other therapeutics for the monitoring, treatment and prevention of diabetes.

For additional information, see the section of this Annual Report under the caption "Risk Factors" in Part I, Item 1A.

**Government Regulation**

Our products are medical devices subject to extensive regulation by the FDA in the United States, corresponding state regulatory authorities and other regulatory bodies in other countries. The U.S. Federal Food, Drug, and Cosmetic Act, (FDCA) and the FDA's implementing regulations govern:

- product design and development;
- pre-clinical and clinical testing;
- establishment registration and product listing;
- product manufacturing;
- labeling and storage;
- pre-market clearance or approval;
- advertising and promotion;
- product sales and distribution;
- recalls and field safety corrective actions; and
- servicing and post-market surveillance.

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

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

There are three new Class II categories classified by the FDA for the interoperability of devices as a complete AID system that are intended to help support continued rapid innovation by streamlining the regulatory pathway for integrated products approved by the FDA. In June 2018, our t:slim X2 was the first insulin pump designated by the FDA as compatible with integrated continuous glucose monitoring (iCGM) devices. In February 2019, we received FDA approval of our de novo application to classify the t:slim X2 to a Class II device, under the new insulin pump classification referred to as Alternate Controller Enabled Infusion Pumps (ACE pumps). In December 2019, we received FDA approval of our de novo application to classify our Control-IQ technology as the first automated insulin dosing software in a new interoperable automated glycemic controller (iAGC) category that automatically adjusts insulin delivery to a person with diabetes by connecting to an ACE pump and iCGM. In connection with the de novo applications for both the ACE pump and the iAGC category, the FDA established certain special controls that we will need to continue to satisfy. In March 2020, our Basal-IQ technology was also cleared as an iAGC. If we are not able to satisfy those special controls, we would be required to seek approval for those products under the traditional PMA submission process.

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

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

- systems may not be deemed safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and clinical trials may be deemed insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

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

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

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

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate expected;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate expected;
- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to the products that are part of our trial;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- we or third-party organizations do not perform data collection, monitoring and analysis in a timely or accurate manner or in a manner consistent with the clinical trial protocol or investigational or statistical plans;
- third-party clinical investigators have significant financial interests related to us or our study that the FDA deems the study results unreliable, or the company or investigators fail to disclose such interests;
- regulatory inspections of our clinical trials or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

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

- establishment registration and device listing;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, production, control, supplier/contractor selection, complaint handling, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations that prohibit the promotion of products for uncleared, unapproved or "off-label" uses, and impose other restrictions on labeling, advertising and promotion;
- the FDA's Medical Device Reporting (MDR) regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- voluntary and mandatory device recalls to address problems when a device is defective and could be a risk to health; and
- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

Also, the FDA may require us to conduct post-market surveillance studies or establish and maintain a system for tracking our products through the chain of distribution to the patient level. We are currently conducting a post-market surveillance study for our t:slim X2 with Control-IQ technology for users with type 1 diabetes age six and above. We may elect to pursue additional post-market surveillance studies in the future.

The FDA and the Food and Drug Branch of the California Department of Health Services enforce regulatory requirements by conducting periodic, unannounced inspections and market surveillance. Inspections may include the manufacturing facilities of our subcontractors.

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

- warning letters or untitled letters that require corrective action;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve future products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries;
- suspension or withdrawal of FDA clearance or approval;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

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

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

***Fraud and Abuse Laws.*** There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including the federal Anti-Kickback Statute and the Physician Self-Referral Law (the Stark Law), the federal civil False Claims Acts, the federal criminal Health Care Fraud Statute, as well as various state laws regulating healthcare. Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs.

***Federal Anti-Kickback Statue.*** The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual, or the furnishing, recommending, or arranging of a good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid.

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

***Physician Self-Referral Law***. The Stark Law prohibits a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, if the physician has a financial relationship with the company. In addition to statutory exceptions, the Centers for Medicare and Medicaid Services (CMS), has issued numerous regulatory exceptions to the Stark Law. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs. Although we believe that we have structured our provider arrangements to comply with current Stark Law requirements, these arrangements may not expressly meet the requirements for applicable exception from the law.

***Federal False Claims Act.*** The federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits under the act. Qui tam actions have increased significantly in recent years, causing greater numbers of healthcare companies to have to defend a false claim action, pay fines and/or be excluded from Medicare, Medicaid or other federal or state healthcare programs as a result of an investigation arising out of such action.

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

***Federal Health Care Fraud Statutes.*** We are also subject to a federal health care fraud statute that, among other things, imposes criminal and civil liability for executing a scheme to defraud any health care benefit program including non-governmental programs, and prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false or fraudulent statement or representation, or making or using any false writing or document with knowledge that it contains a materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services.

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

***Data Privacy and Information Security Laws and Regulations.*** t:connect data is hosted on secure servers and our use of t:connect data is subject to internal policies and procedures that are designed to comply with the federal U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA), as well as applicable U.S state privacy laws (including, but not limited to, the California Consumer Privacy Act). Although t:connect and t:connect HCP are not currently generally available to users or healthcare providers outside the United States, we are also mindful of requirements under Canada's Personal Information Protection and Electronic Documents Act, referred to as PIPEDA, and similar provincial laws, and the E.U. General Data Protection Regulation, commonly known as GDPR, and similar E.U. member state laws. Collectively, these laws and regulations set standards for safeguarding the confidentiality, integrity, and availability of the personal information we collect and use from customers and healthcare providers. These laws also require, among other things, that we are transparent about how we collect and share personal data and that we give t:connect users the ability to know what data we are collecting about them, to obtain a copy of that data, to correct or amend that data, and to request we restrict use of that data.

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

***Physician Payments Sunshine Act.*** The Physician Payments Sunshine Act requires certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians. Manufacturers may be subject to audit for their compliance with this law. Failure to submit the required data in an accurate and timely manner may result in the imposition of civil monetary penalties. We believe we are in substantial compliance with the Physician Payments Sunshine Act to date. However, the reporting requirements are meaningfully expanded beginning in 2021 and we will need to implement additional processes and controls in order to comply with these new tracking and disclosure obligations.

***Anti-Bribery and Anti-Corruption Laws.*** The U.S. Foreign Corrupt Practices Act (FCPA), and similar laws in foreign jurisdictions generally prohibit U.S. corporations and their representatives from offering, promising, authorizing or making improper payments, gifts or transfers to any foreign government official in order to obtain or retain business. The scope of the FCPA would include interactions with certain healthcare professionals and hospital administrators in many countries. We believe we are in substantial compliance with the FCPA and similar foreign regulations.

**International Regulation**

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

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

With the consummation of Brexit and the United Kingdom's (UK) exit from the European Economic Area, the UK is not scheduled to transition to the Medical Device Regulation but will continue to operate under existing directives. Although many classes of devices have grace periods, beginning on January 1, 2021, medical devices placed on the UK market are required to register with the Medicines and Healthcare Products Regulatory Agency. Registrations can only be submitted by UK manufacturers or by a UK Responsible Person who has a place of business in the UK. A UK Responsible Person is a person who acts on behalf of a manufacturer established outside the UK in relation to specified tasks with regard to the manufacturer's obligations.

**Information Security**

All of our employees are required to complete annual information security education training, which includes identifying suspicious emails, preventing virus and ransomware attacks, and avoiding other threats. We regularly review and modify our information security program to reflect changes in technology, laws, regulations, risks, industry practices, and other business needs. On an annual basis, we receive external audits of our information security posture, after which we remediate any findings. We hold cybersecurity insurance to mitigate against losses from a range of potential cyber incidents. Our management briefs our board of directors or a committee thereof on information security on a quarterly basis.

**Environmental Impact and Sustainability**

In 2020, we expanded the number of employees in our environmental, health and safety department and added leadership who bring experience from companies larger and more established than ours. We have a focused effort on understanding the environmental impact of our business and have a number of initiatives in place to support this effort. For example, our standby diesel generators are monitored and regulated by California's Air Pollution Control District and their runtime is limited and closely monitored. In addition, we have dedicated efforts toward the reduction of energy use in our lighting. We have actively pursued rebates from San Diego Gas & Electric to fund energy improvement projects, and our facilities use LED lighting, motion sensors, or both, to reduce energy consumption. We are also working to reduce energy consumption for air conditioning and heating through occupancy scheduling. Our manufacturing processes are not water intensive, and we use hands-free automatic sink faucets and automatic toilet flush valves in all buildings. We are also working to reduce landfill waste by baling and recycling our cardboard, and we have a commingled recycling program in place.

Our t:slim X2 insulin pump utilizes a rechargeable battery via its micro-USB port, eliminating the need to use alkaline batteries, which are commonly used in our competitors' insulin pumps. We estimate that our customers have kept approximately 8.7 million disposable batteries out of landfills since our pumps became available in 2012, and that over the life of their pumps, together these users will save over 18.4 million batteries. Also, our Tandem Device Updater enables our insulin pumps to be remotely updated with new pump software and features, thereby avoiding the environmental effects of physically producing, shipping, exchanging, and disposing of hardware. Since August 2017, over 100,000 of our pumps have been remotely updated through our Tandem Device Updater, which means that fewer screens, batteries, and circuit boards needed to be replaced. In addition, we have reduced the size of our cartridge pouch so that it uses less packaging material. We continue to use innovative techniques to reduce environmental impact and deliver products that can change people's lives.

**Community Outreach and Impact**

We strive to be a good corporate citizen in the communities in which our employees live and work. Our employee community outreach efforts include donations and volunteer work, serving on boards and advisory committees and other corporate and individual actions. In 2020, we extended our employee giving campaigns to include support for PRIDE organizations in San Diego and Boise. We partnered with Athena, a women's advocacy organization in San Diego, offering membership to 15 of our employees, giving them access to Athena's network and benefits. We championed employee participation in the annual Spare a Rose campaign, with funds going to Life For a Child, and continued our annual employee fundraising campaign for the JDRF San Diego One Walk in support of diabetes research. In 2020, we joined JDRF as a national partner, supporting their events nationally at a higher level than ever before. For many people with diabetes, peer support plays a key role in successful diabetes management. To help fulfill this need, we provide support to a broad spectrum of people and organizations providing peer support and education through diabetes programs such as Beyond type 1, Connected in Motion, Riding on Insulin, College Diabetes Network, Diabetes Exercise and Camping Association, Touched by Type 1, and regional diabetes events such as Children with Diabetes, Taking Control of Your Diabetes, American Diabetes Association, and camps where our employees participate and volunteer.

**Human Capital**

As of December 31, 2020, we had approximately 1,500 regular full-time employees, all of whom work in the United States or Canada. The term "employees" in this Annual Report means our regular full-time employees. Our headquarters are in San Diego, CA, where our primary research and development and administrative headquarters are located, and where we also operate a manufacturing facility and a warehousing facility. In addition, we maintain an office in Boise, Idaho, where employees focus primarily on customer care, and an office in Markham, Ontario, Canada. None of our employees are represented by a collective bargaining agreement, and we have never experienced any work stoppage. We believe we have good relations with our employees.

***Culture***

Fostering and maintaining a strong, healthy culture is a key strategic focus. In 2020, the San Diego Business Journal named us as "One of the Best Places to Work" in San Diego, an award given to "outstanding companies whose benefits, policies and practices are among the best in the region". We were also ranked 6th as one of the "Best Places to Work in Idaho" for a company of our size of operations in the state. Our core values statement was created by our employees in a bottom-up, cross-functional process. These core values reflect who we are and the way our employees interact with one another, our customers, partners and stockholders. *Innovate, for real* is our commitment to run our business with the future in mind to deliver products that improve people's lives, ensure continuous product improvements and exemplary customer support. *No shortcuts* is holding ourselves to the highest ethical standards and delivering exceptional quality. *Huddle up* highlights the importance of successful collaboration that is inclusive of diverse perspectives, both inside and outside of the Company. *Stay awesome* reflects a universal respect among employees which allows us the freedom to be ourselves and to be effective at our jobs, knowing at the end of the day that we can trust everyone to do the right thing, for our customers, our investors and each other. *Don't mess with our customers* emphasizes the deep care we have for the people who use our products, their loved ones and health care providers. We are committed to involving end users in the research and development of our products and customer support efforts, to develop products and services that truly bring convenience, innovation, and usability to diabetes management.

We have detailed ethics and compliance policies that instill a commitment to ethical behavior and legal compliance across our company. Employees are encouraged to approach their managers if they believe violations of standards or policies have occurred. Employees are also able to make confidential and anonymous reports using an online or telephone hotline hosted by a third party provider.

***Diversity and Inclusion***

We believe that a culture of inclusion and diversity enables us to create, develop and fully leverage the strengths of our workforce to exceed customer expectations and meet our growth objectives. More than half of our employees are female, including one-third of our employees at the Vice President level or higher, and approximately half of our employees are from an underrepresented ethnic community. We believe that bringing together different perspectives and experiences is fundamental to innovation and continue raising the bar in the field of diabetes technology. In 2020, we formed a diversity and inclusion council, sponsored by executive management, which is staffed by employees with diverse backgrounds, experiences or characteristics who share a common interest in professional development, improving corporate culture and delivering sustained business results. This council is focused on cultivating and supporting our internal culture through diversity of thought, support and advocacy within the diabetes community and continuing to build and maintain a diverse and inclusive workforce.

***Organizational Development***

Attracting, developing and retaining employees is critical to our longer term success. To support the advancement of our employees, we offer training and development programs encouraging advancement from within and continue to fill our team with strong and experienced management talent. We leverage both formal and informal programs to identify, foster, and retain top talent at both the corporate and operating level.

We have established a comprehensive training program to develop employees throughout the organization. *Emerging Leaders* and *Leading in Tandem* are examples of internal programs intended for high performing individual contributors, and newly hired and promoted supervisors and managers, respectively. More than 90% of employees participating in these programs remain employed at Tandem and approximately one-third have been promoted or have had a significant change in scope of responsibility. Our leadership team also mentors rising talent on a more informal basis. This informal mentorship achieves a number of goals, including accelerating the development of top performers, increasing organizational learning, and improving employee performance and retention. The executive team also commits substantial time to evaluating the bench strength of our leadership and working with our leadership to improve their performance.

***Total Rewards***

We have demonstrated a history of investing in our workforce by offering competitive salaries and wages. Annual increases and incentive compensation are based on merit, which is communicated to employees at the time of hiring and documented through our talent management process as part of our annual review procedures and upon internal transfer and/or promotion. To foster a stronger sense of ownership and align the interests of partners with stockholders, stock options and/or restricted stock units are provided to a substantial proportion of our employees under our broad-based stock incentive programs. Also, our employees are able to participate in our employee stock purchase program. Furthermore, we offer comprehensive, locally relevant and innovative benefits to all eligible employees, including health insurance, paid time off, paid and unpaid leaves, a retirement plan and life, disability/accident coverage and a wellness program. In addition, we engage a nationally recognized outside compensation and benefits consulting firm to independently evaluate the effectiveness of our executive compensation and total rewards programs and to provide benchmarking against our peers within the industry.

***Employee Health and Safety***

The health and safety of our employees is our highest priority, and this is consistent with our operating philosophy. We have integrated our employee health and safety efforts with our human resources functions to create a corporate culture with a shared commitment to the well-being of our professionals. Our employee assistance and wellness programs offer a range of benefits and services. For example, as a benefit to our employees and their eligible dependents, we provide access to personal and job-related counseling and assistance resources for addressing concerns such as emotional well-being, family and relationships, legal and financial matters, healthy lifestyles, mental health, substance abuse, and work and life transitions. Every work day we provide a virtual wellness session featuring guided meditation, stretching, yoga, or exercise. Our focused wellness education sessions, generally offered several times per month, cover topics such as parenting, mental health, nutrition, stress management, sleep habits, resilience, and working in a remote environment. We host an online wellness lounge and mental health toolkit with a range of recorded learning sessions and articles, and our monthly benefits newsletter updates employees on our various health and wellness benefits programs. Also, we have comprehensive safety training programs that ensure our employees know how to do their jobs safely and in compliance with laws and regulations. We operate in modern, efficient, and safe facilities, and have had minimal accident and injury rates company-wide. Despite this success, however, our goal remains the same: zero accidents.

In the COVID-19 global pandemic, we have been deemed an essential healthcare business under applicable governmental orders based on the critical nature of the products we offer and the communities we serve. As a result, our manufacturing and warehousing sites continued operating during the COVID-19 pandemic. As such, we have invested in creating physically safe work environments for our employees. Our response to the COVID-19 pandemic also included employee safety measures such as:

- Adding work from home flexibility;
- Increasing cleaning protocols across all locations;
- Initiating regular communication regarding impacts of the COVID-19 pandemic, including health and safety protocols and procedures;
- Implementing temperature screening of employees at the majority of our manufacturing and warehousing facilities;
- Establishing new physical distancing procedures for employees who need to be onsite;
- Providing additional personal protective equipment and cleaning supplies;
- Implementing protocols to address actual and suspected COVID-19 cases and potential exposure;
- Limiting domestic and international non-essential travel for all employees; and
- Requiring masks to be worn in all locations where mandated by local law.

**COVID-19 Global Pandemic Impact and Considerations**

We are deemed an essential healthcare business under applicable governmental orders based on the critical nature of the products we offer and the communities we serve. We experienced a modest impact from the COVID-19 global pandemic during the first quarter of 2020, which became more pronounced beginning in the second quarter through the end of the year. We originally anticipated that our sales outside the United States would experience a greater proportional impact due to differences in the sales process in domestic versus international markets. Initially, the impact on our business was relatively consistent worldwide but we have since seen varying degrees of impact in international markets based on local conditions. We anticipate that our sales and operating results will continue to be adversely impacted and subject to unpredictable variability for the duration of the pandemic. For example, we have experienced delays in certain programs of up to three or six months from when they were originally planned, such as human factors studies associated with our product development efforts. In addition, regulatory timelines may be difficult to predict as the FDA has stated that its review process may take longer than normal due to the impact of the COVID-19 global pandemic. The full extent of the impact of the COVID-19 global pandemic on our future business and operations is difficult to estimate and will depend on a number of factors including the scope and duration of the COVID-19 global pandemic and the relative impact of COVID-19 on the business operations of our contract manufacturers, suppliers, and competitors.

We have taken steps to prioritize the health and safety of our employees and customers during the COVID-19 global pandemic, while working to maintain a continuous supply of products, training and customer support. To that end, we have increased the frequency of our communications to employees, suppliers, customers, and healthcare providers. Since March 2020, we have restricted non-essential employee travel, banned visitors from all of our facilities, and transitioned those employees able to perform their job function outside of our facilities to a remote work environment. For our field-based sales and clinical employees, we initially discontinued all in-person activities and began utilizing technology to remotely engage healthcare providers and customers. We continue to work closely with our healthcare providers and customers, remaining flexible in our method of interaction. To help ensure the safety and health of our employees in manufacturing and warehousing positions involved in production and fulfillment operations, we have implemented preventative measures to comply with social distancing requirements and require temperature checks of our employees before each shift.

In response to developments surrounding the COVID-19 global pandemic, we initiated discussions with our key suppliers in early 2020 regarding their abilities to fulfill existing orders, and we have continued to regularly assess their capacity. During the first six months of 2020, we experienced certain challenges managing our inventory, primarily due to the impacts of the COVID-19 global pandemic. For example, in the first quarter of 2020, we observed customers purchasing cartridges and infusion sets at a higher rate than anticipated. In addition, during the second quarter of 2020, our infusion set manufacturer experienced certain inventory constraints which resulted in us requesting some customers to accept substitutions of similar products to prevent delays in order fulfillment. At this time, we believe many of our suppliers are deemed essential businesses under applicable governmental orders, and we have not experienced, and do not anticipate experiencing, disruption in our ability to manufacture insulin pumps and cartridges due to component procurement limitations. Additionally, our third-party cartridge manufacturer completed validation and commenced commercial-scale manufacturing near the end of the first quarter to supplement our existing cartridge manufacturing capacity, which we believe will assist us in meeting product demand in future periods. Our finished goods and raw material inventory, as well as available manufacturing capacity, position us well to respond to unforeseen disruptions in the near term.

Commercially, we have been communicating with our customers and healthcare providers through social media, direct email outreach and our website, in addition to regular communications sent by our sales and clinical employees. We are also leveraging our technology platforms, such as our t:connect diabetes management application, to support healthcare providers, as many of them are increasingly utilizing telehealth capabilities in their practices. By the end of the first quarter of 2020, we expanded our remote new pump training offering to all customers who purchased a t:slim X2 insulin pump, and in the third quarter, we resumed offering in-person trainings on a limited basis and under specific conditions.

**Management**

***John F. Sheridan*** (age 65) has served as our President and Chief Executive Officer since March 2019 and as a member of our board of directors since June 2019. Mr. Sheridan previously served as Executive Vice President and Chief Operating Officer since April 2013. Prior to joining our company, Mr. Sheridan served as Chief Operating Officer of Rapiscan Systems, Inc., a provider of security equipment and systems, from March 2012 to February 2013. Mr. Sheridan served as Executive Vice President of Research and Development and Operations for Volcano Corporation, a medical technology company, from November 2004 to March 2010. From May 2002 to May 2004, Mr. Sheridan served as Executive Vice President of Operations at CardioNet, Inc., a medical technology company, now operating as BioTelemetry, Inc. (Nasdaq: BEAT). From March 1998 to May 2002, he served as Vice President of Operations at Digirad Corporation, a medical imaging company. Mr. Sheridan holds a B.S. in Chemistry from the University of West Florida and an M.B.A. from Boston University.

***David B. Berger*** (age 51) has served as our Executive Vice President, Chief Business Operations and Compliance Officer since November 2020 and is responsible for the Company's legal, quality, regulatory, clinical and customer technical support functions. He previously served as Executive Vice President, Chief Legal and Compliance Officer since April 2019, and as General Counsel, having overseen the legal department since August 2013. From January 2008 until August 2013, Mr. Berger was employed at Senomyx, Inc., a taste science company, where he most recently served as Senior Vice President and General Counsel. He also served as Corporate Secretary of Senomyx from January 2008 until May 2014. From April 2003 until October 2007, Mr. Berger was responsible for all commercial aspects of legal affairs at Biosite Incorporated (Biosite), a provider of medical diagnostic products, most recently serving as Vice President, Legal Affairs. Previously, Mr. Berger was an attorney at Cooley Godward LLP and Amylin Pharmaceuticals, Inc. Mr. Berger holds a B.A. in Economics from the University of California, Berkeley and a J.D. from Stanford Law School.

***Brian B. Hansen*** (age 53) has served as our Executive Vice President and Chief Commercial Officer since February 2016. Prior to joining our company, Mr. Hansen served from September 2014 as Chief Commercial Officer of Adaptive Biotechnologies Corp. From May 2013 to September 2014, Mr. Hansen served as Head of Commercial, Sales and Marketing, of Genoptix, a Novartis Company. From December 2005 to February 2013, he served in various roles of increasing responsibility at Gen-Probe, Inc., a medical diagnostics company, most recently serving as Senior Vice President, Global Sales and Services from January 2012 to February 2013. Mr. Hansen received a B.S. in Business Administration from the University of Missouri-Columbia, and an M.B.A. from the School of Business at San Diego State University.

***Elizabeth A. Gasser*** (age 45) has served as our Executive Vice President, Strategy and Corporate Development since January 2020. Prior to joining our company, Ms. Gasser served from June 2017 as an independent adviser providing strategic and corporate development solutions to boards and executive teams. From January 2016 to June 2017 she was Vice President of Corporate Strategy at QUALCOMM Technologies, Inc. (QTI), a subsidiary of QUALCOMM Incorporated (Nasdaq: QCOM), a global leader in the development and commercialization of technologies and products used in mobile devices and other wireless products. Prior to that, from November 2012 to January 2016 she was Vice President of Strategic Development at QTI, after serving in other strategic related roles of increasing responsibility beginning in 2006. Ms. Gasser holds a B.A. and an M.A. in Economics from the University of Cambridge.

***Susan M. Morrison*** (age 41) has served as our Chief Administrative Officer since September 2013 and as an Executive Vice President since December 2017, and is responsible for the Company's investor relations, corporate communications, project management, human resources and facilities functions. From April 2013 until September 2013, she served as our Vice President, Human Resources, Corporate and Investor Relations. Ms. Morrison served as our Director, Corporate and Investor Relations, from January 2009 to March 2013, and was our Director, Corporate Services from November 2007 to December 2008. Prior to joining our company, Ms. Morrison held various positions in Corporate and Investor Relations at Biosite from August 2003 through November 2007. Ms. Morrison holds a B.A. in Public Relations from Western Michigan University.

***Leigh A. Vosseller*** (age 48) has served as our Executive Vice President, Chief Financial Officer, and Treasurer since June 2018, and served as Senior Vice President, Chief Financial Officer and Treasurer from January 2018 to May 2018. Ms. Vosseller is our principal financial and accounting officer. She joined us as Vice President of Finance in 2013 and was promoted to Senior Vice President of Finance in August 2017. Prior to that time, she served as Vice President and Chief Financial Officer at Genoptix, beginning in 2011, after initially joining Genoptix in 2008. Prior to that she held a senior finance position at Biosite where she played a key role in developing the financial and administrative infrastructure for international expansion. Ms. Vosseller is a certified public accountant (inactive) and holds a B.S. in Accounting from Missouri State University.

**Family Relationships**

Mr. Sheridan, our President and Chief Executive Officer, and Ms. Vosseller, our Executive Vice President, Chief Financial Officer and Treasurer, are involved in a personal relationship and share a primary residence. Ms. Vosseller reports directly to Mr. Sheridan. Our board of directors is informed of the relationship and due to the direct reporting arrangement, we have taken appropriate actions to ensure compliance with Company policies and procedures. Mr. Sheridan and Ms. Vosseller will not be involved in setting compensation or benefits for one another, which will continue to be determined by our Compensation Committee. In addition, our Audit Committee of the Board of Directors considered whether additional internal disclosure controls and procedures are appropriate in light of the circumstances and, as a result, certain additional internal controls were implemented during the year ended December 31, 2019.

Except as described above, there are no family relationships between any of our directors and executive officers.

**Additional Information**

Our website address is *www.tandemdiabetes.com*. We post links to our website to the following filings as soon as reasonably practicable after they are electronically filed with or furnished to the SEC: annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements, information statements, beneficial ownership reports and any amendments to those reports or statements filed or furnished pursuant to Sections 13(a), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (the Exchange Act). All such filings are available through our website free of charge. However, the information contained on or accessed through our website does not constitute part of this Annual Report, and references to our website address in this Annual Report are inactive textual references only.

## Item 1A. Risk Factors

*An investment in our common stock, or in securities convertible into or exchangeable for our common stock, involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Annual Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results, liquidity, and future prospects. Certain statements below are forward-looking statements. For additional information, see the section of this Annual Report under the caption "Cautionary Note Regarding Forward-Looking Statements."*

### Summary of Risk Factors

*An investment in our common stock, or in securities convertible into or exchangeable for our common stock, involves a high degree of risk. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found below, after this summary.*

**Risks Related to Our Business and Our Industry**

- We have incurred significant operating losses since inception and may not achieve sustained profitability.
- We currently rely on sales of insulin pump products to generate a significant portion of our revenue, and any factors that negatively impact sales of these products may adversely affect us.
- Public health threats, such as the COVID-19 global pandemic, have had a material adverse effect on our business.
- Our ability to maintain and grow our revenue depends on retaining a high percentage of our customer base.
- We operate in a very competitive industry.
- Competitive products or other technological developments may render our products obsolete or less desirable.
- The failure of our insulin pump and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations.
- Failure to secure or retain adequate coverage or reimbursement for our products by third-party payors could adversely affect our business.
- We may face unexpected challenges in marketing and selling our products, and training new customers on the use of our products.
- We may be unable to maintain our existing sales, marketing, clinical and customer service infrastructure.
- If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.
- The third parties on which we rely to assist us with our pre-clinical development or clinical trials may not perform as expected.
- Our failure to successfully complete clinical trials could prevent us from obtaining regulatory approvals for or commercializing our products.
- If assumptions about the potential market for our products are inaccurate our business may be adversely affected.
- Our ability to achieve profitability has dependencies on our ability to reduce the per-unit cost of our products.
- Manufacturing risks may adversely affect our ability to manufacture products,
- We depend on a limited number of third-party suppliers for certain components and products.
- Any disruption at one of our facilities could adversely affect our business and operating results.
- We may not experience the anticipated operating efficiencies from the transition of our manufacturing and warehousing operations.
- If we do not enhance our product portfolio to meet the demands of our market, we may fail to effectively compete.
- Concerns regarding the safety and efficacy of our products could limit sales and cause negative effects to our business.
- We may enter into collaborations or partnerships with third parties that may not result in commercially viable products or the generation of significant revenues.
- We operate our business in regions subject to natural disasters and other catastrophic events.
- A security breach or other significant disruption to our information technology systems could materially disrupt our operations or result in the unauthorized disclosure of sensitive information.

- We may be unable to retain and motivate our senior management or recruit additional qualified personnel
- We may experience a variety of risks associated with international operations.
- Our failure to successfully manage acquisitions could have an adverse effect on our business.

**Risks Related to Our Future Financings and Financial Results**

- We may need to raise additional funds in the future and funds may not be available on commercially reasonable terms.
- Our operating results may fluctuate significantly from quarter to quarter.

**Risks Related to Our Intellectual Property and Potential Litigation**

- Our ability to comprehensively protect our intellectual property and proprietary technology is uncertain.
- The medical device industry is characterized by patent litigation, and we could become subject to such litigation.
- We may be subject to damages resulting from claims that we have wrongfully used or disclosed patient health information or trade secrets, or are in breach of non-competition or non-solicitation agreements.
- We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses.

**Risks Related to Our Legal and Regulatory Environment**

- Our products and operations are subject to extensive governmental regulation.
- Modifications to our products may require new regulatory approvals, or require us to cease marketing or recall modified products.
- A recall of our products, or the discovery of safety issues, could have a negative impact on us.
- Our failure to comply with U.S. federal and state fraud and abuse laws could have an adverse impact on us.
- We may be liable if we engage in the promotion of the off-label use of our products.
- Legislative or regulatory healthcare reforms may result in downward pressure on the price of and decrease reimbursement for our products.

**Risks Related to Our Common Stock**

- The price of our common stock may continue to fluctuate significantly.
- Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.
- We may fail to maintain an effective system of internal control over financial reporting.

**Risks Related to Our Convertible Senior Notes**

- The Notes could adversely affect our financial condition.
- We may not have sufficient cash flow from our business to service the Notes.
- We may take actions which could limit our ability to make payments on the Notes.
- We may not be able to raise the funds necessary to repurchase or settle conversions of the Notes.
- The accounting method for the Notes could have a material effect on our reported financial results.
- Conversion of the Notes may dilute the ownership interest of existing stockholders.

**Risks Related to Our Business and Our Industry**

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

Since our inception in January 2006, we have incurred a significant net loss. As of December 31, 2020, we had an accumulated deficit of $659.2 million. To date, we have funded our operations primarily through cash collected from product sales, private and public offerings of our equity securities, and debt financing. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing and business operations, and the research and development (R&D) of our current products and products under development.

We began commercial sales of our first product, t:slim, in August 2012 and our current flagship pump platform, t:slim X2, in October 2016. The t:slim X2 insulin pump now represents 100% of new pump shipments. Until the third quarter of 2018 we were selling our products only in the United States and have since launched our products in select international geographies.

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, 2020 and 2019, our gross profit was $260.5 million and $194.2 million, respectively. Although we have achieved a positive overall gross margin and have substantially reduced our operating loss, we still operate at a net loss on an annual basis and expect that we may continue to do so for the foreseeable future.

To implement our business strategy and achieve consistent profitability, 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 R&D activities, create additional efficiencies in our manufacturing processes while adding to our capacity, and obtain regulatory clearance or approval to commercialize our products currently under development both domestically and internationally. We expect our expenses will 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, the timing of regulatory approval of our products and the products of our competitors, the actual efficiencies gained in our manufacturing processes, and the scope and duration of the impacts caused by the COVID-19 global pandemic. Any additional operating losses will have an adverse effect on our stockholders' equity, and we cannot assure you that we will be able to sustain profitability.

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

We generate nearly all of our revenue from the sale of t:slim X2 insulin pumps and the related insulin cartridges and infusion sets. Sales of these products 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 MiniMed, a division of Medtronic plc;
- the potential that 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 products, or similar products or technologies of our competitors;
- 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;
- 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 and commercial operations, or destruction, loss, or temporary shutdown of our manufacturing facilities;
- concerns regarding the perceived safety or reliability of any of our products, or any component thereof; and
- claims that any of our products, or any component thereof, 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 or other third parties which, under some circumstances, may be subject to termination, with or without cause, on relatively short notice. Sales of our current or future products may also be negatively impacted in the event of any regulatory or legal actions relating to CGM products that are compatible with our pumps, or in the event of any disruption to the availability of the applicable CGM-related supplies, such as sensors or transmitters, in a given market in which our products are sold. Sales of our products may also be adversely impacted if the CGM products that are compatible with our pumps are not viewed as superior to competing CGM products in markets where our products are sold, or if the price of these products is not competitive with similar products available in the market.

Because we currently rely on sales of our t:slim X2 insulin pump and related products to generate a significant majority of our revenue, any factors that negatively impact sales of these products (or negatively impact the products or components integrated with 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. We believe the COVID-19 global pandemic has had, that it and may continue to have, an adverse impact on sales of our products. For instance, we have seen examples of customers delaying their purchasing decisions or physicians pausing prescriptions for our products. It could also have the effect of magnifying the negative impact of any of the factors described above.

***Public health threats, such as the COVID-19 global pandemic, have had and could continue to have a material adverse effect on our operations, the operations of our business partners, and the global economy as a whole.***

Public health threats and other highly communicable diseases and outbreaks could adversely impact our operations, the operations of our customers, suppliers, distributors and other business partners, as well as the healthcare system in general. For example, the COVID-19 global pandemic, which is currently affecting numerous countries throughout the world, has resulted in a rapid and sustained rise in unemployment and a decrease in global economic activity, and the scope of the COVID-19 global pandemic and its impacts is continuing to fluctuate, and in some instances worsen, in various regions worldwide. While the overall negative impact from the COVID-19 global pandemic during 2020 is difficult to estimate, we anticipate that our sales and operating results will continue to be adversely impacted in future periods and subject to unpredictable variability. In addition, the rise in unemployment and decrease in economic activity due to the COVID-19 global pandemic may negatively impact the affordability of our products for certain customers, which could reduce demand for our products. Further, certain development activities originally planned to occur during 2020, such as human factors studies associated with our product development efforts and activities to support the manufacturing scale-up for new products, were modified or delayed, which has impacted our development timelines and regulatory strategies and also could have a negative impact on our product commercialization efforts and the future demand for our products.

The COVID-19 global pandemic, or other similar outbreaks or epidemics, may have an adverse effect on the overall productivity of our workforce, and we expect to continue to take extraordinary measures to protect the health and safety of our employees and our business partners and reduce the risk of disruptions to our operations. For example, since in March 2020, we have restricted non-essential employee travel, banned visitors from all of our facilities, and transitioned those employees able to perform their job function outside of our facilities to a remote work environment. For our field-based sales and clinical employees, we initially discontinued all in-person activities and began utilizing technology to remotely engage healthcare providers and customers. Where permitted, in-person activities have resumed, though the scope and scale have been limited and we still rely heavily on remote engagement. For our employees in manufacturing and warehousing positions involved in production and fulfillment operations, we have implemented health and safety protocols in compliance with applicable government orders and expert agency guidance, to include physical distancing requirements, requiring temperature checks for our employees before each shift, and other safety measures. We have also increased our staffing in certain operations in order to mitigate potential risks associated with increases in unplanned employee absences or illness. Our adoption of these preventive measures has resulted in incremental costs that have negatively impacted our gross margin, and the impacts could be more significant in future periods. In addition, for the duration of the COVID-19 global pandemic, our employees may be required to continue to operate within a remote work environment for extended periods of time due to illness, travel restrictions, government-imposed orders, school closures or for other reasons, any of which could result in reduced productivity of our workforce.

In addition to the foregoing impacts, disruptions from the COVID-19 global pandemic, or other similar outbreaks or epidemics, could result in delays in or the suspension of our manufacturing operations, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions. In particular, if we or our third-party manufacturers are required to delay or suspend our manufacturing operations, we may encounter severe product shortages, which would adversely affect our results of operations and harm our reputation. We are also dependent upon our third-party suppliers for many of our product components and for our manufacturing-related equipment, and the COVID-19 global pandemic could have a material adverse impact on the operations of one or more of our suppliers, which could prevent them from delivering products to us or supporting our requirements for manufacturing-related equipment on a timely basis, or at all. For example, we continue to focus on increasing our cartridge inventory to targeted levels, but there can be no assurance that we or our third-party cartridge manufacturer will be able to manufacture cartridges in the quantities we require to meet product demand. In addition, at various times during 2020 our primary infusion set manufacturer experienced certain inventory constraints. There can be no assurance our supplier will be able to provide infusion sets in the quantities we require to meet customer demand. If we experience these or similar manufacturing challenges in the future, it could have a negative impact on product sales and harm our reputation.

The full extent of the impact of the COVID-19 global pandemic on our business and operations is highly uncertain and subject to change, and will continue to depend on a number of factors, including the scope and duration of the pandemic. We expect any further spread or escalation of the COVID-19 global pandemic, or even the threat or perception that this could occur, or any protracted duration of decreased economic activity, could have a material adverse impact on our business, operations and financial 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 our customers, their caregivers and healthcare providers, which include training specific to our products, ongoing support by our sales and clinical employees, and technical support and customer service. Demand for our products from our existing customers could decline or could fail to increase in line with our projections as a result of a number of factors, including the introduction of competitive products, breakthroughs for the monitoring, treatment or prevention of diabetes, changes in reimbursement rates or policies, manufacturing problems, perceived safety or reliability issues with our products or components or the products of our competitors, the failure to secure regulatory clearance or approvals for products or product features in a timely manner or at all, product development or commercialization delays, the impacts and disruptions caused by the COVID-19 global pandemic, or for other reasons.

Further, the COVID-19 global pandemic has resulted in substantial restrictions on our engagement efforts with customers and healthcare providers, including through the cancellation or postponement of company-sponsored educational events, as well as third-party conferences, trade shows and similar events. These restrictions have negatively impacted, and are likely to continue negatively impacting, our ability to promote our new products and features to customers and healthcare providers, which could adversely impact our product sales and customer retention rates, as well as the strength of our brand.

The failure to retain a high percentage of our customers and increase sales to these customers consistent with our forecasts would 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, or if the competitive environment harms our business partners, our financial condition 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 multiple daily injection (MDI) therapy.

Our primary competitors are major medical device companies that are publicly traded companies or divisions or subsidiaries of publicly traded companies, including Insulet and Medtronic MiniMed. In addition, Eli Lilly & Co. has announced a collaboration to commercialize an insulin pump currently under development. There are also a number of other companies developing and marketing their own insulin delivery systems and/or related software applications, including insulin pumps and Bluetooth-enabled insulin pens to support MDI therapy. While these industry changes are significant, it is difficult to know how they will impact our business or the competitive landscape in which we operate. 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 ability to respond to competitive pressures, regulatory uncertainty, or challenges within the financial markets;
- 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 medical industry generally and the diabetes industry in particular;
- 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 R&D, 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, Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set and Medtronic recently announced the acquisition of a connected insulin pen delivery device.

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. In 2017 Abbott launched blood glucose sensors which compete with Dexcom CGMs. In June 2020, we entered into an agreement with Abbott to develop and commercialize integrated diabetes solutions. There can be no assurance that our collaborations with Dexcom and Abbott will be successful or that we will not experience delays, business disputes, or other unanticipated challenges. Competitive pressures within our industry, as well as the impacts and disruptions associated with the COVID-19 global pandemic, could negatively impact the financial condition of our business partners and impact their ability to fulfill contractual obligations to us, which could negative impact our product sales, result in delays in obtaining regulatory approvals for new products, harm our reputation, 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, 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 grow our business and 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, provide superior treatment outcomes, 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 and medical researchers are pursuing new delivery devices, delivery technologies, sensing technologies, treatment techniques, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any 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 companies will continue to dedicate significant resources to developing competitive products and technologies. The 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 hardware products to resemble modern consumer electronic devices to address certain embarrassment and functionality concerns consumers have raised with respect to traditional pumps. Similarly, our newer mobile software applications are being designed to incorporate features and functions that are common to other consumer-oriented applications. These consumer industries are themselves 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 technology, our products may become less desirable.

***The failure of our insulin pump and related 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 and growth strategy is highly dependent on our insulin pump and related products achieving and maintaining market acceptance. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that 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 diabetes monitoring, treatment or prevention 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, beneficial treatment outcomes, 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 achieve sales below our expectations.

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;
- 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 products, or components thereof, or of similar products or technologies of our competitors;
- adverse regulatory or legal actions relating to our insulin pump products or similar products or technologies; and
- results of clinical studies relating to our existing products or products under development or similar competitive products.

In addition, 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 breakthroughs, or the perception that advancements or breakthroughs 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. We anticipate that customers may delay their purchasing decisions, or physicians may pause prescriptions of our products, as a result of the COVID-19 global pandemic.

If our insulin pump products do not achieve and maintain widespread market acceptance, we may fail to achieve sales consistent with our projections, in which case our business, financial condition and operating results could be materially and adversely affected.

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

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 (CMS), which administers the U.S. Medicare program. Medicare periodically reviews its reimbursement practices for diabetes-related products, and there is uncertainty as to the future Medicare reimbursement rate for our products. Effective January 1, 2020, in addition to the existing reimbursement code for insulin pumps, CMS established additional reimbursement codes for insulin pumps with AID and CGM integration and associated supplies. In light of complexities surrounding use and payment of the codes, CMS subsequently determined the new codes will not be valid for Medicare submission at this time. It is also possible that CMS may continue to review and modify the current coverage and reimbursement of diabetes-related products in connection with anticipated changes to the regulatory approval process for insulin pumps and related products, software applications and services. In addition, third-party payors that do not follow the CMS guidelines may adopt different coverage and reimbursement policies for our current and future products. Further, it is possible that some third-party payors will not offer any coverage for our current or future products. For instance, it is possible that third-party payors may adopt policies in the future that designate one or more of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps and that such policies would discourage or prohibit the payors' members from purchasing our products, which would adversely impact our ability to sell our products.

We currently have contracts establishing reimbursement for our insulin pump products with a number of 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 add 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 have limited experience securing reimbursement in international markets. 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 limited experience marketing and selling our newer products as well as training new customers on their use, particularly in international markets. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have limited experience marketing and selling our products to customers with type 2 diabetes.

In addition, due to the current COVID-19 global pandemic, starting in March 2020 we temporarily discontinued in-person activities for our field-based sales and clinical employees and are utilizing technology to remotely engage healthcare providers and customers. While we have authorized limited in-person activities to resume, many restrictions persist that have been imposed by state and local governmental authorities or expert agencies, as well as by the health systems and professional organizations with which we interact. The scope and duration of these restrictions on our field-based employees remains highly uncertain, and it is difficult to predict the extent of any adverse impacts on the demand for our products resulting from these restrictions.

Our financial condition and operating results are and will continue to be highly dependent on our ability to adequately promote, market and sell our t:slim X2 insulin pump 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 continue to be restricted in their ability to interact with healthcare providers and customers, 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, marketing, clinical and customer service personnel driving adoption of our products. We have significantly increased the number of sales, marketing, clinical and customer service personnel employed by us since we commenced commercial sales. However, we have faced considerable challenges in growing and managing these resources, including with respect to recruiting, training and assimilation of sales territories. We expect to continue to face significant challenges as we seek to further increase the number of our sales, clinical and customer service personnel in order to optimize the coverage of our existing sales territories, as well as expand the number and scope of our existing sales territories. These challenges may be even greater in connection with our commercial expansion outside of the United States, where we have limited experience. Unexpected turnover among our sales, marketing, clinical and customer service personnel, or unanticipated challenges in recruiting additional 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 the oversight of our sales, marketing, clinical and customer service personnel will continue to place significant burdens on our management team. These burdens may be even higher while we seek to manage and expand a remote workforce during the duration of the COVID-19 global pandemic. 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.***

We believe 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 increase, particularly in light of our reliance on independent distributors outside of the United States. For example, our dependence upon independent distributors domestically 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 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. None of our independent distributors domestically has been required to sell our products exclusively and each of them may freely sell the products of our competitors. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

For the year ended December 31, 2020, our two largest independent distributors in the United States collectively comprised approximately 29% of our worldwide sales, and our three largest independent international distributors collectively comprised approximately 53% of our international 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 we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, the terms of the arrangements could result in our product margins being 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, 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 clearance or 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.

***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. 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 in 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, which represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we receive 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 such market research responses 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 expect to face complexities frequently encountered by companies in competitive and rapidly evolving markets, which may make it difficult to evaluate our business and forecast our future sales and operating results.***

We operate in a competitive and rapidly evolving market. Important industry changes, such as the FDA approval and launch of new products by our competitors, as well as changes specific to our business, such as the timing of our launch of new products currently in development, increasing reliance on digital health products and connected devices, and our potential expansion of commercial sales in international markets, combine to make it more difficult for us to predict our future sales and operating results, as well as our expected timeframe to achieve profitability. The significant uncertainty resulting from the COVID-19 global pandemic will make it more difficult for us to accurately forecast our financial results and achieve sustained profitability. In assessing our business prospects, you should consider these factors as well as the various risks and difficulties frequently encountered by companies in competitive and rapidly evolving markets, particularly those 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, marketing, clinical and customer service infrastructure to grow sales of our existing and proposed products, and enhance our ability to provide service and support to our customers;
- achieve and maintain market 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;
- enhance 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;
- manage cybersecurity and other technological risks associated with our expanding portfolio of digital health products, and align these products to a dynamic threat landscape.
- 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.

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.

***Our ability to achieve profitability will depend, in part, on our ability to reduce the per-unit cost of our products while also increasing production volume.***

We believe our ability to reduce the per-unit cost of our insulin pumps and related products will have a significant impact on our ability to achieve profitability. Our cost of sales includes raw materials and component parts, labor costs, product training expenses, freight, reserves for expected warranty costs, royalties, scrap and charges for excess and obsolete inventories. It also includes manufacturing overhead costs, including expenses relating to quality assurance, manufacturing engineering, material procurement and inventory control, facilities, equipment, information technology and operations supervision and management. Our warranty reserve requires a significant amount of judgment and are primarily estimated based on historical experience. Recently released versions of our pump may not incur warranty costs in a manner similar to previously released pumps and the launch of our mobile app also may result in unanticipated changes in historical trends.

In response to the COVID-19 global pandemic, we have taken steps to prioritize the health and safety of our employees and customers, while working to maintain a continuous supply of products, training and customer support. For example, we have implemented preventative safety measures for our employees involved in production and fulfillment operations as well as for any field-based employees. For employees in other functions, we have adopted measures designed to help employees remain effective in a work-from-home environment. We have also increased our staffing in certain operations in order to mitigate potential risks associated with increases in unplanned employee absences or illness. Each of these measures has resulted in unanticipated expenses that will negatively impact our gross margin and may adversely impact our ability to achieve profitability. We may also incur additional incremental expenses to help us support our ongoing operations during a period of unpredictable variability in the demand for our products, including throughout the duration of the COVID-19 pandemic.

If we are unable to increase our production volumes while sustaining or reducing our overall cost of sales, including through arrangements such as volume purchase discounts, negotiation of pricing and cost reductions with our suppliers, more efficient training programs for customers, improved warranty performance or fluctuations in warranty estimates, it will be difficult to reduce our per-unit costs and our ability to achieve profitability will be constrained.

In addition, the per-unit cost of our products is significantly impacted by our overall production volumes, and any factors that prevent our products from achieving market acceptance, cause our production volumes to decline, alter our product mix, result in our sales growing at a slower rate than we expect, or result in the closure of our manufacturing facilities, would significantly impact our expected per unit costs, which would adversely impact our gross margins. Further, we may not achieve anticipated improvements in manufacturing efficiency as we undertake actions to expand our manufacturing capacity. 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.

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

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

- quality or reliability defects in product components that we source from third-party suppliers;
- our inability to secure product components in a timely manner, in sufficient quantities and on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our failure to increase production of products to meet demand;
- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently produce future products or implement changes in current products in response to consumer demand or regulatory requirements;
- our inability to manufacture multiple products simultaneously while utilizing common manufacturing equipment;
- government-mandated or voluntary closures of, or operational limitations impacting, our manufacturing facilities; and
- potential damage to or destruction of our manufacturing equipment or 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. We may also increase our utilization of third parties to perform contracted manufacturing services for us, and we may need to acquire additional custom designed equipment to support the expansion of our manufacturing capacity. 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, qualifying and implementing additional equipment and procedures, obtaining new regulatory approvals, or developing 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.

In response to the COVID-19 global pandemic, in early 2020 we initiated discussions with our key suppliers regarding their abilities to fulfill existing orders and we have continued to regularly assess their capacity. At various times during 2020, our primary infusion set manufacturer experienced certain inventory constraints which resulted in us requesting some customers to accept substitutions of similar products to prevent delays in order fulfillment. Additionally, during 2020 our cartridge inventory was below our targeted stocking levels. We now have finished goods and raw material inventory on hand across all products that meets targeted stocking levels. Currently, we do not anticipate a significant disruption in our ability to manufacture insulin pumps and cartridges, nor do we anticipate our third-party manufacturers will be unable to provide sufficient quantities to meet product demand. If we experience these or similar manufacturing challenges in the future, it could have a negative impact on product sales and harm our reputation.

If we and our suppliers 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 components and products, and the loss of any of these suppliers, their inability to provide us with an adequate supply of components or products, or our ability to adequately forecast customer demand, 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 and products 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.

Although we have long-term supply agreements with many of our suppliers, these agreements do not include long-term capacity commitments. Under most of our supply agreements, we make purchases on a purchase order basis and 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. In addition, our suppliers may encounter problems that limit their ability to manufacture components or products for us, including financial difficulties, damage to their manufacturing equipment or facilities or problems with their own suppliers. As a result, our ability to purchase adequate quantities of our components or products may be limited. If we fail to obtain sufficient quantities of high-quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed, and our business could suffer.

We generally use a small number of suppliers for our components and products, some of which are located outside the United States, including in China and Mexico. Depending on a limited number of suppliers exposes us to risks, including limited control over costs such as tariffs, 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 inventories that are 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. These risks associated with the procurement of critical components from a limited number of suppliers may be increased as a result of the COVID-19 global pandemic. Failure of any of our suppliers to deliver products at the level our business requires could harm our reputation and limit our ability to meet our sales projections, which could have a material adverse effect on our business, financial condition and operating results.

We place orders with our suppliers using our forecasts of customer demand, which are based on a number of assumptions and estimates, in advance of purchase commitments from our customers. As a result, we incur inventory and manufacturing costs in advance of anticipated sales, which sales ultimately may not materialize or may be lower than expected. If we overestimate customer demand, we may experience higher inventory carrying costs and increased excess or obsolete inventory, which would negatively impact our results of operations. We expect it will be particularly difficult to accurately forecast demand during the global pandemic.

We may also have difficulty obtaining 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.

***Any disruption at one of our facilities could adversely affect our business and operating results.***

Although we operate in multiple locations, most of our current operations are still conducted in San Diego, California, including our final pump assembly and related manufacturing processes, and most research and development, management and administrative functions. In addition, the majority of our inventories of component supplies and finished goods is stored at two facilities in San Diego. Over the past year we substantially expanded various quality and customer and technical support activities in Boise, Idaho. We take precautions to safeguard our facilities, including by 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 disaster, such as an earthquake, fire or flood, or other catastrophic event, could damage or destroy our manufacturing equipment or our inventories 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 coverage may not be sufficient to provide coverage with respect to the damages incurred in any particular case, and our insurance carrier may deny coverage with respect to all or a portion of our claims. Regardless of the level of insurance coverage or other precautions taken, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

***We may not experience the anticipated operating efficiencies from the transition of our manufacturing and warehousing operations.***

At the beginning of 2018 we completed the transition of our manufacturing operations to a facility located on Barnes Canyon Road in San Diego, and during the fourth quarter of 2019 we commenced operations at a new logistics warehouse in San Diego. We expect that both of these actions will allow for future capacity for product manufacturing and warehousing expansion. However, we may not experience the anticipated operating efficiencies at either facility. In addition, beginning in 2020 we outsourced a portion of our cartridge manufacturing demand to an experienced third-party contract manufacturer and it is possible that we may consider outsourcing other aspects of our operations in the future. 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 addition, we or our contract manufacturers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints and environmental factors, any of which could delay or impede our ability to meet customer demand and have a material adverse impact on our business, financial condition and operating results. Further, because of the custom nature of our cartridge manufacturing process and product components, and the highly regulated nature of our products overall, in the event of any problems with a contract manufacturer, we may not be able to quickly establish additional or alternative arrangements.

We expect that the management and support of our new facilities and the increase of our manufacturing volumes will place significant burdens on our management team, particularly in areas relating to operations, quality, regulatory, facilities and information technology. We may not be able to effectively manage our ongoing manufacturing operations and we may not achieve the operating efficiencies that we anticipate, either from our own facilities or from our use of contract manufacturing. Further, additional increases in demand for our products may require that we further expand our business operations, which may require that we obtain additional facilities, make additional investments in capital equipment or increase our utilization of external third parties to perform contracted manufacturing services for us.

***If we do not enhance our product portfolio to meet the demands of our market, 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 portfolio 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;
- 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.

***Any concerns regarding the safety and efficacy of our products could limit sales and cause unforeseen negative effects to our business prospects and financial results.***

Studies to evaluate the safety or effectiveness of our products in a controlled setting are only recently available. As a result, people with insulin-dependent diabetes and healthcare providers may not be familiar with our studies and may be slower to adopt or recommend our products. Further, even with data from controlled studies third-party payors may not be willing to provide coverage or reimbursement for our products and we remain subject to 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 recalls may negatively impact our financial results and business prospects depending on a number of factors, including the scope and seriousness of the problem, degree of publicity, reaction of our customers and healthcare professionals, competitive response, and consumer perceptions generally. 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. Furthermore, general concerns regarding the perceived safety or reliability of any of our products, or any component thereof, may have a similar adverse effect on us.

***We may enter into collaborations, 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, licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products or technologies, pursue new markets, or protect our intellectual property assets. We may also elect to amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process, and may subject us to business risks. For example, other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities, or may be the counterparty in any such arrangements. We may not be able to identify or complete any such collaboration 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 collaborations that we do identify and complete. In particular, these collaborations may not result in the development of products or technologies that achieve commercial success or result in positive financial results, or may otherwise fail to have the intended impact on our business.

Additionally, we may not be in a position to exercise sole decision-making authority regarding a collaboration, licensing or other similar arrangement, which could create the potential risk of creating impasses on decisions. Further, our collaborators and business partners 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 and other business partners, 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 or other licenses of intellectual property rights. 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 Abbott, or any future collaborators devote to our arrangement with them or our future products. Disputes between us and our current, future or potential 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 and commercialization agreements with Dexcom, which provide us non-exclusive licenses to integrate various currently available and future generations of Dexcom CGM technology with our insulin pump products. Under certain circumstances, these agreements may be terminated by either party without cause or on short notice. Our current agreements with Dexcom do not grant us rights to integrate future generations of Dexcom CGM technology, other than G7 CGM devices, with any of our current or future products. Termination of any of our agreements with Dexcom would 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. The termination of our existing commercial agreements with Dexcom would disrupt our ability to commercialize our existing products and our development of future products, which could have a material adverse impact on our financial condition and results of operations, negatively impact our ability to compete and cause our stock price to decline.

***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. For example, a portion of our office facilities located in San Diego are in an area that is prone to flooding, which has occasionally temporarily disrupted our business operations. 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. Any future disruptions to our operations could have a material adverse impact on our financial condition and results of operations in future periods.

***A security breach or other significant disruption to our information technology systems, or failures of our pumps' software to perform as we anticipate, could materially disrupt our operations or result in the loss, theft, misuse, unauthorized disclosure, or unauthorized access to sensitive information relating to our customers, suppliers, employees or other individuals, which could damage our relationships, expose us to litigation or regulatory proceedings, or harm our reputation, any of which could have an adverse and material effect on our business, financial condition and operating results.***

The efficient operation of our business depends on our information technology and communication systems, as well as those of our third-party business partners. We rely on such systems to effectively store, process and transit proprietary 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 our t:connect uploader software and cloud-based web application, our current and future mobile applications, as well as those involved in the operation of our Tandem Device Updater, are vulnerable to damage or interruption from a number of causes, including earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, malware, ransomware or other destructive software, cyber-attacks, power losses, and computer system or data network failures. Should any of those risks occur, it could adversely impact the availability, confidentiality and integrity of information assets contained in those systems.

Our business also involves the storage and transmission of a substantial amount of confidential, personal, or other sensitive information, including health information and other personal information relating to our customers, the personal information of our employees and other individuals, and our proprietary, financial, operational or strategic information. Should any of the foregoing risks occur, it could also result in the loss, theft, misuse, unauthorized disclosure, or unauthorized access of such sensitive information, which could lead to significant reputational or competitive harm, litigation involving us or our business partners, regulatory proceedings, or substantial liabilities, fines, penalties or expenses. As a result, we strive to maintain and regularly update reasonable security measures, and to respond quickly and effectively if and when data security incidents do occur. Like many businesses, we are subject to numerous data privacy and security risks, including threats arising from computer viruses or hackers, cyber-attacks and ransomware attacks, as well as the risk that one or more of our employees may fail to comply, whether knowingly or accidentally, with established security measures, or with internal policies relating to use, storage or transmission of confidential or sensitive information. We are unable to predict the direct or indirect impact of any such incidents to our business. Further, many of our service providers are subject to similar risks. Whether or not our security measures and those of our service providers are ultimately successful, our expenditures on those measures could have an adverse impact on our financial condition and results of operations, and divert management's attention from pursuing our strategic objectives.

In addition to the risks regarding information technology systems and processing of sensitive information, our insulin pumps and other products rely on software, some of which is developed by third-party service providers, that could contain unanticipated vulnerabilities, which could make our products subject to computer viruses, cyber-attacks, or failures. These risks significantly increased when we received FDA clearance of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps and may be higher following the launch of our new mobile application in the second half of 2020. We may also face new risks relating to our information technology systems as we continue to commercialize our products outside of the United States and are subject to additional regulations relating to the use and protection of personal information and as we launch new mobile applications or new features to our existing applications.

The failure of our or our service providers' information technology systems or our pumps' software or other mobile applications to perform as we anticipate, or our failure to effectively implement new information technology systems and privacy policies and controls, 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, any of which could have a material adverse effect on our business, financial condition and operating results.

***We experienced a breach of our information technology systems in January 2020.***

On January 17, 2020, we learned that an unauthorized person gained access to an employee's email account through a cyber-attack commonly known as "phishing." We investigated the incident, and learned that a limited number of our employee email accounts may have been accessed by an unauthorized user in a similar manner between January 17, 2020 and January 20, 2020. Our continued investigation indicated that customer information, as well as proprietary Company information, may have been contained in one or more of the employee email accounts affected by the incident. Our investigation has not determined whether an unauthorized person viewed any such information. As a result of this incident, we are presently defending a class action lawsuit entitled *Joseph Deluna et al v. Tandem Diabetes Care, Inc.*, which is pending in the Superior Court of the State of California in the County of San Bernardino.

The risks posed by this lawsuit and any future related matters include civil monetary damages, attorney fees and costs, other legal penalties, reputational damage, loss of goodwill, and competitive harm.

***If we are found to have violated laws concerning the privacy and security of patient health information or other personal 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 domestic and international laws protecting the privacy and security of personal information. These laws include the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA) and related regulations, U.S. state laws (such as the California Consumer Privacy Act (CCPA)), Canada's Personal Information and Electronic Documents Act (PIPEDA) or the applicable provincial alternatives, the EU's General Data Protection Regulation (GDPR), EU member states directives, or similar applicable laws. These laws place limits on how we may collect, use, share and store medical information and other personal information, and they impose obligations to protect that information against unauthorized access, use, loss, and disclosure. The putative class action lawsuit described above alleges violations of some of these laws.

If we, or any of our service providers who have access to the personal data for which we are responsible, are found to be in violation of the privacy or security requirements of HIPAA, PIPEDA, GDPR, or applicable U.S. state and Canadian provincial laws, 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. Although we utilize a variety of measures to secure the data that we control, even compliant entities can experience security breaches or have inadvertent failures despite employing reasonable practices and safeguards.

We may also face new risks relating to data privacy and security as the United States, individual U.S. states or Canadian provinces, E.U. member states, and other international jurisdictions adopt or implement new data privacy and security laws and regulations as we continue to commercialize our products worldwide. For example, amendments to the CCPA, once effective, may impose additional requirements on us and increase our regulatory and litigation risk. As we continue to expand, our business will need to adapt to meet these and other similar legal requirements.

***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. 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. In our industry, it is common to attract and retain executive talent and other employees with compensation packages that include a significant equity component. 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. It may be more difficult to continue to incentivize employees during a period of rapid growth in our overall headcount while limiting the utilization of the share reserve under our current stock incentive plans. 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.

***We began commercialization of 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.***

During 2018, we began commercialization of the t:slim X2 insulin pump in select geographies outside of the United States. We have limited experience commercializing our products outside of the United States and expect that we will be subject to additional risks related to international business markets, including:

- different regulatory requirements for product approvals in foreign countries;
- differing U.S. and foreign medical device import and export rules;
- more restrictive privacy laws relating to personal information of end-users and employees, including GDPR;
- reduced protection for our intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad or with U.S. regulations that would apply to activities in such foreign jurisdictions, such as the Foreign Corrupt Practices Act;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters, or incidence of disease, including as a result of the COVID-19 global pandemic.

In addition, entry into international markets may require significant financial resources, impose additional demands on our manufacturing, quality, regulatory, customer support and other general and administrative personnel, and could divert management's attention from managing our core business. We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. If we are unable to expand internationally, manage the complexity of our global operations successfully or if we incur unanticipated expenses, we may not achieve the expected benefits of this expansion and our financial condition and results of operations could be materially and adversely impacted.

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

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

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or investments;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or to comply with regulatory requirements or other compliance matters.

We may experience one more or of those risks in connection with our acquisition of Sugarmate made in 2020. We do not know if we will be able to identify future acquisitions or investments we deem suitable, whether we will be able to successfully complete any such acquisitions or investments on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies into our business. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

**Risks Related to Our Future Financings and Financial Results**

***We may need or otherwise determine to raise additional funds in the future and if we are unable to raise additional funds when necessary or desirable, we may not be able to achieve our strategic objectives.***

At December 31, 2020, we had $484.9 million in cash, cash equivalents and short-term investments. Our management expects the continued growth of our business, including the expansion of our customer service infrastructure to support our growing base of customers, our plans to expand commercial sales of our products outside of the United States, the growth of our manufacturing and warehousing operations, increase the size of our facility footprint due to increasing headcount and additional R&D activities, will continue to increase our expenses. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Accordingly, our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our insulin pump products, and the related insulin cartridges and infusion sets, and any other future products that we may develop and commercialize;
- the gross profits and gross margin we realize from the sales we generate;
- the costs associated with maintaining and expanding an appropriate sales, marketing, clinical and customer service infrastructure;
- the expenses we incur or other capital expenditures we make to maintain or enhance our manufacturing operations, including leasing additional property, hiring additional personnel, purchasing additional manufacturing equipment and other measures taken to add manufacturing capacity;
- the expenses associated with developing and commercializing our proposed products or technologies;
- the costs associated with maintaining and expanding our customer service infrastructure;
- the cost of obtaining and maintaining regulatory clearance or approval for our products and our manufacturing facilities;
- the cost of ongoing compliance with legal and regulatory requirements;
- the expenses we incur in connection with potential litigation or governmental investigations;
- expenses we may incur or other financial commitments we may make in connection with current and potential new acquisitions, investments, business or commercial collaborations, development agreements or licensing arrangements;
- anticipated or unanticipated capital expenditures;
- unanticipated general and administrative expenses; and
- impacts and disruptions resulting from geopolitical actions, including war and terrorism, natural disasters, or incidence of disease, including as a result of the impacts from the COVID-19 global pandemic.

As a result of these and other factors we may in the future seek additional capital from public or private offerings of our equity or debt securities, or from other sources. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing or debt service costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaborations, licensing, joint ventures, strategic alliances, partnership arrangements or other similar arrangements, it may be necessary to relinquish valuable rights to our potential future products or proprietary technologies, or grant licenses on terms that are not favorable to us.

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

***Our operating results may fluctuate significantly from quarter to quarter.***

There has been and may continue to be meaningful variability in our operating results from quarter to quarter, as well as within each quarter, especially around the time of anticipated new product launches or regulatory approvals by us or our competitors, and as a result of the commercial launch of our products in geographies outside of the United States. Our operating results, and the variability of these operating results, will be affected by numerous factors, including:

- our ability to increase sales and gross profit from our insulin pump products, including the related insulin cartridges and infusion sets, and to commercialize and sell our future products;
- the number and mix of our products sold in each quarter;
- acceptance of our products by people with insulin-dependent diabetes, their caregivers, healthcare providers and third-party payors;
- the pricing of our products and competitive products, including the use of discounts, rebates or other financial incentives by us or our competitors;
- the effect of third-party coverage and reimbursement policies;
- our ability to maintain our existing infrastructure;
- the amount of, and the timing of the payment for, insurance deductibles required to be paid by our customers and potential customers under their existing insurance plans;
- interruption in the manufacturing or distribution of our products;
- our ability to simultaneously manufacture multiple products that meet quality, reliability and regulatory requirements;
- seasonality and other factors affecting the timing of purchases of our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- results of clinical research and trials on our existing and future products;
- the ability of our suppliers to timely provide us with an adequate supply of components that meet our requirements for product quality and reliability;
- regulatory clearance or approvals affecting our products or those of our competitors; and
- the timing of revenue and expense recognition associated with our product sales pursuant to applicable accounting standards.

In addition, we expect our operating expenses will continue to increase as we expand our business, which may exacerbate the quarterly fluctuations in our operating results. If our quarterly or annual operating results fall below the expectation of investors or securities analysts, the price of our common stock could decline substantially. Further, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially, and these price fluctuations could result in further pressure on our stock price. We believe quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

**Risks Related to Our Intellectual Property and Potential Litigation**

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

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of December 31, 2020, our patent portfolio consisted of approximately 103 issued U.S. patents and 69 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2038. We are also seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we also have 81 trademark registrations, including 19 U.S. trademark registrations and 62 foreign trademark registrations.

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

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

We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, temporary employees and consultants regarding our intellectual property and proprietary technology. We also enter into confidentiality agreements with potential collaborators and other counterparties, and the terms of our collaboration agreements typically contain provisions governing the ownership and control of intellectual property. In the event of unauthorized use or disclosure or other breaches of those agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information.

If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult, expensive and time consuming. Patent law relating to the scope of claims in the industry in which we operate is subject to rapid change and constant evolution and, consequently, patent positions in our industry can be uncertain. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could divert management's attention from managing our business. Moreover, we may not have sufficient resources or incentive to defend our patents or trademarks against challenges or to enforce our intellectual property rights. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, pursuing litigation may provoke third parties to assert counterclaims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. The occurrence of any of these events may have a material adverse effect on our business, financial condition and operating results.

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

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

From time to time, we may receive communications from third parties alleging our infringement of their intellectual property rights or offering a license to intellectual property that is alleged to relate to products that we are currently developing. Any intellectual property-related discussions, disputes or litigation could force us to do one or more of the following:

- stop selling our products or using technology that contains the allegedly infringing intellectual property;
- prevent or limit our ability to sell a product that we are currently developing;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing;
- redesign those products that contain the allegedly infringing intellectual property; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

We do not currently maintain insurance to cover the expense or any liability that may arise from an intellectual property dispute with a third party. Any litigation or claim against us, even those without merit, or even preparing for a potential dispute or litigation before it arises, may cause us to incur substantial costs, and could place a significant strain on our financial resources and divert the attention of management from our core business. Any litigation or claim against us may also harm our reputation. Further, as we launch new products and increase our sales, and the number of participants in the diabetes market increases, we believe the possibility of our involvement in intellectual property disputes will increase.

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

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

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

Our business exposes us to potential product liability claims that are inherent in the design, manufacture, testing and sale of medical devices. We are subject to product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition, injury or death to customers. The risk of one or more product liability claims or lawsuits may be even greater after we launch new products with new features or enter new markets where we have no prior experience selling our products and rely on newly-hired staff or new independent distributors or contractors to provide new customer training and customer support. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, including death, which could result in product liability claims. We may also identify deficiencies in our products that we determine are immaterial and do not pose safety risks, and therefore decide not to initiate a voluntary recall. However, any such deficiency may be more significant than we expect and lead to product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and adversely affect our ability to attract and retain customers, any of which could have a material adverse effect on our business, financial condition and operating results.

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

**Risks Related to Our Legal and Regulatory Environment**

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

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state regulatory agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other U.S. governmental agencies regulate numerous elements of our business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- labeling and storage;
- marketing, manufacturing, sales and distribution;
- pre-market clearance or approval;
- servicing and post-market surveillance;
- advertising and promotion; and
- recalls and field safety corrective actions.

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

If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our forecasts.

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

- our inability to demonstrate that our products are safe and effective for their intended users;
- the data from our clinical trials may be insufficient to support clearance or approval; and
- failure of the manufacturing process or facilities we use to meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared or approved products on a timely basis. More recently, the FDA has stated that the review process for new submissions may take longer than normal due to the impact of the COVID-19 global pandemic.

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

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

Further, we commenced commercial sales of our products in select international markets during the third quarter of 2018. As we expand our operations outside of the United States and launch new products, we will become subject to various additional regulatory and legal requirements under the applicable laws and regulations of the international markets we enter. These additional legal and regulatory requirements may result in our incurring significant costs and expenditures. We have limited experience complying with applicable laws and regulations in international markets generally, and in particular when we enter new markets, and if we are not able to comply with any such requirements, our international expansion and business could be significantly harmed.

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

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

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

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

We and our third-party suppliers, contract manufacturers and service providers are required to comply with the FDA's Quality System Regulation (QSR), which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may impose inspections or audits at any time. We cannot assure you that our facilities or our contract manufacturer or component suppliers' facilities would pass any future quality system inspection or audit. If we or our suppliers, contract manufacturers and service providers have significant non-compliance issues or if any corrective action plan that we or our suppliers, contract manufacturers or service providers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us and the manufacturing or distribution of our devices could be interrupted and our operations disrupted.

If we, or our suppliers, manufacturers and service providers, fail to adhere to QSR requirements, this could delay production of our products and lead to fines, difficulties in obtaining regulatory clearances, recalls, enforcement actions, including injunctive relief or consent decrees, or other consequences, which could, in turn, have a material adverse effect on our financial condition or results of operations.

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

The FDA and equivalent foreign regulatory authorities have the authority to require the recall or suspension, either temporarily or permanently, of commercialized products in the event of material deficiencies or defects in quality systems, product design or manufacture or in the event that a product poses an unacceptable risk to health. Regulatory authorities have broad discretion to require the recall or suspension of a product or to require that manufacturers alert customers of safety risks, and may do so even in circumstances where we do not believe our product poses an unacceptable risk to health. In addition, manufacturers may, under their own initiative, recall a product or suspend sales if any material deficiency in a product is found or alert customers of unanticipated safety risks. A government-mandated or voluntary recall or suspension by us, one of our distributors or any of our other third-party suppliers could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls, suspensions or other notices relating to any products that we distribute would divert managerial and financial resources, and have an adverse effect on our reputation, financial condition and operating results.

Further, under the FDA's Medical Device Reporting regulations and equivalent regulations in other geographies, we are required to maintain appropriate quality systems and report incidents in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall or suspension of product sales, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results. We have initiated product recalls in the past, and our risk of future product recalls may increase as we launch new products or offer new software updates for existing products.

Any adverse event involving any products that we distribute, either domestically or internationally, could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. For example, in 2020 we received a notice from the Australian Therapeutic Goods Administration, TGA, proposing to suspend the sale of our insulin pump products. Most of our historical pump sales in Australia were of our t:slim X2 with Dexcom G5 CGM and more recently we commenced sales of our t:slim X2 with Basal-IQ technology. To date we have not offered our Control-IQ technology in Australia. Although we provided a response to this initial regulatory inquiry, the TGA suspended our pump product sales in Australia commencing November 24, 2020. We are presently engaged in discussions with the TGA in an effort to lift the suspension. However, unless the decision is reversed or delayed we will be unable to continue to sell our pump products in Australia. Any corrective actions we take in response to this action or future matters with other regulatory bodies, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, may harm our reputation and financial results or could result in additional regulatory scrutiny in other geographies.

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

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

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

- the federal healthcare programs' Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering, paying or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and state Medicaid programs;

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

- federal and state physician self-referral laws, such as the Stark Law, that prohibit a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, with which the physician has a financial relationship unless that financial relationship meets an exception under the applicable law;

- federal and state laws, such as the Civil Monetary Penalties Law, that prohibit an individual or entity from offering or transferring remuneration to any person eligible for benefits under a federal or state health care program which such individual or entity knows or should know are likely to influence such eligible individual's choice of provider, practitioner or supplier of any item or service for which payment may be made under federal health care programs such as Medicare and state Medicaid programs;

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

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

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

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

- federal and state laws governing the use, disclosure and security of personal information, including protected health information, such as HIPAA and the Health Information Technology for Economic and Clinical Health.

Possible sanctions for violation of these laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other federal healthcare programs, and forfeiture of amounts collected in violation of those prohibitions and in some circumstances, treble damages. Any violation of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results. The reporting requirements under the Physician Payments Sunshine Act were recently expanded, and we will need to implement additional processes and controls in order to comply with these new tracking and disclosure obligations. Any failure to submit the required data in an accurate and timely manner may result in the imposition of civil monetary penalties. Recently, federal government agencies have issued final rules making modifications to the Anti-Kickback Statute "safe harbors" and the Stark Law regulations, and the full impact of how such modifications may impact the health care industry and our business operations is not yet known. Further, the federal government has recently published proposed rules for public comment which would make material modifications to HIPAA. It is unknown if or when these proposed rules may be adopted and what final form the proposed rules may take and how they may impact our business operations.

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

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any of these challenges could have a material adverse effect on our reputation, business, financial condition and operating results. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

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

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

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

The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States continue to propose and pass new legislation and regulations designed to, among other things, expand healthcare coverage to more individuals, contain or reduce the cost of healthcare, and improve the quality of healthcare outcomes. This legislation and regulation may result in decreased reimbursement for medical devices, which may create additional pressure to reduce the prices charged for medical devices. Reduced reimbursement rates could significantly decrease our revenue, which in turn would place significant downward pressure on our gross margins and impede our ability to become profitable.

The Patient Protection and Affordable Care Act, a component of the Affordable Care Act (ACA), substantially changed the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services, and significantly impacts the medical device industry. However, a number of legislative changes have been proposed and adopted since the ACA was enacted, and legislation has also been and will likely continue to be proposed that could modify or repeal the ACA. The uncertainties regarding the future of the ACA, and other healthcare reform initiatives, may have an adverse effect on our customers' purchasing decisions regarding our products.

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

**Risks Related to Our Common Stock**

***The price of our common stock may continue to fluctuate significantly.***

The trading price of our common stock has been volatile in recent years. We believe our stock price has been, and will continue to be, subject to wide fluctuations in response to a variety of factors, including the following:

- actual or anticipated fluctuations in our financial and operating results from period to period;
- our actual or perceived need for additional capital to fund our operations;
- market acceptance of our current products and products under development, and the recognition of our brand;
- introduction of proposed products, technologies or treatment techniques by us or our competitors;
- announcements of significant contracts, acquisitions or divestitures by us or our competitors;
- regulatory approval of our products or the products of our competitors, or the failure to obtain such approvals on the projected timeline or at all;
- speculative trading practices of market participants;
- issuance of securities analysts' reports or recommendations;
- threatened or actual litigation and government investigations;
- sales of shares of our common stock by our employees, directors or principal stockholders; and
- general political or economic conditions, including the impacts and disruptions caused by the COVID-19 global pandemic.

These and other factors might cause the market price of our common stock to fluctuate substantially. Fluctuations in our stock price may negatively affect the liquidity of our common stock, which could further impact our stock price.

In recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. These changes may occur without regard to the financial condition or operating performance of the affected companies. Accordingly, the price of our common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce the market price of our common stock.

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

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

- authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;
- provide for the adoption of a staggered board of directors whereby the board is divided into three classes each of which has a different three-year term;
- provide that the number of directors shall be fixed by the board;
- prohibit our stockholders from filling board vacancies;
- provide for the removal of a director only with cause and then by the affirmative vote of the holders of a majority of the outstanding shares;
- prohibit stockholders from calling special stockholder meetings;
- prohibit stockholders from acting by written consent without holding a meeting of stockholders;
- require the vote of at least two-thirds of the outstanding shares to approve amendments to the certificate of incorporation or bylaws; and
- require advance written notice of stockholder proposals and director nominations.

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

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

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

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

As of December 31, 2020, we had accumulated federal and state net operating loss (NOL) carryforwards of approximately $340.0 million, and $288.7 million, respectively, which included the reduction recorded in 2019 discussed below. Of the total federal NOL carryforwards, approximately $131.5 million were generated after January 1, 2018, and therefore do not expire. NOL generated after January 1, 2018, is subject to 80% limitation in accordance with the Tax Cuts and Jobs Act of 2017. The remaining federal NOL carryforwards of $208.5 million will begin to expire in 2026, and state tax loss carryforwards begin to expire in 2021, unless previously utilized. If there is an "ownership change" with respect to our company, as defined under Section 382 of the Code, the utilization of our NOL and research credit carryforwards may be subject to substantial limitations imposed by the Code, and similar state provisions. Limitations imposed on our ability to utilize NOL carryforwards could cause U.S. federal income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause NOL carryforwards to expire unused, in each case reducing or eliminating the benefit of our NOL carryforwards. In general, an ownership change occurs whenever there is a shift in ownership of our company by more than 50% by one or more 5% stockholders over a specified time period.

We have completed analyses through December 31, 2020 to determine whether our net operating losses and credits are likely to be limited by Section 382. Based on the 2018 study completed in 2019, the Company determined that offerings of our securities caused an ownership change, as defined under Section 382, in 2018 and the resulting limitation significantly reduced the Company's ability to utilize its net operating loss and credit carryovers before they expire. As a result, in 2019 the Company significantly reduced its deferred tax assets for the net operating loss and research credit carryforwards that were projected to expire unused. In addition, future ownership changes under Section 382 may further limit the Company's ability to fully utilize any remaining tax benefits.

In response to the COVID-19 global pandemic, the CARES Act was enacted on March 27, 2020, to provide aid and economic stimulus to the economy. Among other provisions, the CARES Act eliminates the 80% NOL limitation for tax years 2018, 2019, and 2020, and allows NOLs generated in those years to be carried back for five years. We believe that any impact of the CARES Act provisions are not significant to our financial position, results of operations or cash flows.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Accordingly, investors may have to sell some or all of their shares of our common stock in order to generate cash flow from their investment.

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

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. For example, Mr. Sheridan, our principal executive officer, and Ms. Vosseller, our principal financial and accounting officer, are involved in a personal relationship and share a primary residence. While our board of directors is informed of the relationship and appropriate actions have been taken to ensure compliance with Company policies and procedures, the existence of this relationship could create additional risk, or the perception of additional risk, that our controls and procedures may not be effective. In addition, any testing by us conducted in connection with Section 404(a) of the Sarbanes-Oxley Act, or any testing conducted by our independent registered public accounting firm in connection with Section 404(b) of the Sarbanes-Oxley Act may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We are required to disclose changes made to our internal control procedures on a quarterly basis and our management is required to assess the effectiveness of these controls annually. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

***We may be at increased risk of securities class action litigation.***

In the past, securities class action litigation has been instituted against companies following periods of volatility in the overall market and in the price of a company's securities. We believe this risk may be particularly relevant to us as we have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business, financial condition and results of operations. Our stock price volatility and the increase in our market capitalization during the past year may also result in higher expenses associated with our directors' and officers' liability insurance program.

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

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

***Risks Related to Our Convertible Senior Notes***

***We have indebtedness in the form of convertible senior notes, which could adversely affect our financial condition and our ability to respond to changes in our business.***

In May 2020, we completed the offering of $287.5 million principal amount of 1.50% Convertible Senior Notes due 2025 (the Notes), which we refer to as the Note Offering. Holders of the Notes will have the right to require us to repurchase their Notes upon the occurrence of a fundamental change (as defined in the indenture governing the Notes) at a purchase price equal to 100% of the principal amount of the Notes to be purchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion, we will be required to make cash payments in respect of the Notes being converted. Furthermore, the indenture governing the Notes provides that, in the event of an event of default (as defined in the indenture) for the Notes, it may result in the principal, premium, if any, and interest, if any, becoming due prior to the maturity date for the Notes. There can be no assurance that we will be able to pay these amounts when due, or that we will be able to refinance this indebtedness on acceptable terms or at all.

As a result of our increased level of indebtedness after the completion of the Notes Offering:

- our level of vulnerability to adverse economic conditions and competitive pressures will be heightened;
- we will be required to dedicate a portion of our liquidity position or cash flow from operations to interest payments, limiting the availability of cash for other purposes;
- our flexibility in planning for, or reacting to, changes in our business and industry may be more limited; and
- our ability to obtain additional financing in the future for working capital, capital expenditures, acquisitions, investments or general corporate purposes may be impaired.

We cannot be sure that our leverage resulting from the completion of the Notes Offering will not materially and adversely affect our ability to finance our operations or capital needs or to engage in other business activities. In addition, we cannot be sure that additional financing will be available when required or, if available, will be on terms satisfactory to us.

***Servicing the Notes will require a significant amount of cash, and we may not have sufficient cash flow from our business to repay the Notes.***

Our ability to make scheduled payments of the principal and interest on or to refinance the Notes depends on our future business operations and liquidity, which are subject, to some extent, on economic, financial, regulatory, competitive and other factors that are beyond our control, including, without limitation, market acceptance of our products, regulatory approval for our products under development, and the impacts and disruptions caused by the COVID-19 global pandemic. Our business may not generate or sustain a level of cash flow from operations sufficient to service the Notes and any future indebtedness we may incur, while operating our business and making necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as reducing or delaying capital expenditures, selling or licensing assets, refinancing indebtedness, or obtaining additional equity capital. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations. Our ability to successfully engage in these activities will depend on a number of factors, including the value of our assets, our operating results and financial condition, the value of our common stock, and the status of the capital markets at such time. We may not be able to engage in any of these activities on commercially reasonable terms or at all, which could result in a default on the Notes or our future indebtedness.

***We may incur substantial additional debt or take other actions which could diminish our ability to make payments on the Notes.***

We and our subsidiaries are not prevented by the terms of the indenture governing the Notes, or otherwise, from incurring substantial additional indebtedness in the future, which may include the issuance of secured debt. We are not restricted under the terms of the indenture governing the Notes from incurring additional indebtedness, securing existing or future indebtedness, or recapitalizing our indebtedness. We are similarly not restricted under the terms of the indenture from taking a number of other actions that could have the effect of diminishing our ability to make payments on the Notes when due.

***We may not have the ability to raise the funds necessary to repurchase the Notes upon a fundamental change, or to settle conversions of the Notes, and our future indebtedness may contain limitations on our ability to pay cash upon repurchase or conversion of the Notes.***

Holders of the Notes have the right to require us to repurchase their Notes upon the occurrence of a fundamental change at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. In addition, upon conversion of the Notes, unless we elect to deliver solely shares of our common stock to settle such conversion, we will be required to make cash payments in respect of the Notes being converted. However, we may not have enough available cash or be able to obtain financing at the time we are required to make repurchases of Notes surrendered therefor or Notes being converted. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited by law, by regulatory authority or by agreements governing our future indebtedness. Our failure to repurchase Notes at a time when the repurchase is required by the indenture, or to pay any cash payable on future conversions of the Notes as required by the indenture, would constitute an event of default under the indenture. An event of default under the indenture, or the fundamental change itself, could also lead to an event of default under agreements governing any future indebtedness we may have issued. If the repayment of the related indebtedness were to be accelerated, we may not have sufficient funds to repay the indebtedness, while also repurchasing the Notes or making cash payments upon conversions thereof.

***The conditional conversion feature of the Notes may adversely affect our liquidity.***

In the event the conditional conversion feature of the Notes is triggered, holders of the Notes will be entitled to convert the Notes at any time during specified periods at their option. If one or more holders elect to convert their Notes, unless we elect to satisfy our conversion obligation by delivering solely shares of our common stock, we would be required to settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. In addition, even if holders do not elect to convert their Notes, we could be required, under applicable accounting rules, to reclassify all or a portion of the outstanding principal of the Notes as a current rather than long-term liability, which would adversely affect our liquidity.

***The accounting method for convertible debt securities that may be settled in cash, such as the Notes, could have a material effect on our reported financial results.***

Under Accounting Standards Codification 470-20, Debt with Conversion and Other Options, an entity must evaluate the ability to separately account for the liability and equity components of the convertible debt instruments (such as the Notes) that may be settled entirely or partially in cash upon conversion in a manner that reflects the issuer's economic interest cost. The determination of the effect of the guidance on the accounting for the Notes is that the equity component has been included in the additional paid-in capital section of stockholders' equity on our consolidated balance sheet at the issuance date, and the value of the equity component has been treated as debt discount for purposes of accounting for the debt component of the Notes. As a result, we have recorded non-cash interest expense as a result of the amortization of the discounted carrying value of the Notes to their face amount over the term of the Notes. Accordingly, we have reported a greater net loss in our financial results because the guidance requires interest to include both the amortization of the debt discount and the instrument's coupon interest rate, which could adversely affect the trading price of our common stock.

In addition, under certain circumstances, convertible debt instruments (such as the Notes) that may be settled entirely or partly in cash are currently accounted for utilizing the treasury stock method, the effect of which is that the shares issuable upon conversion of the Notes are not included in the calculation of diluted earnings (loss) per share except to the extent that the conversion value of the Notes exceeds their principal amount. Under the treasury stock method, for diluted earnings (loss) per share purposes, the transaction is accounted for as if the shares of common stock that would be necessary to settle such excess, if we elected to settle such excess in shares, are issued.

In June 2020, the Financial Accounting Standards Board issued ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which is intended to simplify the accounting for convertible instruments. Under the new guidance, an entity is no longer required to separately account for the liability and equity components of convertible debt instruments. ASU 2020-06 is effective for public business entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is in the process of determining whether to early adopt the new standard and the method of adoption. When we adopt this new guidance, this could have the impact of reducing non-cash interest expense, and thereby reducing our net loss, or increasing our net income.

***Conversion of the Notes will, to the extent we deliver shares upon conversion of such Notes, dilute the ownership interest of existing stockholders and may otherwise have a negative impact on the trading price of our common stock.***

The conversion of some or all of the Notes will dilute the ownership interests of existing stockholders, including holders who had previously converted their Notes, to the extent we deliver shares upon conversion of any of the Notes. Any sales in the public market of the common stock issued upon the conversion of the Notes could adversely affect prevailing market prices of our common stock. In addition, the perception that some or all of the Notes may be converted into shares of our common stock in the future could have a negative impact on the trading price of our common stock.

***The fundamental change repurchase feature of the Notes may delay or prevent an otherwise beneficial takeover attempt.***

The terms of the Notes require us to repurchase the Notes in the event of a fundamental change. A takeover of the Company would trigger an option of the holders of the Notes to require us to repurchase the Notes. In addition, if a make-whole fundamental change (as defined in the indenture) occurs prior to the maturity date of the Notes, we will, in some cases, be required to increase the conversion rate of the Notes for a holder that elects to convert its Notes in connection with such make-whole fundamental change. These and other provisions set forth in the indenture may have the effect of delaying or preventing a takeover of the Company.

***The Capped Call Transactions may affect the value of the Notes and our common stock.***

In connection with the issuance of the Notes, we entered into capped call transactions (the Capped Call Transactions) with the option counterparties. The Capped Call Transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of the Notes and/or offset any cash payments we are required to make in excess of the principal amount of converted Notes, as the case may be, with such reduction and/or offset subject to a cap.

The option counterparties or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Notes (and are likely to do so during any observation period related to a conversion of Notes). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Notes, which could affect a Note holder's ability to convert the Notes and, to the extent the activity occurs during any observation period related to a conversion of Notes, it could affect the number of shares and the value of the consideration that a Note holder will receive upon conversion of the Notes. In addition, if such Capped Call Transactions fail to become effective, the option counterparties or their respective affiliates may unwind their hedge positions with respect to our common stock, which could adversely affect the value of our common stock.

The potential effect, if any, of any of these transactions and activities on the market price of our common stock or the Notes will depend in part on market conditions and cannot be ascertained at this time, but any of these activities could adversely affect the value of our common stock and the value of the Notes and, under certain circumstances, the ability of the Note holders to convert the Notes.

We do not make any representation or prediction as to the direction or magnitude of any potential effect that the transactions described above may have on the value of the Notes or the trading price of our common stock. In addition, we do not make any representation that the option counterparties will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

***We are subject to counterparty risk with respect to the Capped Call Transactions.***

The option counterparties are financial institutions, and we will be subject to the risk that any or all of them may default under the Capped Call Transactions. Our exposure to the credit risk of the option counterparties will not be secured by any collateral. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under our transactions with that option counterparty. Our exposure will depend on many factors but, in general, an increase in our exposure will be correlated to an increase in the market price and volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of the option counterparties.

**Item 1B. Unresolved Staff Comments.**

Not applicable.

**Item 2. Properties.**

Substantially all of our operations are currently conducted at leased facilities, including our manufacturing processes, research and development activities, customer and technical support, and management and administrative functions. As of December 31, 2020, we occupied facilities with an aggregate total of approximately 352,000 square feet, as follows:

- Roselle Street Leases: 77,458 square feet of general office and laboratory space located on Roselle Street in San Diego, California. All of our existing leases for facilities on Roselle Street are scheduled to expire in May 2023.
- Vista Sorrento Parkway Lease: 59,013 square feet of general office space located on Vista Sorrento Parkway in San Diego, California, which is scheduled to expire in January 2023. We have a one-time option to extend the term of the Vista Sorrento Parkway Lease for a period of four years, by delivering written notice to the landlord in accordance with the terms of the lease.
- Barnes Canyon Lease: 48,880 square feet of general office, manufacturing and warehouse space located on Barnes Canyon Road in San Diego, California, which is scheduled to expire in November 2023. We have a one-time option to extend the term of the Barnes Canyon Lease for a period of not less than three years and not greater than five years, by delivering notice to the landlord in accordance with the terms of the lease.
- Marindustry Place Lease: 40,490 square feet of general office and warehouse space located on Marindustry Place in San Diego, California, which is scheduled to expire in April 2026. We have a one-time option to extend the term of the Marindustry Place Lease for a period of no less than three years and no more than five years by delivering written notice to the landlord in accordance with the terms of the lease.

- High Bluff Lease: 30,703 square feet of general office space located on High Bluff Drive in San Diego, California. The High Bluff Lease is scheduled to expire in March 2022.

- Shoreline Lease: 94,562 square feet of general office space located on Shoreline Drive in Boise, Idaho. The Shoreline Lease term commenced in July 2020, and is scheduled to expire in June 2027. We have a one-time option to extend the term of the Shoreline Lease for a period of three years by delivering written notice to the landlord in accordance with the terms of the lease.

- Markham Lease: 667 square feet of general office space located in Markham, Ontario, Canada. This is a month-to-month lease that can be canceled by delivering written notice to the landlord in accordance with the terms of the lease.

We believe that the facilities that we presently occupy will be sufficient to support our current operations and that suitable additional facilities would be available to us should our operations require it.

**Item 3. Legal Proceedings.**

In May 2020, we were named as a defendant in three California state court class action lawsuits arising from a data breach that we experienced in January 2020. Collectively, these lawsuits seek statutory, compensatory, actual, and punitive damages; equitable relief, including restitution; pre- and post-judgment interest; injunctive relief; and attorney fees, costs, and expenses from us. On July 24, 2020, these three pending lawsuits were consolidated into a single case in the Superior Court of the State of California in the County of San Bernardino entitled *Joseph Deluna et al v. Tandem Diabetes Care, Inc.* The consolidated case alleges violations of the Confidentiality of Medical Information Act (CMIA), CCPA, California's Unfair Competition Law (UCL), and breach of contract. We filed a demurrer seeking dismissal of all claims, which was heard by the Court on October 27, 2020, and which resulted in the following outcome: (i) the demurrer of the CMIA claim was denied; and (ii) the demurrer of the CCPA, UCL, and contract claims were sustained with leave to amend the pending complaint. A second amended complaint was filed by the plaintiffs on November 25, 2020 and we filed a demurrer to such second amended complaint on December 28, 2020.

In September 2020, we were named as a defendant in a lawsuit entitled *Buck Walsh, individually and on behalf of others similarly situated v. Tandem Diabetes Care, Inc.*, which was filed in the Superior Court of the State of California in San Diego County. The alleged violations include business and professions code and labor code violations for failure to compensate wages, unpaid meal and rest periods, and failure to reimburse for necessary business-related expenses. The proposed class of plaintiffs includes hourly paid or non-exempt employees of the Company who were employed from April 6, 2016 through the date of adjudication.

Although we intend to vigorously defend against these claims, there is no guarantee that we will prevail. Accordingly, we are unable to determine the ultimate outcome of these lawsuits or determine the amount or range of potential losses associated with the lawsuits.

From time to time, we are involved in various other legal proceedings arising from or related to claims incident to the normal course of our business activities, including actions with respect to intellectual property, employment, regulatory, product liability and contractual matters. Although the results of such legal proceedings and claims cannot be predicted with certainty, we believe we are not currently a party to any legal proceeding(s) which, if determined adversely to us, would, individually or taken together, have a material adverse effect on our business, operating results, financial condition or cash flows. However, regardless of the merit of the claims raised or the outcome, legal proceedings may have an adverse impact on us as a result of defense and settlement costs, diversion of management time and resources, and other factors.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

### Market Information

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

| | Price Range | |
|---|---|---|
| | High | Low |
| **Year Ended December 31, 2020** | | |
| First Quarter | $ 91.65 | $ 43.69 |
| Second Quarter | $ 99.33 | $ 59.24 |
| Third Quarter | $ 116.89 | $ 91.93 |
| Fourth Quarter | $ 123.74 | $ 84.56 |
| | | |
| **Year Ended December 31, 2019** | | |
| First Quarter | $ 74.81 | $ 32.00 |
| Second Quarter | $ 72.19 | $ 51.37 |
| Third Quarter | $ 74.30 | $ 56.69 |
| Fourth Quarter | $ 71.99 | $ 52.31 |

### Holders of Record

As of February 19, 2021, there were approximately 44 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

### Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans, as set forth in this Annual Report under the caption "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in Part III, Item 12, is incorporated herein by reference.

### Unregistered Sales of Equity Securities

None.

### Repurchases of Equity Securities

We did not repurchase any of our equity securities during the years ended December 31, 2020 and 2019.

## PART II

### Item 6. Selected Financial Data.

*The selected financial data presented below under the heading "Consolidated Statement of Operations Data" for the years ended December 31, 2020, 2019, and 2018 and the selected financial data presented below under the heading "Consolidated Balance Sheet Data" as of December 31, 2020 and 2019 have been derived from our audited consolidated financial statements included in Part II, Item 8 of this Annual Report. The selected financial data presented below under the heading "Consolidated Statement of Operations Data" for the years ended December 31, 2017 and 2016 and the selected financial data presented below under the heading "Consolidated Balance Sheet Data" as of December 31, 2018, 2017 and 2016 are derived from our audited consolidated financial statements not included in this Annual Report. The selected financial data presented below should be read in conjunction with the information included under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 and the consolidated financial statements and the related notes in Part II, Item 8. Our historical financial results for any prior period are not necessarily indicative of results to be expected in any future period.*

**Consolidated Statement of Operations Data:**

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| **(in thousands, except per share data)** | **2020** | **2019** | **2018** | **2017** | **2016** |
| Sales | $ 498,830 | $ 362,305 | $ 183,866 | $ 107,601 | $ 84,248 |
| Cost of sales | 238,310 | 168,093 | 94,044 | 63,507 | 60,656 |
| Gross profit | 260,520 | 194,212 | 89,822 | 44,094 | 23,592 |
| Operating expenses: | | | | | |
| Selling, general and administrative | 204,903 | 165,735 | 105,226 | 86,377 | 82,834 |
| Research and development | 63,574 | 45,199 | 29,227 | 20,661 | 18,809 |
| Total operating expenses | 268,477 | 210,934 | 134,453 | 107,038 | 101,643 |
| Operating loss | (7,957) | (16,722) | (44,631) | (62,944) | (78,051) |
| Total other income (expense), net | (28,325) | (7,882) | (77,929) | (10,081) | (5,411) |
| Loss before income taxes | (36,282) | (24,604) | (122,560) | (73,025) | (83,462) |
| Income tax expense (benefit) | (1,900) | 149 | 51 | 8 | (15) |
| Net loss | $ (34,382) | $ (24,753) | $ (122,611) | $ (73,033) | $ (83,447) |
| Net loss per share, basic and diluted | $ (0.56) | $ (0.42) | $ (2.55) | $ (12.87) | $ (27.30) |
| Weighted average shares used to compute basic and diluted net loss per share | 60,990 | 58,507 | 48,129 | 5,677 | 3,057 |

**Consolidated Balance Sheet Data:**

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| **(in thousands)** | **2020** | **2019** | **2018** | **2017** | **2016** |
| Cash and cash equivalents | $ 94,613 | $ 51,175 | $ 41,826 | $ 13,700 | $ 44,678 |
| Short-term investments | $ 390,323 | $ 125,283 | $ 87,201 | $ 479 | $ 8,860 |
| Working capital | $ 533,383 | $ 176,745 | $ 121,597 | $ 28,071 | $ 60,616 |
| Property and equipment, net | $ 50,022 | $ 32,923 | $ 17,151 | $ 19,631 | $ 18,409 |
| Total assets | $ 716,415 | $ 326,110 | $ 206,294 | $ 95,346 | $ 112,392 |
| Notes payable | $ 202,984 | $ — | $ — | $ 76,541 | $ 78,960 |
| Total stockholders' equity (deficit) | $ 366,305 | $ 194,979 | $ 131,275 | $ (29,148) | $ (5,927) |

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

*You should read the following discussion and analysis together with "Selected Financial Data" in Part II, Item 6 and our consolidated financial statements and related notes in Part II, Item 8. The following discussion contains forward-looking statements, which statements are subject to considerable risks and uncertainties. Our actual results could differ materially from those expressed or implied in any forward-looking statements as a result of various factors, including those set forth under the caption "Risk Factors" in Part I, Item 1A.*

*Certain statements contained in this Annual Report are "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act, and are subject to the "safe harbor" created by these sections. Future filings with the SEC, future press releases and future oral or written statements made by us or with our approval, which are not statements of historical fact, may also contain forward-looking statements. Because such statements include risks and uncertainties, many of which are beyond our control, actual results may differ materially from those expressed or implied by such forward-looking statements. Some of the factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements can be found under the caption "Risk Factors" in Part I, Item 1A, and elsewhere in this Annual Report. The forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they are made.*

### Overview

We are a medical device company with a positively different approach to the design, development and commercialization of products for people with insulin-dependent diabetes. Diabetes management can vary greatly person-to-person, creating multiple market segments based on clinical needs and personal preferences. We aim to improve and simplify the lives of all people living with insulin-dependent diabetes and those of their healthcare providers, by delivering innovative hardware and software solutions, as well as best-in-class customer support. Our goal is to lead in insulin therapy management by building a robust ecosystem and portfolio of data-driven products and services around our flagship insulin pumps. We believe our competitive advantage is rooted in our consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing, sales and support activities principally focus on our flagship pump platform, the t:slim X2 Insulin Delivery System (t:slim X2) and our complementary product offerings.

Since our initial commercial launch, we have been able to rapidly innovate and bring more products to market than our competitors. We have commercially launched seven insulin pump configurations in the United States since 2012 and three insulin pump configurations outside the United States since 2018. Today, our software-updatable t:slim X2 hardware platform represents 100% of our new pump shipments.

Our simple-to-use t:slim X2 is based on our proprietary technology platform and is the smallest durable insulin pump available. We have commercially offered our pump technology integrated with three generations of Dexcom's continuous glucose monitoring (CGM) sensors. The t:slim X2 is the only pump on which remote software updates have been commercially available in the United States. This experience, which offers and supports different software updates, provides us with a unique competitive advantage. Two of our updates provided our users access to our AID algorithms, Basal-IQ technology and Control-IQ technology. Basal-IQ technology launched in August 2018 and is a predictive low glucose suspend feature that is designed to temporarily suspend insulin delivery to help reduce the frequency and duration of hypoglycemic events. Control-IQ technology launched in January 2020 and is an advanced hybrid-closed loop feature, designed to help increase a user's time in targeted glycemic range. It is the first and only system cleared by the FDA to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. Outside the United States we began selling efforts with t:slim X2 with Dexcom G5 integration in the third quarter of 2018, offering no-cost software updates for Basal-IQ technology in the third quarter of 2019 and for Control-IQ technology beginning in the third quarter of 2020. We intend to complete our scaled launch of Control-IQ technology outside the United States in the first half of 2021, subject to securing necessary regulatory clearances or approvals. We continue to offer both AID algorithms on the market to support the varying needs of people living with diabetes.

Our insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, we sell disposable products that are used together with our pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body, as well as a variety of accessories designed for enhanced usability. We also offer t:connect, a web-based data management application that provides users, their caregivers and their healthcare providers with a fast, easy and visual way to display diabetes therapy management data from our pumps, integrated CGMs and supported blood glucose meters.

In the four-year period ended December 31, 2020, we shipped more than 215,000 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. More than 170,000 of these pumps were shipped to customers in the United States, and nearly 45,000 were shipped to international markets.

For the years ended December 31, 2020, 2019 and 2018, our consolidated sales were $498.8 million, $362.3 million, and $183.9 million, respectively. For the years ended December 31, 2020, 2019 and 2018, our net loss was $34.4 million, $24.8 million, and $122.6 million, respectively. Worldwide pump sales accounted for 63%, 68%, and 67% of our total sales, respectively, for the years ended December 31, 2020, 2019 and 2018, while pump-related supplies and accessories accounted for the remainder in each year. Our accumulated deficit as of December 31, 2020 and 2019 was $659.2 million and $624.8 million, respectively. These amounts included $292.1 million and $216.6 million of non-cash stock-based compensation charges and non-cash changes in the fair value of common stock warrants as of December 31, 2020 and 2019, respectively.

In support of our digital health strategy, we continue to offer and improve t:connect and the Tandem Device Updater, and also develop and launch other complementary offerings. In the first quarter of 2020, we began a limited launch in the United States of our first-generation t:connect mobile application, followed by general availability in July 2020. This mobile app wirelessly uploads pump data to our t:connect diabetes management application, receives notification of pump alerts and alarms, and provides a discrete, secondary display of glucose and insulin data. The availability of this mobile app is intended to reduce patient burden and increase healthcare provider office efficiency by reducing the manual and more time-consuming steps historically required for data extraction. In addition, in the second quarter of 2020, we acquired Sugarmate, the developer of a popular app designed to help people visualize diabetes therapy data in innovative ways that also connects with many other popular, consumer-friendly devices. We intend to support the Sugarmate app in addition to our t:connect mobile app to provide a wide variety of features intended to benefit a broad community of people with diabetes.

In the United States, we have rapidly increased sales since the commercial launch of our first product by expanding our sales, clinical and marketing organization, by developing, commercializing and marketing multiple differentiated products that utilize our proprietary technology platform and consumer-focused approach, and by providing strong customer support. Our sales have further increased following our scaled product launches in geographies outside the United States. We believe that by demonstrating our product benefits and the shortcomings of existing insulin therapies, more people will choose our insulin pumps for their therapy needs, allowing us to further penetrate and expand the market worldwide. In addition, we believe publications, such as the results from studies using Control-IQ technology that were published in the New England Journal of Medicine in October 2019 and August 2020, and post-market real-world data will be valuable in demonstrating the clinical outcome benefits derived from our system to healthcare providers and payors. We also believe we are positioned well to address consumers' needs and preferences with our current products and products under development and by offering customers access to our future innovations through the Tandem Device Updater, as they are approved by the local regulating bodies. At the same time, by innovating and offering new product features and benefits using our t:slim X2 platform, we are able to leverage a shared global manufacturing and supply chain infrastructure. In the United States, we are able to leverage a single sales, marketing, and clinical organization, as well as our customer support services. In Canada, we have a separate sales organization and our customer support infrastructure benefits from close collaboration with our United States organization. In other international geographies, we have contracted with experienced distribution partners to commercialize and support our t:slim X2 platform.

***COVID-19 Global Pandemic Impact and Considerations***

We are deemed an essential healthcare business under applicable governmental orders based on the critical nature of the products we offer and the communities we serve. We experienced a modest impact from the COVID-19 global pandemic during the first quarter of 2020, which became more pronounced beginning in the second quarter and continuing through the end of the year. We originally anticipated that our sales outside the United States would experience a greater proportional impact due to differences in the sales process in domestic versus international markets. Initially, the impact on our business was relatively consistent worldwide but we have since seen varying degrees of impact in international markets based on local conditions. We anticipate that our sales and operating results will continue to be adversely impacted and subject to unpredictable variability for the duration of the pandemic. For example, we have experienced delays in certain programs of up to three or six months from when they were originally planned, such as human factors studies associated with our product development efforts. In addition, regulatory timelines may be difficult to predict as the FDA has stated that its review process may take longer than normal due to the impact of the COVID-19 global pandemic. The full extent of the impact of the COVID-19 global pandemic on our future business and operations is difficult to estimate and will depend on a number of factors including the scope and duration of the COVID-19 global pandemic and the relative impact of COVID-19 on the business operations of our contract manufacturers, suppliers and competitors.

We have taken steps to prioritize the health and safety of our employees and customers during the COVID-19 global pandemic, while working to maintain a continuous supply of products, training and customer support. To that end, we have increased the frequency of our communications to employees, suppliers, customers, and healthcare providers. Since March 2020, we have restricted non-essential employee travel, banned visitors from all of our facilities, and transitioned those employees able to perform their job function outside of our facilities to a remote work environment. For our field-based sales and clinical employees, we initially discontinued all in-person activities and began utilizing technology to remotely engage healthcare providers and customers. We continue to work closely with our healthcare providers and customers, remaining flexible in our method of interaction. To help ensure the safety and health of our employees in manufacturing and warehousing positions involved in production and fulfillment operations, we have implemented preventative measures to comply with social distancing requirements and require temperature checks of our employees before each shift.

In response to developments surrounding the COVID-19 global pandemic, we initiated discussions with our key suppliers in early 2020 regarding their abilities to fulfill existing orders, and we have continued to regularly assess their capacity. During the first six months of 2020, we experienced certain challenges managing our inventory, primarily due to the impacts of the COVID-19 global pandemic. For example, in the first quarter of 2020, we observed customers purchasing cartridges and infusion sets at a higher rate than anticipated. In addition, during the second quarter of 2020, our infusion set manufacturer experienced certain inventory constraints which resulted in us asking some customers to accept substitutions of similar products to prevent delays in order fulfillment. At this time, we believe many of our suppliers are deemed essential businesses under applicable governmental orders, and we have not experienced, and do not anticipate experiencing, disruption in our ability to manufacture insulin pumps and cartridges due to component procurement limitations. Additionally, our third-party cartridge manufacturer completed validation and commenced commercial-scale manufacturing near the end of the first quarter to supplement our existing cartridge manufacturing capacity, which we believe will assist us in meeting product demand in future periods. Our finished goods and raw material inventory, as well as available manufacturing capacity, position us well to respond to unforeseen disruptions in the near term.

Commercially, we have been communicating with our customers and healthcare providers through social media, direct email outreach and our website, in addition to regular communications sent by our sales and clinical employees. We are also leveraging our technology platforms, such as our t:connect diabetes management application, to support healthcare providers, as many of them are increasingly utilizing telehealth capabilities in their practices. By the end of the first quarter of 2020, we expanded our remote new pump training offering to all customers who purchased a t:slim X2 insulin pump, and in the third quarter, we resumed offering in-person trainings under specific conditions.

We are prudently managing our use of cash and completed a convertible debt financing in May 2020 to further strengthen our balance sheet. We believe that our total cash and investments on hand are sufficient to sustain our existing operations for at least the next 12 months from the date of this filing. In the meantime, we are focused on making necessary investments in the organization as originally planned to continue to progress against our long-term sales and profitability initiatives, including recruitment of key employees, advancement of our R&D pipeline, and implementation of technology solutions. We will continue to evaluate our business operations and strategy based on new information as it becomes available and will make changes that we consider necessary in light of this information.

***Products Under Development***

Our products under development support our strategy of focusing on both consumer and clinical needs, and include a connected (mobile) health offering, a next-generation hardware platform, which we refer to as the t:sport Insulin Delivery System (t:sport), AID system enhancements, and additional CGM integrations with our current and future products. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionality that will allow us to meet the needs of people in differentiated segments of the insulin-dependent diabetes market, including the following:

- *Connected (Mobile) Health Offerings* – In July of 2020, we began offering the first version of our t:connect mobile application that wirelessly uploads pump data to our cloud-based t:connect diabetes management application, receives notification of pump alerts and alarms, and provides a discrete, secondary display of glucose and insulin data. Future updates of our mobile application are planned to include mobile bolus delivery, additional pump control features, integrate other health-related information from third-party sources and support future capabilities for our products under development. We plan to transition our mobile health offerings to a single, global digital platform, which is intended to provide all users, including pump users, caregivers and healthcare providers, with a simplified and tailored user experience. The platform is being designed to enhance the user experience, streamline the pump and supplies purchasing process, and provide internal efficiencies. In the future, data from our centralized system may be used for new product development, continuous product improvement, and for the generation of health economic outcomes data, and may ultimately support other advanced technology and patient monitoring services.

- *t:sport Insulin Delivery System* – Approximately half the size of our t:slim X2 pump, the t:sport pump is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. We anticipate that t:sport will feature a 200-unit cartridge, an on-pump bolus button, a rechargeable battery, an AID algorithm, and a Bluetooth radio. t:sport is being designed for use with leading U-100 insulins, and we are evaluating the use of insulin concentrates to provide to people with greater insulin needs. We anticipate that t:sport will be our first insulin pump to support full pump-control from our mobile application, subject to FDA review and approval. A separate controller may be offered in addition to full mobile control availability.

- *AID Enhancements* – We intend to further enhance our automated insulin delivery system and are considering alternative strategies to deliver new features and benefits to our customers on a regular basis. In addition to algorithm enhancements intended to improve clinical outcomes, we are also developing new features for greater personalization and refinements to the overall system usability.

- *Additional CGM Integration* – In June 2020 we announced an agreement with Abbott to develop and commercialize integrated diabetes solutions that combine Abbott's CGM technology with our insulin delivery systems to provide more options for people to manage their diabetes. Following the completion of our integrated product development work, and after obtaining required regulatory clearances or approvals, we intend to focus our initial commercial activities on integrated products in the U.S. and Canada, with additional geographies considered in the future.

For additional information, see the section of this Annual Report under the caption "Business" in Part I, Item 1.

***Pump Shipments***

From inception through June 2018, we derived nearly all of our sales from the shipment of insulin pumps and associated supplies to customers in the United States. Starting in the third quarter of 2018, we commenced sales of our t:slim X2 insulin pump in select international geographies. We consider the number of insulin pump units shipped per quarter domestically and internationally to be an important metric for managing our business.

In the four-year period ended December 31, 2020, we shipped more than 215,000 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. Approximately 170,000 of these pumps were shipped to customers in the United States, and nearly 45,000 were shipped to international markets. In the year ended December 31, 2020, we shipped 90,771 insulin pumps worldwide, compared to 73,431 insulin pumps shipped in 2019.

Pump shipments to customers in the United States by fiscal quarter were as follows:

| | Pump Units Shipped for Each of the Three Months Ended in Respective Years - U.S. | | | | |
|---|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 | Total |
| 2012 | — | 9 | 204 | 844 | 1,057 |
| 2013 | 852 | 1,363 | 1,851 | 2,406 | 6,472 |
| 2014 | 1,723 | 2,235 | 2,935 | 3,929 | 10,822 |
| 2015 | 2,487 | 3,331 | 3,431 | 6,234 | 15,483 |
| 2016 | 4,042 | 4,582 | 3,896 | 4,418 | 16,938 |
| 2017 | 2,816 | 3,427 | 3,868 | 6,950 | 17,061 |
| 2018 | 4,444 | 5,447 | 7,379 | 12,935 | 30,205 |
| 2019 | 9,669 | 12,799 | 13,814 | 17,453 | 53,735 |
| 2020 | 13,158 | 14,735 | 18,380 | 24,552 | 70,825 |

Pump shipments to international customers by fiscal quarter were as follows:

| | Pump Units Shipped for Each of the Three Months Ended in Respective Years - International | | | | |
|---|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 | Total |
| 2018 | N/A | N/A | 1,055 | 3,233 | 4,288 |
| 2019 | 5,063 | 8,459 | 4,025 | 2,149 | 19,696 |
| 2020 | 4,220 | 3,952 | 3,641 | 8,133 | 19,946 |

***Trends Impacting Financial Results***

Overall, we have experienced considerable sales growth since the commercial launch of our first product in the third quarter of 2012, while incurring operating losses since our inception. Our operating results have historically fluctuated on a quarterly or annual basis, particularly in periods surrounding anticipated regulatory approvals, the commercial launch of new products by us and our competitors, the commercial launch of our products in geographies outside of the United States and due to general seasonality in the United States. We expect these periodic fluctuations in our operating results to continue.

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

- market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers;
- the introduction of new products, treatment techniques or technologies for the treatment of diabetes, including the timing of the commercialization of new products by us and our competitors;
- seasonality in the United States associated with annual insurance deductibles and coinsurance requirements associated with the medical insurance plans utilized by our customers and the customers of our distributors;
- incidence of disease or illness, including the COVID-19 global pandemic, that may impact customer purchasing patterns or disrupt our supply chain;
- timing of holidays and summer vacations, which may vary by geography;
- the buying patterns of our distributors and other customers, both domestically and internationally;
- changes in the competitive landscape, including as a result of companies entering or exiting the diabetes therapy market;
- access to adequate coverage and reimbursement for our current and future products by third-party payors, and reimbursement decisions by third-party payors;
- the magnitude and timing of any changes to our facilities, manufacturing operations and other infrastructure, and factors impacting our ability to access our facilities;

- the impact of any privacy breaches, which may subject us to legal and regulatory proceedings and substantial fines, penalties and expenses, as well as significant reputational harm;
- anticipated and actual regulatory approvals of our products and competitive products; and
- product recalls impacting, or the suspension or withdrawal of regulatory clearance or approval relating to, our products or the products of our competitors.

In addition to these general trends, we believe the following specific factors have materially impacted, and could continue to materially impact, our business going forward:

- the disruptions caused by the COVID-19 global pandemic on suppliers, third-party manufacturers, healthcare providers, distributors and our existing or potential customers;
- continued increase, in demand following the commercial launch of t:slim X2 with Control-IQ technology, and the demonstrated success of our Tandem Device Updater;
- anticipated new product launches;
- increased opportunity to achieve customer renewals as customers become eligible for insurance reimbursement to purchase a new insulin pump at the end of the typical four-year reimbursement cycle;
- opportunity to transition former customers of Animas Corporation (Animas) to our t:slim X2 insulin pump in 2018 and 2019 following the announcement by Johnson & Johnson that it had discontinued the operations of Animas and discontinued the availability of Animas pump supplies in September 2019;
- designation by UnitedHealthcare of one of our competitors as its preferred, in-network durable medical equipment provider of insulin pumps for most customers age seven and above from July 2016 through June 2020;
- ability to enter into and maintain agreements with CGM partners for CGM integration;
- expansion and new product launches in select international geographies, including initial orders to stock inventories; and
- ability to effectively scale our operations to support rapid growth, including expanding our facilities, advancing our research and development efforts, increasing manufacturing capacity through third-party manufacturers, and hiring and retaining employees in customer service and support functions.

In addition to working to achieve our sales growth expectations, in the long-term we intend to continue to leverage our infrastructure investments to realize additional manufacturing, sales, marketing and administration cost efficiencies with the goal of improving our operating margins and ultimately achieving sustained profitability. We achieved profitability for the first time in the fourth quarter of 2018, and again in both the fourth quarters of 2019 and 2020. Though we may be unable to achieve profitability consistently from period to period, we believe we can ultimately achieve sustained profitability by driving incremental sales growth in U.S. and international markets, meeting our pump renewal sales objectives, maximizing manufacturing efficiencies on increased production volumes, and leveraging the investments made in our sales, clinical, marketing and customer support organizations.

**Components of Results of Operations**

***Sales***

We offer products for people with insulin-dependent diabetes. We commenced commercial sales of our original t:slim insulin pump platform in the United States in the third quarter of 2012 and continued to launch various iterations of that platform during the following years. In October 2016, we began shipping our flagship pump platform, the t:slim X2 insulin pump. The t:slim X2 insulin pump platform with advanced software algorithms and remote software update capabilities, now represents 100% of our new pump shipments and is used by nearly all of our in-warranty customers. Our products also include disposable cartridges and infusion sets, as well as our complementary t:connect, Tandem Device Updater and mobile application products. We also offer additional accessories including protective cases, belt clips, and power adapters, although sales of these products are not significant.

We primarily sell our products through national and regional distributors in the United States on a non-exclusive basis. These distributors are generally providers of medical equipment and supplies to individuals with diabetes. Our primary end customers are people with insulin-dependent diabetes. Similar to other durable medical equipment, the primary payor is generally a third-party insurance carrier and the customer is usually responsible for any medical insurance plan copay or coinsurance requirements. We believe our existing sales, clinical, and marketing infrastructure will allow us to continue to increase sales by allowing us to promote our products to a greater number of potential customers, caregivers and healthcare providers, although the COVID-19 global pandemic has had, and may continue to have, an adverse impact on our sales.

In the third quarter of 2018, we began the launch of our t:slim X2 hardware platform through distribution partners outside the United States, including in select European countries, Australia, New Zealand, and South Africa. The software version on the t:slim X2 hardware platform has progressed from Dexcom G5 CGM integration at initial launch, followed by Basal-IQ technology scaling across various international markets beginning in the second quarter of 2019, and more recently our Control-IQ technology beginning in the third quarter of 2020. Our launch of Control-IQ technology in international markets will continue to scale across all geographies through the first half of 2021, contingent upon regulatory and reimbursement approvals.

In the first quarter of 2020, we expanded into additional international markets, including initial orders to support product launches in France and Germany occurring in the second and third quarters of 2020, respectively. Our independent international distributor partners perform all sales, customer support and training in their respective markets. In Canada, we market with a direct sales force and, similar to the United States, use distribution partners for certain billing and fulfillment activities. Historically, we have experienced consistent levels of reimbursement for our products in the United States, but we expect the average sales price will vary in international markets based on a number of factors, such as the geographical mix, nature of the reimbursement environment, government regulations and the extent to which we rely on distributor relationships to provide sales, clinical and marketing support.

In general, in the United States we have experienced pump shipments being weighted heavily towards the second half of the year, with the highest percentage of pump shipments expected in the fourth quarter due to the nature of the reimbursement environment. Consistent with these historical seasonality trends, our domestic pump shipments have typically decreased significantly from the fourth quarter to the following first quarter. Internationally, we do not expect this same impact from seasonality associated with reimbursement, although the quarterly sales trends may be impacted by a number of factors, including summer vacations and product launches into new geographies. While the opportunity to transition former Animas customers positively impacted our 2019 quarterly sales trends worldwide, we did not see a material benefit in 2020.

During 2020, the COVID-19 global pandemic had a major impact on businesses around the world. While we experienced only a modest negative impact from the pandemic during the first quarter of 2020, which became more pronounced in the second quarter and remained through the end of the year, and we anticipate that our sales and operating results will continue to be adversely impacted for the duration of the pandemic. Starting in March 2020, we ceased nearly all in-person sales, marketing and training activities and adopted numerous other changes to our daily business operations. These changes primarily remain in effect as of the date of this report and it remains uncertain when we may be able to resume our normal operations. Accordingly, we anticipate that our sales may not follow historical trends and will be adversely impacted in the coming months as customers delay their purchasing decisions or physicians pause their prescriptions of new products. Our sales outside the United States have been negatively impacted due to similar disruptions. Initially, the impact was relatively consistent worldwide but we have since seen varying degrees of impact in international markets based on local conditions. The full extent of the impact of the COVID-19 global pandemic on our business and operations will depend on a number of factors, including the scope and duration of the pandemic, varying government responses to the pandemic and potential delays to product development timelines.

Separate from any impacts of the COVID-19 global pandemic, our quarterly sales have historically fluctuated, and may continue to fluctuate substantially in the periods surrounding anticipated and actual regulatory approvals and commercial launches of new products by us or our competitors. We believe customers may defer purchasing decisions if they believe a new product may be launched in the future. Additionally, upon the announcement of FDA approval or commercial launch of a new product, either by us or one of our competitors, potential new customers may reconsider their purchasing decisions or take additional time to consider such FDA approval or product launch before making their purchasing decisions. For instance, we believe certain customers paused their decision-making during the second half of 2019 in anticipation of the commercial availability of the t:slim X2 with Control-IQ technology. However, it is difficult to quantify the extent of the impact of these or similar events on future purchasing decisions.

***Cost of Sales***

Historically, we have manufactured our pumps and disposable cartridges at our manufacturing facility in San Diego, California. Near the end of the first quarter of 2020, our third-party cartridge manufacturer completed validation and commenced commercial-scale manufacturing to supplement our existing cartridge manufacturing capacity. We expect to increase production capacity and volumes at our third-party cartridge manufacturer over the next 24 months. Infusion sets and pump accessories are manufactured by third-party suppliers. Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs, royalties, freight, reserves for expected warranty costs, costs of supporting our digital health platforms, scrap and charges for excess and obsolete inventories. Manufacturing overhead expenses include expenses relating to quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management. We anticipate that our cost of sales will continue to increase as our product sales increase.

Over the long term, we expect our overall gross margin percentage, which for any given period is calculated as sales less cost of sales divided by sales, to improve, as our sales increase and our overhead costs are spread over larger production volumes. We expect we will be able to leverage our manufacturing cost structure across our products that utilize the same technology platform and manufacturing infrastructure and will be able to further reduce per unit costs with increased automation, process improvements and raw materials cost reductions. We also expect our warranty cost per unit to decrease as we release additional product features and functionality utilizing the Tandem Device Updater. Pumps have, and are expected to continue to have, a higher gross margin percentage than our pump-related supplies. Therefore, the percentage of pump sales relative to total sales will have a significant impact on our overall gross margin percentage. In the event that customers delay their pump purchasing decisions or physicians pause in prescribing new pumps, whether as a result of the COVID-19 global pandemic, or for other reasons, it is possible that we may experience a higher percentage of pump-related supply sales than anticipated, which in turn could adversely impact our overall gross margin percentage. However, our overall gross margin percentage may fluctuate in future quarterly periods as a result of numerous factors aside from those associated with production volumes and product mix. For instance, as a result of the COVID-19 global pandemic we have implemented operational changes that may introduce unpredictable variability to our cost of sales, such as supplemental staffing, incremental expenses to protect the health, safety and welfare of our employees working on-site and to enable other employees to work remotely. In addition, as demand for our products increases, we may continue to make additional investments in manufacturing capacity or increase our reliance on third parties for manufacturing-related services, either of which could have a negative impact on our gross margins. Specifically, in 2020 we invested in additional manufacturing equipment to double our existing capacity in order to meet anticipated long-term demand for our cartridges, which may initially place downward pressure on the gross margin percentage associated with our pump-related supplies.

Other factors impacting our overall gross margin percentage may include the changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors in domestic and international markets, the timing and success of new regulatory approvals and product launches, the impact of the valuation and amortization of employee stock awards on non-cash stock-based compensation expense allocated to cost of sales, changes in warranty estimates, training costs, licensing and royalty costs, increased costs to support our digital health platforms, cost associated with excess and obsolete inventories, and changes in our manufacturing processes, capacity, costs or output.

***Selling, General and Administrative***

Our selling, general and administrative (SG&A) expenses primarily consist of salary, cash-based incentive compensation, fringe benefits and non-cash stock-based compensation, which also includes our clinical, customer support, technical services, and insurance verification. We began expanding our U.S. field sales and clinical organization during the third quarter of 2019 to support an expected increase in demand for our products. We had approximately 90 sales territories in the United States as of December 31, 2020 and are expanding modestly to approximately 95 in 2021. Our existing territories are generally maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel, which have also been rapidly expanding to support our growing installed base. Our operations in Canada are comprised of approximately ten sales territories. Other significant SG&A expenses include those incurred for product demonstration samples, commercialization activities associated with new product launches, travel, trade shows, outside legal fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs. Overall, we expect our SG&A expenses, including the cost of our customer support infrastructure, to increase as our customer base grows in the United States and international markets. We will continue to evaluate, and may further increase, the number of our field sales and clinical personnel in order to optimize the coverage of our existing territories. Additionally, we realized a notable increase in non-cash stock-based compensation expense allocated to SG&A beginning in the third quarter of 2018, and again in the second quarter of 2019, due to the valuation of certain 2018 and 2019 employee stock option grants and the impact on the valuation of the significant increase in our stock price over the previous year. We recognized higher non-cash stock-based compensation expense through the first half of 2020, and experienced a reduction in expense beginning in the third quarter of 2020 as certain 2018 employee stock option grants became fully amortized. We anticipate that we will continue to see improvement in non-cash stock-based compensation as a percent of sales in future years. Our SG&A expenses may be affected by our response to the COVID-19 global pandemic, including reduced spending in areas such as non-essential employee travel, which may be offset by increased spending to support measures designed to prioritize the retention, health, safety and welfare of our employees. In the longer term, SG&A expenses may also increase due to anticipated costs associated with additional compliance and regulatory reporting requirements.

***Research and Development***

Our research and development (R&D) activities primarily consist of engineering and research programs associated with our products under development, as well as activities associated with our core technologies and processes. R&D expenses are primarily related to employee compensation, including salary, cash-based incentive compensation, fringe benefits, non-cash stock-based compensation and temporary employee expenses. We also incur R&D expenses for supplies, development prototypes, outside design and testing services, depreciation, allocated facilities and information services, clinical trial costs, payments under our licensing, development and commercialization agreements and other indirect costs. We expect our R&D expenses to increase as we advance our products under development and develop new products and technologies, but will continue to see a reduction in non-cash stock-based compensation as a percent of sales in the longer term. Similar to our SG&A expenses, our future R&D spending may be impacted by the COVID-19 global pandemic. For instance, we may experience lower spending associated with delays in the advancement of particular programs, which may be offset by increased spending to support the retention, health, safety and welfare of our employees or to enable development activities under alternative conditions.

***Other Income and Expense***

Other income and expense primarily consists of changes in the fair value of certain warrants issued in connection with our public offering of common stock in October 2017 (Series A Warrants), interest expense which includes the amortization of debt discount and debt issuance costs related to our Convertible Senior Notes issued in May 2020 (our Notes), and interest earned on our cash equivalents and short-term investments. We expect interest expense in future years to be higher than 2020 as our Notes were not outstanding for the entire twelve month period ended December 31, 2020. We expect total other income and expense, net to fluctuate from period to period primarily due to the revaluation of the outstanding Series A warrants, which expire in the fourth quarter of 2022.

***Income Tax Expense (Benefit)***

Because we are in a net loss position with respect to federal income taxes, income tax expense is expected to primarily consist of state and foreign income tax expense as a result of current taxable income in those jurisdictions. Income tax expense (benefit) may fluctuate in future quarters due to adjustments related to non-recurring transactions and changes in certain tax assessments.

**Results of Operations**

| (in thousands, except percentages) | Year Ended December 31, 2020 | 2019 | 2018 |
|---|---|---|---|
| Sales: | | | |
| Domestic | $ 415,680 | $ 302,084 | $ 174,188 |
| International | 83,150 | 60,221 | 9,678 |
| Total sales | 498,830 | 362,305 | 183,866 |
| Cost of sales | 238,310 | 168,093 | 94,044 |
| Gross profit | 260,520 | 194,212 | 89,822 |
| Gross margin | 52.2 % | 53.6 % | 48.9 % |
| Operating expenses: | | | |
| Selling, general and administrative | 204,903 | 165,735 | 105,226 |
| Research and development | 63,574 | 45,199 | 29,227 |
| Total operating expenses | 268,477 | 210,934 | 134,453 |
| Operating loss | (7,957) | (16,722) | (44,631) |
| Other income (expense), net: | | | |
| Interest income and other, net | 1,567 | 3,193 | 1,439 |
| Interest expense | (12,805) | — | (7,561) |
| Loss on extinguishment of debt | — | — | (5,313) |
| Change in fair value of common stock warrants | (17,087) | (11,075) | (66,494) |
| Total other expense, net | (28,325) | (7,882) | (77,929) |
| Loss before income taxes | (36,282) | (24,604) | (122,560) |
| Income tax expense (benefit) | (1,900) | 149 | 51 |
| Net loss | $ (34,382) | $ (24,753) | $ (122,611) |

**Comparison of Years Ended December 31, 2020 and 2019**

*Sales*. For the year ended December 31, 2020, sales were $498.8 million, which included $83.2 million of international sales. For the year ended December 31, 2019, sales were $362.3 million, which included $60.2 million of international sales.

The increase in worldwide sales of $136.5 million in 2020, as compared to 2019, was primarily driven by a $69.4 million increase in pump-related supplies sales due to 52% growth in our estimated worldwide installed base of customers, and a $67.1 million increase in pump sales driven by a 24% increase in worldwide pump shipments to 90,771 in 2020, compared to 73,431 in 2019 which benefited from the effect of certain non-recurring international market dynamics.

Domestic sales by product were as follows (in thousands):

| | Year Ended December 31, 2020 | 2019 |
|---|---|---|
| Pump | $ 269,856 | $ 205,492 |
| Infusion sets | 99,743 | 66,034 |
| Cartridges | 45,342 | 30,022 |
| Other | 739 | 536 |
| Total Domestic Sales | $ 415,680 | $ 302,084 |

Domestic pump sales were $269.9 million for the year ended December 31, 2020, compared to $205.5 million in the year ended December 31, 2019, as pump shipments increased 32% compared to the same period in the prior year due to continued strong demand for our products following the January 2020 domestic launch of our t:slim X2 insulin pump with Control-IQ technology. Domestic pump shipments were 70,825 in the year ended December 31, 2020 compared to 53,735 in 2019. Sales of pump-related supplies increased primarily due to a 46% increase in our estimated domestic installed base of customers. Sales to distributors accounted for 70% and 73% of our total domestic sales for the years ended December 31, 2020 and 2019, respectively. Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor.

International sales by product were as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Pump | $ 44,851 | $ 42,094 |
| Infusion sets | 28,016 | 11,221 |
| Cartridges | 9,884 | 6,656 |
| Other | 399 | 250 |
| Total International Sales | $ 83,150 | $ 60,221 |

International pump sales were $44.9 million for the year ended December 31, 2020, compared to $42.1 million in the year ended December 31, 2019. The first half of 2019 was positively impacted by the transition of former Animas customers to our products and the fulfillment of certain international pump demand from backlog that existed at the end of 2018 due to supply constraints in prior periods. Sales of pump-related supplies benefited from an 83% increase in our estimated international installed base of customers. The ordering patterns of our international distributors for pumps and supplies is highly variable from period to period. This variability was compounded by the varying levels of impact of the global pandemic across the international markets in which we operate. Sales to distributors accounted for 94% and 92% of our total international sales for the years ended December 31, 2020 and 2019, respectively.

*Cost of Sales and Gross Profit*. Our cost of sales for the year ended December 31, 2020 was $238.3 million, resulting in gross profit of $260.5 million, compared to cost of sales of $168.1 million for the year ended December 31, 2019, resulting in gross profit of $194.2 million. The gross margin for 2020 was 52%, compared to 54% in 2019.

The increase in our gross profit for the year ended December 31, 2020, was primarily the result of the $136.5 million increase in total sales. Gross profit and gross margin in 2020 were negatively impacted by royalty costs, for which there was no comparable expense in 2019. During the year ended December 31, 2020, we recognized $6.7 million of product royalty costs, or approximately one percent of sales, associated with sales of pumps with Control-IQ technology launched in the first quarter of 2020, and free software updates downloaded by existing customers in the United States, as well as in certain international markets where we launched Control-IQ beginning in the third quarter of 2020. Excluding the impact of royalty, gross margins for both pumps and supplies saw improvement compared to the prior year, but were still slightly pressured by the product mix. Gross margin was also pressured to a lesser extent by other factors that are more temporary in nature or anticipated to be leveraged through growth in future quarters, including costs associated with COVID-19 risk mitigation, managing pump production to achieve desired stocking levels, the expansion of cartridge manufacturing capacity and increased spending to support our digital health product offerings. Other factors that have and may continue to have an impact on the gross margin percentage are changes in product and geographical mix and the level of non-cash stock-based compensation allocated to cost of sales. Pump sales, which have the highest gross margin, were 63% of total worldwide sales for the year ended December 31, 2020, versus 68% in 2019. Non-cash stock-based compensation expense allocated to cost of sales was $8.2 million for the year ended December 31, 2020, compared to $6.4 million in the same period of 2019, representing 2% of sales in both periods.

*Selling, General and Administrative Expenses.* SG&A expenses increased 24% to $204.9 million for the year ended December 31, 2020, from $165.7 million for the same period in 2019. Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. The increase compared to 2019 was primarily the result of a $32.8 million increase in salaries, incentive compensation and other employee benefits due to an increase in personnel to support additional sales territories, higher sales and other services in support of our growing installed customer base, offset by a $1.3 million decrease in non-cash stock-based compensation expense. Non-cash stock-based compensation expense allocated to SG&A was $41.6 million in 2020, compared to $42.9 million in 2019. The increase in non-cash stock-based compensation expense associated with increased headcount in 2020 was more than offset by a decrease in non-cash stock-based compensation expense from the valuation of certain 2018 employee stock option grants which are now fully amortized. We also experienced increased costs for equipment and supplies, and outside consulting and services of $11.2 million, offset by a $2.9 million decrease in travel costs.

*Research and Development Expenses*. R&D expenses increased 41% to $63.6 million for the year ended December 31, 2020, from $45.2 million for the same period in 2019. The increase in R&D expenses was primarily the result of an increase of $9.9 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts, as well as an increase of $8.5 million in outside consulting and services, equipment and supplies attributable to R&D. Non-cash stock-based compensation expense allocated to R&D was $8.7 million in 2020, compared to $8.8 million in 2019.

*Other Income (Expense)*. Total other expense, net for the year ended December 31, 2020 was $28.3 million, compared to $7.9 million in 2019. Other expense for 2020 primarily consisted of a $17.1 million revaluation loss from the change in the fair value of certain warrants due to the appreciation of our stock price during 2020, and $12.8 million of interest expense which includes the amortization of debt discount and debt issuance costs related to our Notes issued in the second quarter of 2020. Other expense for 2019 consisted primarily of an $11.1 million revaluation loss from the change in the fair value of certain warrants due to the appreciation in our stock price during 2019. Interest income and other, for the years ended December 31, 2020 and 2019 primarily consisted of interest earned on our cash equivalents and short-term investments, and decreased in 2020 primarily due to the lower interest rate environment as compared to 2019.

*Income Tax Expense (Benefit).* We recognized an income tax benefit of $1.9 million on a pre-tax loss of $36.3 million for the year ended December 31, 2020, compared to income tax expense of $0.1 million on a pre-tax loss of $24.6 million for the same period in 2019. The income tax benefit for the year ended December 31, 2020 was primarily due to benefit associated with the release of valuation allowance related to the acquisition of certain intangible assets, partially offset by state and foreign income tax expense as a result of current taxable income in those jurisdictions. Income tax expense for the year ended December 31, 2019 was primarily attributable to state and foreign income tax expense as a result of current taxable income in those jurisdictions.

**Comparison of Years Ended December 31, 2019 and 2018**

*Sales*. For the year ended December 31, 2019, sales were $362.3 million, which included $60.2 million of international sales. For the year ended December 31, 2018, sales were $183.9 million, which included $9.7 million of international sales which commenced in the third quarter of 2018.

The increase in worldwide sales of $178.4 million in 2019, as compared to 2018, was primarily driven by a $123.6 million increase in pump sales driven by a 113% increase in worldwide pump shipments to 73,431 in 2019, compared to 34,493 in 2018. In addition, worldwide sales in 2019 and 2018 were positively impacted by the transition of former Animas customers to our products. Sales of pump-related supplies increased $54.8 million, or 91%, primarily due to an overall increase in our installed base of customers reordering supplies.

Domestic sales by product were as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | **2019** | **2018** |
| Pump | $ 205,492 | $ 115,719 |
| Infusion sets | 66,034 | 40,260 |
| Cartridges | 30,022 | 17,796 |
| Other | 536 | 413 |
| Total Domestic Sales | $ 302,084 | $ 174,188 |

Domestic pump sales were $205.5 million for the year ended December 31, 2019, compared to $115.7 million in the year ended December 31, 2018, as pump shipments increased 78% compared to the same period in the prior year due to continued strong demand for our products following the August 2018 domestic launch of t:slim X2 with Basal-IQ technology. Domestic pump shipments were 53,735 in the year ended December 31, 2019 compared to 30,205 in 2018. Sales of pump-related supplies increased primarily due to a 48% increase in our estimated domestic installed base of customers. Sales to distributors accounted for 73% and 78% of our total domestic sales for the years ended December 31, 2019 and 2018, respectively. Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor.

International sales by product were as follows (in thousands):

| | Year Ended December 31, | |
|---|---|---|
| | 2019 | 2018 |
| Pump | $ 42,094 | $ 8,205 |
| Infusion sets | 11,221 | 629 |
| Cartridges | 6,656 | 781 |
| Other | 250 | 63 |
| Total International Sales | $ 60,221 | $ 9,678 |

International pump sales were $42.1 million for the year ended December 31, 2019, compared to $8.2 million in the year ended December 31, 2018. Our first full year of international sales was 2019, as we commenced commercial sales of t:slim X2 with G5 integration in select international geographies beginning in the third quarter of 2018. The first half of 2019 was also positively impacted by the transition of former Animas customers to our products, and the fulfillment of certain international pump demand from backlog that existed at the end of 2018 due to supply constraints in prior periods. Sales of pump-related supplies benefited from the growing international installed base of customers. Sales to distributors accounted for 92% and 100% of our total international sales for the years ended December 31, 2019 and 2018, respectively.

*Cost of Sales and Gross Profit*. Our cost of sales for the year ended December 31, 2019 was $168.1 million, resulting in gross profit of $194.2 million, compared to cost of sales of $94.0 million for the year ended December 31, 2018, resulting in gross profit of $89.8 million. The gross margin for 2019 was 54%, compared to 49% in 2018.

The improvement in both gross profit and gross margin was primarily the result of the $123.7 million increase in insulin pump sales which have a higher gross margin than pump-related supplies. Gross margin and gross profit also increased as a result of per-unit manufacturing cost improvements from higher production volumes and continued overall manufacturing efficiencies gained from our new manufacturing facility which became fully operational at the beginning of 2018. On an aggregate basis, other non-manufacturing costs, which primarily consist of warranty, freight and training costs, also reflected improvement on a per unit basis. Non-cash stock-based compensation expense allocated to cost of sales increased to $6.4 million in 2019 compared to $2.6 million in 2018, due primarily to the valuation of certain 2018 and 2019 employee stock option grants and the impact on the valuation of the significant increase in our stock price.

*Selling, General and Administrative Expenses.* SG&A expenses increased 58% to $165.7 million in 2019 from $105.2 million in 2018. Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. These expenses increased $49.6 million during 2019, compared to 2018, which included an increase of $23.6 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our growing installed customer base, and a $26.0 million increase in non-cash stock-based compensation expense. Non-cash stock-based compensation expense allocated to SG&A increased to $42.9 million in 2019, compared to $16.8 million in 2018, due primarily to the valuation of certain 2018 and 2019 employee stock options grants and the impact on the valuation of the significant increase in our stock price. We also experienced increased costs for equipment and supplies, outside consulting and services, and travel of $10.9 million.

*Research and Development Expenses*. R&D expenses increased 55% to $45.2 million in 2019 from $29.2 million in 2018. The increase in R&D expenses was primarily the result of an increase of $4.8 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts, and a $4.5 million increase in non-cash stock-based compensation expense, as well as a $5.8 million increase in costs for outside consulting and services, clinical trials, and supplies. Non-cash stock-based compensation expense allocated to R&D increased to $8.8 million in 2019, compared to $4.3 million in 2018, due primarily to the valuation of certain 2018 and 2019 employee stock option grants and the impact on the valuation of the significant increase in our stock price.

*Other Income (Expense)*. Total other expense, net for the year ended December 31, 2019 was $7.9 million, compared to $77.9 million for the same period in 2018. Other expense in 2019 primarily consisted of an $11.1 million revaluation loss from the change in the fair value of certain warrants due to the appreciation in our stock price during 2019. Other expense in 2018 consisted primarily of a $66.5 million revaluation loss from the change in the fair value of certain warrants due to the significant appreciation in our stock price during 2018, and $7.6 million of interest expense associated with the term loan agreement with Capital Royalty Partners and its affiliated funds (the Term Loan Agreement), which was originally executed in in 2012, and was amended multiple times between 2016 and 2018. Additionally, we recorded a $5.3 million loss on extinguishment of debt associated with the full repayment of our Term Loan Agreement in August 2018. Interest income and other, net primarily consisted of interest earned on our cash equivalents and short-term investments, and increased in 2019 as our average invested balances were significantly higher as compared to 2018.

**Liquidity and Capital Resources**

At December 31, 2020, we had $484.9 million in cash and cash equivalents and short-term investments. We believe that our cash and cash equivalents and short-term investments balance will be sufficient to satisfy our liquidity requirements for at least the next 12 months from the date of this filing.

Historically, our principal sources of cash have included cash collected from product sales, private and public offerings of equity securities, exercises of employee stock awards, and debt financing. Since the beginning of 2018, we completed the following financing activities:

- In May 2020, we raised $278.7 million in net proceeds from the issuance of the Notes, and used $34.1 million of the net proceeds to purchase capped call options in connection with the transaction (see Note 6, “Debt”).
- From January 2019 through December 31, 2020, we issued 3,758,420 shares of common stock upon the exercise of stock options, and 631,581 shares of common stock were purchased under our 2013 Employee Stock Purchase Plan, which generated aggregate proceeds of $90.7 million.
- In February 2018, we completed a registered public offering of 34,500,000 shares of common stock at a public offering price of $2.00 per share. The gross proceeds from the offering were approximately $69.0 million, before deducting underwriting discounts and commissions and other offering expenses.
- In August 2018, we completed a registered public offering of 4,035,085 shares of common stock at a public offering price of $28.50 per share. The gross proceeds from the offering were $115.0 million, before deducting underwriting discounts and commissions and other offering expenses. From January 2019 through December 2020, we received proceeds of $1.2 million from the exercise of 356,085 outstanding warrants which were originally issued in a registered public offering of common stock in October 2017. As of December 31, 2020, there were warrants to purchase 154,700 shares outstanding relating to the October 2017 offering.
- From January 2019 through December 2020, we received proceeds of $2.0 million from the exercise of 32,911 outstanding warrants which were originally issued between August 2011 and August 2012. As of December 31, 2020, there were warrants to purchase 30,861 warrants outstanding relating to these issuances.

Our historical cash outflows have primarily been associated with cash used for operating activities such as the development and commercialization of our products, the expansion and support of our sales, marketing, clinical and customer support organizations, the expansion of our R&D activities, the expansion of our commercial activities to select international geographies, the acquisition of intellectual property, expenditures related to increases in our manufacturing capacity and improvements to our manufacturing efficiency, overall expansion of our facilities and operations, and other working capital needs. Additionally, we have used cash to pay the interest expense associated with our convertible senior notes and our Term Loan Agreement. The outstanding balance associated with the Term Loan Agreement was fully repaid in August 2018, and we have ceased incurring interest expense and other costs associated with the Term Loan Agreement subsequent to the third quarter of 2018.

We expect our sales performance and the resulting operating income or loss, as well as the status of each of our new product development programs, will significantly impact our cash flow from operations, liquidity position and cash management decisions.

The following table shows a summary of our cash flows for the years ended December 31, 2020, 2019 and 2018:

| | Year Ended December 31, | | |
|---|---|---|---|
| **(in thousands)** | **2020** | **2019** | **2018** |
| Net cash provided by (used in): | | | |
| Operating activities | $ 24,669 | $ 41,906 | $ (8,319) |
| Investing activities | (296,056) | (56,955) | (90,739) |
| Financing activities | 314,438 | 24,207 | 117,184 |
| Effect of foreign exchange rate changes on cash | 387 | 191 | — |
| Net increase in cash and cash equivalents | $ 43,438 | $ 9,349 | $ 18,126 |

*Operating activities*. Net cash provided by operating activities was $24.7 million and $41.9 million for the years ended December 31, 2020 and 2019, respectively, compared to net cash used of $8.3 million for the same period in 2018.

The decrease in net cash provided by operating activities for 2020 compared to 2019 was driven by net changes in working capital, partially offset by a reduction in net loss when adjusted for non-cash expenses, particularly stock-based compensation expense, the change in the fair value of common stock warrants and non-cash interest expense. Working capital changes in 2020 primarily consisted of increases in accounts receivable and inventories, offset by increases in employee-related liabilities, deferred revenue, and other current and long-term liabilities, all of which are related to the growth in our business. Accounts receivable increased to $82.2 million at December 31, 2020 from $46.6 million at December 31, 2019, as a result of higher sales in the fourth quarter of 2020 as compared to the fourth quarter of 2019. Inventories increased to $63.7 million at December 31, 2020 from $49.1 million at December 31, 2019, primarily to support the growth in our business.

The improvement to net cash provided by operating activities for 2019 compared to 2018 was primarily driven by higher sales and gross margins in 2019, which resulted in a significant reduction in net loss when adjusted for non-cash expenses, particularly stock-based compensation expense and the change in the fair value of common stock warrants, offset by net changes in working capital. Working capital changes in 2019 primarily consisted of increases in accounts receivable and inventories, offset by increases in accounts payable, accrued expenses, employee-related liabilities, deferred revenue, and other long-term liabilities related to warranty reserves for 2019 pump sales. Accounts receivable increased to $46.6 million at December 31, 2019 from $35.2 million at December 31, 2018, as a result of higher sales in the fourth quarter of 2019 as compared to the fourth quarter of 2018. Inventories increased to $49.1 million at December 31, 2019 from $19.9 million at December 31, 2018, primarily to support the growth in our business.

*Investing activities*. Net cash used by investing activities was $296.1 million for the year ended December 31, 2020, which was primarily related to purchases of short-term investments of $497.1 million using the net proceeds from the issuance of our convertible notes in May of 2020, and $27.4 million in purchases of property and equipment, offset by $233.3 million in proceeds from maturities and sales of short-term investments. Net cash used by investing activities was $57.0 million for the year ended December 31, 2019, which was primarily related to purchases of short-term investments of $164.6 million and $19.5 million in purchases of property and equipment, offset by $127.2 million in proceeds from maturities of short-term investments. Net cash used by investing activities was $90.7 million for the year ended December 31, 2018, which was primarily related to purchases of short-term investments of $123.6 million using the net proceeds from our public offering of common stock in August of 2018, and $3.0 million in purchases of property and equipment, offset by $35.8 million in proceeds from maturities of short-term investments.

*Financing activities.* Net cash provided by financing activities was $314.4 million for the year ended December 31, 2020, which primarily consisted of $278.7 million in proceeds from the issuance of the Convertible Senior Notes which was partially offset by $34.1 million in payments for the purchase of the related Capped Call Options (see Note 6, “Debt”), and $66.9 million in proceeds from the issuance of common stock under our stock plans. Net cash provided by financing activities was $24.2 million for the year ended December 31, 2019, which was primarily the result of proceeds of $23.9 million from the issuance of common stock under our stock plans. Net cash provided by financing activities was $117.2 million for the year ended December 31, 2018, which was primarily the result of net proceeds of approximately $172.9 million from the public offerings of our common stock in February 2018 and August 2018, as well as proceeds of $29.6 million from the exercise of common stock warrants that were issued in the public offering of common stock in October 2017, offset by the $87.7 million repayment of our term loan and associated financing fees.

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

- our ability to generate sales, the timing of those sales, the mix of products sold and the collection of receivables from period to period;
- the timing of any additional financings, and the net proceeds raised from such financings;
- the timing and amount of the exercise of outstanding warrants, and proceeds from the issuance of equity awards pursuant to employee stock plans;
- fluctuations in gross margins and operating margins;
- fluctuations in working capital, including changes in accounts receivable, inventories, accounts payable, employee-related liabilities, and operating lease liabilities; and
- the impacts and disruptions caused by the COVID-19 global pandemic.

Our primary short-term capital needs are expected to include expenditures related to:

- support of our commercialization efforts related to our current and future products;
- expansion of our customer support resources for our growing installed customer base;
- research and product development efforts, including clinical trial costs;
- acquisitions, leasing or licensing of equipment, technology, intellectual property and other assets;
- additional facilities leases and related tenant improvements, and manufacturing equipment to support business growth and increase manufacturing capacity; and
- payments under licensing, development and commercialization agreements.

Although we believe the foregoing items reflect our most likely uses of cash in the short-term, we cannot predict with certainty all of our particular cash uses or the timing or amount of cash used. In addition, from time to time we may consider opportunities to acquire or license other products or technologies that may enhance our product platform or technology, expand the breadth of our markets or customer base, or advance our business strategies. Any such transaction may require short-term expenditures that may impact our capital needs. If for any reason our cash and cash equivalents balances, or cash generated from operations is insufficient to satisfy our working capital requirements, we may in the future be required to seek additional capital from public or private offerings of our equity or debt securities, or we may elect to borrow capital under new credit arrangements or from other sources. We may also seek to raise additional capital from such offerings or borrowings on an opportunistic basis when we believe there are suitable opportunities for doing so. If we issue equity or debt securities to raise additional funds, our existing stockholders may experience dilution, we may incur significant financing or debt service costs, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. There can be no assurance that financing will be available on acceptable terms, or at all. Our ability to raise additional financing may be negatively impacted by a number of factors, including our recent and projected financial results, recent changes in and volatility of our stock price, perceptions about the dilutive impact of financing transactions, the competitive environment in our industry, uncertainties regarding the regulatory environment in which we operate and conditions impacting the capital markets more generally, including economic weakness, inflation, political instability, war and terrorism, natural disasters, incidence of illness or disease, or other events beyond our control.

**Indebtedness**

In May 2020, the Company entered into a purchase agreement with certain counterparties for the sale of an aggregate of $287.5 million principal amount of 1.50% Convertible Senior Notes due 2025 in a private offering to qualified institutional buyers (the Notes). The Notes were issued pursuant to an Indenture, dated May 15, 2020, between the Company and U.S. Bank National Association, as trustee. The net proceeds from the issuance of the Notes were $244.6 million, net of debt issuance costs and cash used to purchase the capped call transactions (see Note 6, “Debt”). The Notes are the Company’s senior unsecured obligations. Interest is payable in cash semi-annually in arrears beginning on November 1, 2020 at a rate of 1.50% per year. The Notes mature on May 1, 2025 unless repurchased, redeemed, or converted in accordance with their terms prior to the maturity date.

***Repayment of Term Loan Agreement***

In August 2018, we fully repaid our term loan with CRG pursuant to the Term Loan Agreement. The balance of the outstanding debt at the time of repayment was $82.7 million. The total repayment amount of $88.8 million included approximately $1.1 million in accrued interest, and approximately $5.0 million in associated financing fees that became due. Therefore, we did not have any borrowings outstanding under the Term Loan Agreement as of December 31, 2019 and December 31, 2018. At the time of repayment, the remaining $5.3 million debt discount balance associated with the financing fees and certain debt issuance costs was accelerated and recognized as a loss on extinguishment of debt during the third quarter of 2018.

**Contractual Obligations & Commitments**

The following table summarizes the payments due by fiscal period for our outstanding contractual obligations at December 31, 2020:

| | Payments Due by Period | | | | |
|---|---|---|---|---|---|
| (in thousands) | Total | Less than 1 year | 1-3 years | 3-5 years | More than 5 years |
| Operating lease obligations [1] | $ 28,373 | $ 9,421 | $ 13,096 | $ 3,757 | $ 2,099 |
| Firm purchase commitments [2] | 90,830 | 84,536 | 6,294 | — | — |
| Convertible senior notes [3] | 306,907 | 4,313 | 8,625 | 293,969 | — |
| Total contractual obligations | $ 426,110 | $ 98,270 | $ 28,015 | $ 297,726 | $ 2,099 |

(1) Operating lease obligations of $25.3 million were included in operating lease liabilities current and long-term in the consolidated balance sheet at December 31, 2020 (see Note 5, "Leases").

(2) Includes purchase orders that are cancellable under the standard terms of our purchase order agreements. In certain cases, cancellation of outstanding purchase commitments may require payment of costs incurred through the date of cancellation.

(3) Amounts represent contractual payments of interest and principal.

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

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

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements included in this Annual Report, we believe that the following accounting policies are the most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

***Revenue Recognition***

Our revenue is generated primarily from sales of our insulin pumps, disposable cartridges and infusion sets to individual customers and third-party distributors that resell the product to insulin-dependent diabetes customers. We are paid directly by customers who use the products, distributors and third-party insurance payors. We recognize revenue when control of our products is transferred to our customers in an amount that reflects the consideration we expect to receive from our customers in exchange for those products. This process involves identifying the contract with a customer, determining the performance obligations in the contract, determining the contract price, allocating the contract price to the distinct performance obligations in the contract, and recognizing revenue when the performance obligations have been satisfied. Revenue recognition for contracts with multiple performance obligations is based on the separate satisfaction of each distinct performance obligation within the contract. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. We consider a performance obligation satisfied once we have transferred control of a product to the customer, meaning the customer has the ability to use and obtain the benefit of the product. Complementary products, such as the t:connect cloud-based data management application and the Tandem Device Updater, are considered performance obligations satisfied over time, as access and support for these products is provided throughout the typical four-year warranty period of the insulin pumps. Accordingly, revenue related to the complementary products is deferred and recognized ratably over a four-year period. There is no standalone value for these complementary products. Therefore, we determine their value by applying the expected cost plus a margin approach and then allocate the residual to the insulin pumps.

***Warranty Reserve***

We generally provide a four-year warranty on our insulin pumps to end user customers and may replace any pumps that do not function in accordance with the product specifications. Insulin pumps returned to us may be refurbished and redeployed. Additionally, we offer a six-month warranty on disposable cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. We evaluate the reserve quarterly. Warranty costs are primarily estimated based on the current expected product replacement cost and expected replacement rates utilizing historical experience. Recently released versions of our pump may not incur warranty costs in a manner similar to previously released pumps, on which we initially base our warranty estimate of newer pumps. We may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to length of time the pump version has been in the field and future expectations of performance based on new features and capabilities that may become available through Tandem Device Updater. Changes to the actual replacement rates or the expected product replacement cost could have a material impact on our estimated warranty reserve.

***Income Taxes***

Significant judgment is required in determining our provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. We will continue to assess the need for a valuation allowance on our deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

Utilization of our net operating loss and research credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitations may result in the expiration of net operating loss carryforwards before utilization. We have completed analyses through December 31, 2020 to determine whether our net operating losses and credits are likely to be limited by Section 382. Based on the 2018 study completed in 2019, we determined that an ownership change, as defined under Section 382, occurred in 2018 and the resulting limitation significantly reduced our ability to utilize our net operating loss and credit carryovers before they expire. As a result, in 2019 we reduced our deferred tax assets for the net operating loss and research credit carryforwards that were projected to expire unused with a corresponding offset to the valuation allowance recorded against such assets. Additionally, future ownership changes under Section 382 may also limit our ability to fully utilize any remaining tax benefits.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. We recognize liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While we believe we have appropriate support for the positions taken on our tax returns, we regularly assess the potential outcomes of examinations by tax authorities in determining the adequacy of our provision for income taxes. We continually assess the likelihood and amount of potential revisions and adjust the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

***Convertible Senior Notes***

In accounting for the issuance of the convertible senior notes, we separated the notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of similar debt instruments that do not have associated convertible features. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the respective notes. The equity component is not remeasured as long as it continues to meet the condition for equity classification. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense over the term of the notes.

We allocated the issuance costs incurred to the liability and equity components of the notes based on their relative fair values. Issuance costs attributable to the liability component were recorded as a reduction to the liability portion of the notes and are being amortized to interest expense over the term of the notes. Issuance costs attributable to the equity component, representing the conversion option, were netted with the equity component in stockholders' equity.

**Off-Balance Sheet Arrangements**

As of December 31, 2020, we did not have any off-balance sheet arrangements.

**Item 7A. Quantitative and Qualitative Disclosures about Market Risk.**

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

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

Because of the short-term maturities of our financial instruments, we do not believe that an increase or decrease in market interest rates would have any significant impact on the realized value of our investment portfolio. If a 10% change in interest rates were to have occurred on December 31, 2020, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Our operations are primarily located in the United States, and nearly all of our sales since inception have been made in U.S. dollars. With the exception of a portion of our sales in Canada, our sales outside of the United States are currently made to independent distributors under agreements denominated in U.S. dollars. Accordingly, we believe we do not currently have any material exposure to foreign currency rate fluctuations. As our business in markets outside of the United States increases, we may be exposed to foreign currency exchange risk. We believe this is currently limited to our operations in Canada, where fluctuations in the rate of exchange between the U.S. dollar and the Canadian dollar could adversely affect our financial results. In addition, from time to time, we may have foreign currency exchange risk related to existing assets and liabilities, committed transactions and forecasted future cash flows. In certain circumstances, we may seek to manage such foreign currency exchange risk by using derivative instruments such as foreign currency exchange forward contracts to hedge our risk. In general, we may hedge foreign currency exchange exposures up to 12 months in advance. However, we may choose not to hedge some exposures for a variety of reasons, including prohibitive economic costs.

**Item 8. Consolidated Financial Statements and Supplementary Data**

Our consolidated financial statements as of December 31, 2020 and 2019 and for each of the three years in the period ended December 31, 2020, and the Report of the Independent Registered Public Accounting Firm are included in this report as listed in the index.

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

## Report of Independent Registered Public Accounting Firm

**To the Stockholders and the Board of Directors of Tandem Diabetes Care, Inc.**

**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Tandem Diabetes Care, Inc. (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2020 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 24, 2021 expressed an unqualified opinion thereon.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

**Critical Audit Matters**

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

**Warranty reserve – Estimation of Product Replacement Reserve**

*Description of the Matter*

As discussed in Note 2 to the consolidated financial statements, the Company has a warranty reserve of $22.1 million. The Company provides insulin pump end customers with a four-year warranty and may replace any pumps that do not function in accordance with the product specifications. Warranty costs are estimated at the time of shipment. Management applies significant judgment to determine relevant assumptions to calculate the reserve, including the assessment of historical warranty experience and replacement cost.

Auditing management's estimate of warranty reserve on pumps was complex and judgmental due to the significant estimation required by management in estimating the value of the warranty reserve. In particular, the warranty reserve estimate is sensitive due to significant assumptions including replacement rates and replacement product costs, especially as it relates to recently released pump versions for which replacement rates specific to that version are not yet known. As such, replacement rates of recently released pumps are based primarily upon historical rates of prior versions which ultimately may not be predictive of the experience of new pumps, due to new features and capabilities of the more recent releases. These assumptions are affected by actual customer experience and changes in these assumptions could have a material impact on the Company's estimated reserve. This in turn led to a high degree of auditor judgment, subjectivity, and effort in performing procedures and evaluating audit evidence related to these determinations and management's significant assumptions for the warranty reserve.

*How We Addressed the Matter in Our Audit*

We obtained an understanding, evaluated the design and tested the operating effectiveness of the Company's controls over the warranty reserve estimation process. For example, we tested controls over management's review and calculation of significant assumptions underlying the warranty reserve, such as replacement rates and actual replacement product costs, and tested controls over the accuracy and completeness of data used.

To test the Company's warranty reserve, we performed audit procedures that included, among others, testing the completeness and accuracy of the underlying data used in the estimation calculation and evaluated the appropriateness of management's methodology to calculate the warranty reserve. We also evaluated the reasonableness of management's significant assumptions related to replacement rates and replacement cost, including review for contrary evidence. Evaluating management's significant assumptions involved evaluating the historical claims data utilized by management in estimating both the replacement rates and costs of known and anticipated claims. We assessed the historical accuracy of management's estimates by performing a lookback analysis and performing sensitivity analyses of the significant assumptions to evaluate the impact of changes in the warranty reserve that would result from changes in the assumptions. We tested the mathematical accuracy of the warranty reserve calculation and obtained documentation and performed inquiries of Company management to evaluate the completeness of the Company's estimate. In addition, for revisions made to the estimated reserve, we evaluated the reasonableness of the subsequent changes by comparing the revised assumptions to the original estimated assumptions and evaluated the reasons for the subsequent change.

**Valuation of Convertible Notes**

*Description of the Matter*

As described in Note 7 to the consolidated financial statements, in May 2020 the Company issued $287.5 million of convertible senior notes due in 2025 (Convertible Notes), which permit the Company to settle in cash or stock at its option. The Company entered into separate capped call transactions to reduce potential dilution upon conversion of the Convertible Notes. These transactions are collectively referred to as the Convertible Notes Transactions.

Auditing the Company's determination of the value allocated to the liability and equity components was complex and highly judgmental as a result of the significant estimation required to determine the fair value of the liability component, measured at the estimated fair value of similar debt without the conversion option. The difference between the initial proceeds of the Convertible Notes and the value allocated to the liability component being recognized in stockholders' equity (deficit) as the carrying amount of the equity component. The fair value of similar debt that does not have an associated conversion feature was determined using the Company's effective interest rate. The effective interest rate for the Convertible Notes was estimated using a binomial lattice model with various assumptions, the most significant assumptions being expected volatility of the Company's common stock and discount rate. Additionally, the Company performed a detailed analysis of the terms of the Convertible Notes Transactions to identify whether any derivatives that required separate mark-to-market accounting under applicable accounting guidance were present.

*How We Addressed the Matter in Our Audit*

We obtained an understanding, evaluated the design, and tested the operating effectiveness of controls over the Company's Convertible Notes Transactions. For example, we tested the Company's controls over the initial recognition and measurement of the Convertible Notes Transactions, including the assessment of the risk adjusted yield and the recording of the associated liability and equity components.

Our testing of the Company's initial accounting for the Convertible Notes Transactions, among other procedures, included reading the underlying agreements and evaluating the Company's accounting analysis of the initial accounting of the Convertible Notes Transactions, including the determination of the balance sheet classification of each transaction and identification of any derivatives included in the arrangements. To test the estimated fair value of the conversion option, our audit procedures included, among others, evaluating methodologies used in the valuation model and testing the significant assumptions. For example, we compared the discount rate that was adjusted for the Company's credit risk to the interest rates on comparable debt instruments, and we compared the forward-looking implied volatility to our independently calculated estimated equity volatility specific to the convertible note. In addition, we involved our internal valuation specialists to assist in our evaluation of the significant assumptions and methodologies used by the Company. We have also evaluated the Company's financial statement disclosures related to these matters included in Note 7 to the consolidated financial statements.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2009.

San Diego, California
February 24, 2021

**TANDEM DIABETES CARE, INC.**
**CONSOLIDATED BALANCE SHEETS**
**(In thousands except par value)**

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 94,613 | $ 51,175 |
| Short-term investments | 390,323 | 125,283 |
| Accounts receivable, net | 82,195 | 46,585 |
| Inventories | 63,721 | 49,073 |
| Prepaid and other current assets | 6,383 | 4,025 |
| Total current assets | 637,235 | 276,141 |
| Property and equipment, net | 50,022 | 32,923 |
| Operating lease right-of-use assets | 19,773 | 15,561 |
| Other long-term assets | 9,385 | 1,485 |
| Total assets | $ 716,415 | $ 326,110 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 17,805 | $ 17,745 |
| Accrued expenses | 4,783 | 8,014 |
| Employee-related liabilities | 34,159 | 28,320 |
| Deferred revenue | 6,082 | 3,869 |
| Common stock warrants | 14,261 | 23,509 |
| Operating lease liabilities | 9,421 | 6,320 |
| Other current liabilities | 17,341 | 11,619 |
| Total current liabilities | 103,852 | 99,396 |
| Convertible senior notes, net - long-term | 202,984 | — |
| Operating lease liabilities - long-term | 15,914 | 14,063 |
| Other long-term liabilities | 27,360 | 17,672 |
| Total liabilities | 350,110 | 131,131 |
| Commitments and contingencies (Note 10) | — | — |
| Stockholders' equity: | | |
| Common stock, $0.001 par value; 200,000 shares authorized, 62,335 and 59,396 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively. | 62 | 59 |
| Additional paid-in capital | 1,025,233 | 819,626 |
| Accumulated other comprehensive income | 220 | 122 |
| Accumulated deficit | (659,210) | (624,828) |
| Total stockholders' equity | 366,305 | 194,979 |
| Total liabilities and stockholders' equity | $ 716,415 | $ 326,110 |

*The accompanying notes are an integral part of the consolidated financial statements.*

**TANDEM DIABETES CARE, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(In thousands, except per share data)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Sales | $ 498,830 | $ 362,305 | $ 183,866 |
| Cost of sales | 238,310 | 168,093 | 94,044 |
| Gross profit | 260,520 | 194,212 | 89,822 |
| Operating expenses: | | | |
| Selling, general and administrative | 204,903 | 165,735 | 105,226 |
| Research and development | 63,574 | 45,199 | 29,227 |
| Total operating expenses | 268,477 | 210,934 | 134,453 |
| Operating loss | (7,957) | (16,722) | (44,631) |
| Other income (expense), net: | | | |
| Interest income and other, net | 1,567 | 3,193 | 1,439 |
| Interest expense | (12,805) | — | (7,561) |
| Loss on extinguishment of debt | — | — | (5,313) |
| Change in fair value of common stock warrants | (17,087) | (11,075) | (66,494) |
| Total other expense, net | (28,325) | (7,882) | (77,929) |
| Loss before income taxes | (36,282) | (24,604) | (122,560) |
| Income tax expense (benefit) | (1,900) | 149 | 51 |
| Net loss | $ (34,382) | $ (24,753) | $ (122,611) |
| Other comprehensive income (loss): | | | |
| Unrealized gain (loss) on short-term investments | $ (20) | $ 77 | $ (13) |
| Foreign currency translation gain | 118 | 58 | — |
| Comprehensive loss | $ (34,284) | $ (24,618) | $ (122,624) |
| | | | |
| Net loss per share - basic and diluted | $ (0.56) | $ (0.42) | $ (2.55) |
| Weighted average shares used to compute basic and diluted net loss per share | 60,990 | 58,507 | 48,129 |

*The accompanying notes are an integral part of the consolidated financial statements.*

**TANDEM DIABETES CARE, INC.**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)**
**(In thousands)**

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at December 31, 2017** | 10,119 | $ 10 | $ 448,455 | $ — | $ (477,613) | $ (29,148) |
| Exercise of stock options | 136 | — | 1,027 | — | — | 1,027 |
| Issuance of common stock for Employee Stock Purchase Plan | 81 | — | 1,364 | — | — | 1,364 |
| Exercise of common stock warrants | 8,603 | 9 | 29,566 | — | — | 29,575 |
| Fair value of common stock warrants at time of exercise | — | — | 54,000 | — | — | 54,000 |
| Issuance of common stock in public offering, net of underwriter's discount and offering costs | 38,535 | 38 | 172,891 | — | — | 172,929 |
| Stock-based compensation expense | 80 | — | 24,003 | — | — | 24,003 |
| Unrealized loss on short-term investments | — | — | — | (13) | — | (13) |
| Adjustment to retained earnings from adoption of ASC 606 | — | — | — | — | 149 | 149 |
| Net loss | — | — | — | — | (122,611) | (122,611) |
| **Balance at December 31, 2018** | 57,554 | $ 57 | $ 731,306 | $ (13) | $ (600,075) | $ 131,275 |
| Exercise of stock options | 1,422 | 1 | 17,674 | — | — | 17,675 |
| Issuance of common stock for Employee Stock Purchase Plan | 327 | 1 | 6,205 | — | — | 6,206 |
| Exercise of common stock warrants | 93 | — | 327 | — | — | 327 |
| Fair value of common stock warrants at time of exercise | — | — | 5,492 | — | — | 5,492 |
| Stock-based compensation expense | — | — | 58,622 | — | — | 58,622 |
| Unrealized gain on short-term investments, net of deferred tax | — | — | — | 77 | — | 77 |
| Foreign currency translation adjustments | — | — | — | 58 | — | 58 |
| Net loss | — | — | — | — | (24,753) | (24,753) |
| **Balance at December 31, 2019** | 59,396 | $ 59 | $ 819,626 | $ 122 | $ (624,828) | $ 194,979 |
| Issuance of common stock under equity incentive plans | 2,341 | 2 | 57,748 | — | — | 57,750 |
| Issuance of common stock for Employee Stock Purchase Plan | 303 | 1 | 9,115 | — | — | 9,116 |
| Exercise of common stock warrants | 295 | — | 2,950 | — | — | 2,950 |
| Fair value of common stock warrants at time of exercise | — | — | 26,335 | — | — | 26,335 |
| Equity component of convertible notes issuance, net of issuance cost | — | — | 85,803 | — | — | 85,803 |
| Purchase of capped call options related to convertible notes | — | — | (34,069) | — | — | (34,069) |
| Stock-based compensation expense | — | — | 57,725 | — | — | 57,725 |
| Unrealized loss on short-term investments | — | — | — | (20) | — | (20) |
| Foreign currency translation adjustments | — | — | — | 118 | — | 118 |
| Net loss | — | — | — | — | (34,382) | (34,382) |
| **Balance at December 31, 2020** | 62,335 | $ 62 | $ 1,025,233 | $ 220 | $ (659,210) | $ 366,305 |

*The accompanying notes are an integral part of the consolidated financial statements.*

**TANDEM DIABETES CARE, INC.**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(In thousands)**

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| **Operating Activities** | | | |
| Net loss | $ (34,382) | $ (24,753) | $ (122,611) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities: | | | |
| Depreciation and amortization expense | 10,451 | 6,072 | 5,821 |
| Amortization of debt discount and debt issuance costs | 10,096 | — | 1,721 |
| Provision for expected credit losses | 3,016 | 2,322 | 1,448 |
| Provision (recovery) for inventory obsolescence | (57) | 2,353 | 607 |
| Change in fair value of common stock warrants | 17,087 | 11,075 | 66,494 |
| Amortization of premium (discount) on short-term investments | (1,296) | (565) | 539 |
| Benefit for deferred income taxes | (2,126) | (25) | — |
| Stock-based compensation expense | 58,431 | 58,071 | 23,736 |
| Loss on extinguishment of debt | — | — | 5,313 |
| Other | 38 | (295) | 152 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable, net | (38,837) | (13,698) | (15,848) |
| Inventories | (15,361) | (30,975) | 6,756 |
| Prepaid and other current assets | (2,427) | (584) | (1,576) |
| Other long-term assets | 129 | (580) | (26) |
| Accounts payable | 1,118 | 8,910 | 1,641 |
| Accrued expenses | (3,256) | 4,076 | 1,097 |
| Employee-related liabilities | 5,339 | 4,285 | 9,542 |
| Deferred revenue | 7,029 | 4,589 | 2,074 |
| Other current liabilities | 5,789 | 4,216 | 2,434 |
| Other long-term liabilities | 3,888 | 7,412 | 2,367 |
| Net cash provided by (used in) operating activities | 24,669 | 41,906 | (8,319) |
| **Investing Activities** | | | |
| Purchases of short-term investments | (497,076) | (164,572) | (123,553) |
| Proceeds from maturities of short-term investments | 180,922 | 114,908 | 35,800 |
| Proceeds from sales of short-term investments | 52,392 | 12,250 | — |
| Purchases of property and equipment | (27,408) | (19,541) | (2,986) |
| Acquisition of intangible assets | (4,886) | — | — |
| Net cash used in investing activities | (296,056) | (56,955) | (90,739) |
| **Financing Activities** | | | |
| Proceeds from issuance of convertible senior notes, net of $8,809 debt issuance costs | 278,691 | — | — |
| Purchase of capped call options related to convertible senior notes | (34,069) | — | — |
| Principal payments on notes payable | — | — | (87,711) |
| Proceeds from public offerings, net of offering costs | — | — | 172,929 |
| Proceeds from issuance of common stock under Company stock plans | 66,866 | 23,880 | 2,391 |
| Proceeds from exercise of common stock warrants | 2,950 | 327 | 29,575 |
| Net cash provided by financing activities | 314,438 | 24,207 | 117,184 |
| Effect of foreign exchange rate changes on cash | 387 | 191 | — |
| Net increase in cash and cash equivalents | 43,438 | 9,349 | 18,126 |
| Cash and cash equivalents and restricted cash at beginning of period | 51,175 | 41,826 | 23,700 |
| Cash and cash equivalents at end of period | $ 94,613 | $ 51,175 | $ 41,826 |
| **Supplemental disclosures of cash flow information** | | | |
| Interest paid | $ 2,707 | $ — | $ 10,805 |
| Income taxes paid | $ 177 | $ 67 | $ 16 |
| **Supplemental schedule of non-cash investing and financing activities** | | | |
| Right-of-use assets obtained in exchange for operating lease obligations | $ 11,022 | $ 11,635 | $ — |
| Property and equipment included in accounts payable | $ 1,082 | $ 2,134 | $ 125 |
| Intangible costs in accounts payable and other long-term liabilities | $ 2,244 | $ — | $ — |

*The accompanying notes are an integral part of the consolidated financial statements*

**TANDEM DIABETES CARE, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

## 1. Organization and Basis of Presentation

### *The Company*

Tandem Diabetes Care, Inc. is a medical device company with a positively different approach to the design, development and commercialization of products for people with insulin-dependent diabetes. The Company is incorporated in the state of Delaware. Unless the context requires otherwise, the terms the "Company" or "Tandem" refer to Tandem Diabetes Care, Inc., together with its wholly-owned subsidiaries in the U.S. and Canada.

The Company manufactures, sells and supports insulin pump products that are designed to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. The Company's manufacturing, sales and support activities principally focus on the t:slim X2 Insulin Delivery System (t:slim X2), the Company's flagship pump platform which is capable of remote feature updates and is designed to display continuous glucose monitoring (CGM) sensor information directly on the pump home screen. The Company's insulin pump products are compatible with other complementary digital health offerings, such as the t:connect cloud-based data management application (t:connect) and the Tandem Device Updater, a Mac and PC-compatible tool for the remote update of the Company's insulin pump software. The Company's insulin pump products are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, the Company sells disposable products that are used together with the pumps and are replaced every few days, including cartridges for storing and delivering insulin, and infusion sets that connect the insulin pump to a user's body, as well as other accessories for enhanced usability.

### *Basis of Presentation and Principles of Consolidation*

The Company has prepared the accompanying consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The statements include the accounts of Tandem Diabetes Care, Inc. and its wholly-owned subsidiaries in the U.S. and Canada. All significant intercompany balances and transactions have been eliminated in consolidation.

The functional currency of the Company's foreign subsidiary is the local currency. The Company translates the financial statements of its foreign subsidiary into U.S. dollars using period-end exchange rates for assets and liabilities and average exchange rates for each period for revenue, costs and expenses. Translation related adjustments are included in comprehensive loss and in accumulated other comprehensive income (loss) in the stockholders' equity section of the Company's consolidated balance sheets. Foreign exchange gains or losses resulting from balances denominated in a currency other than the functional currency are recognized in interest income and other, net in the Company's consolidated statements of operations.

### *Reclassifications*

Prior year amounts related to the presentation of other income (expense), net on the Company's consolidated statements of operations and comprehensive loss, have been reclassified to conform to the current year presentation. Starting with the third quarter of 2020, the first full quarter in which the Company's convertible senior notes were outstanding, the Company began to present non-operating expenses unrelated to the convertible senior notes with interest income and other, net. In prior periods, other non-operating expenses were combined with interest expense and reported as interest and other expense.

## 2. Summary of Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the year ended December 31, 2020, as compared to those disclosed in this Annual Report with the exception of policies put in place with regards to its convertible senior notes issued in May 2020.

### *Use of Estimates*

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements and accompanying notes as of the date of the consolidated financial statements. Some of those judgments can be subjective and complex, and therefore, actual results could differ materially from those estimates under different assumptions or conditions.

***Cash Equivalents***

The Company considers all highly liquid investments with a maturity of three months or less from the date of purchase and that can be liquidated without prior notice or penalty to be cash equivalents.

***Short-Term Investments***

The Company's short-term investments are classified as available-for-sale securities. Such securities are carried at fair value as determined by prices for identical or similar securities at the balance sheet date. The Company's short-term investments consist of Level 1 and Level 2 financial instruments in the fair value hierarchy. The net unrealized gains or losses on available-for-sale securities are reported as a component of other comprehensive gain (loss) within the statements of operations and accumulated other comprehensive gain (loss) as a separate component of stockholders' equity on the consolidated balance sheets. The Company determines realized gains or losses on the sale of available-for-sale securities using the specific identification method and includes net realized gains and losses as a component of other income or expense within the consolidated statements of operations. The Company periodically reviews available-for-sale securities for other than temporary declines in fair value below the cost basis whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. To date, the Company has not identified any other than temporary declines in fair value of its short-term investments.

***Accounts Receivable***

The Company grants credit to various customers in the ordinary course of business and is paid directly by customers who use the products, distributors and third-party insurance payors. The Company maintains an allowance for its current estimate of expected credit losses. Provisions for expected credit losses are estimated based on historical experience, assessment of specific risk, review of outstanding invoices, forecasts about the future, and various assumptions and estimates that are believed to be reasonable under the circumstances, which included the Company's estimates of credit risks as a result of the novel coronavirus pandemic (COVID-19 global pandemic). Uncollectible accounts are written off against the allowance after appropriate collection efforts have been exhausted and when it is deemed that a balance is uncollectible.

***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company maintains deposit accounts in federally insured financial institutions in excess of federally insured limits. The Company also maintains investments in money market funds that are not federally insured. Additionally, the Company has established guidelines regarding investment instruments and their maturities, which are designed to maintain preservation of principal and liquidity.

The following table summarizes customers who accounted for 10% or more of accounts receivable, net:

| | December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Customer A | 12.7 % | N/A |
| Customer B | 12.3 % | N/A |
| Customer C | N/A | 20.4 % |
| Customer D | N/A | 10.1 % |

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

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Customer B | 15.9 % | 14.8 % | 19.4 % |
| Customer C | 12.9 % | 15.4 % | 15.6 % |

***Fair Value of Financial Instruments***

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and employee-related liabilities are reasonable estimates of their fair values because of the short-term nature of these assets and liabilities. Short-term investments are carried at fair value. The Company determined the fair value of its convertible senior notes at December 31, 2020 to be $333.5 million, based on Level 2 quoted market prices as of that date (see Note 6, “Debt”). The estimated fair value of certain of the Company’s common stock warrants was determined using the Black-Scholes pricing model as of December 31, 2020 and 2019 (see Note 4, "Fair Value Measurements").

***Valuation of Inventories***

Inventories are valued at the lower of cost or net realizable value, determined by the first-in, first-out method. Inventory is recorded using standard cost, including material, labor and overhead costs. The Company periodically reviews inventories for potential impairment and adjusts inventory for potentially excess or obsolete goods to state inventories at their net realizable value. Factors influencing these adjustments include quantities on hand and firm purchase commitments, expectations of future use, judgments based on quality control testing data and assessments of the likelihood of scrapping or obsoleting certain inventories based on future demand for its products and market conditions.

***Long-Lived Assets***

*Property and Equipment*

Property and equipment, which primarily consist of office furniture and equipment, manufacturing equipment, scientific equipment, computer equipment, and leasehold improvements, are stated at cost, less accumulated depreciation. Property and equipment are depreciated over the estimated useful lives of the assets, generally three to seven years, using the straight-line method. Leasehold improvements are amortized over the lesser of the estimated useful lives of the assets or the remaining lease term. Maintenance and repair costs are expensed as incurred.

*Operating Lease Right-of-Use Assets and Liabilities*

In February 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-02, *Leases*. The new standard and its related amendments (collectively referred to as ASC 842) require lessees to recognize right-of-use assets and corresponding lease liabilities for all leases with lease terms of greater than 12 months. The new standard was effective for the Company starting in the first quarter of 2019. The Company adopted the new standard using the modified retrospective approach and recognized right-of-use leased assets and corresponding operating lease liabilities of $12.4 million on the consolidated balance sheet as of January 1, 2019. The Company did not restate prior periods. Deferred rent of $1.0 million and $3.8 million as of January 1, 2019 was reclassified from other current liabilities and deferred rent long-term, respectively, to a reduction of the right-of-use leased assets in connection with the adoption of the standard.

Lease right-of-use assets represent the Company’s right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized when the Company takes possession of the leased property (the Commencement Date) based on the present value of lease payments over the lease term. For lease agreements entered into or reassessed after the adoption of ASC 842, the Company combines lease and non-lease components. Rent expense on noncancelable leases containing known future scheduled rent increases is recorded on a straight-line basis over the term of the respective leases beginning on the Commencement Date. The difference between rent expense and rent paid is accounted for as a component of operating lease right-of-use assets on the Company’s consolidated balance sheet. Landlord improvement allowances and other similar lease incentives are recorded as a reduction of the right-of-use leased assets, and are amortized on a straight-line basis as a reduction to operating lease costs.

*Intangible Assets Subject to Amortization*

On June 24, 2020, the Company acquired Sugarmate, Inc. (Sugarmate), the developer of a popular mobile app for people with diabetes who use insulin, which is designed to help people with diabetes visualize diabetes therapy data in innovative ways. The Sugarmate acquisition was accounted for as an acquisition of assets in accordance with *ASU No. 2017-01, Business Combinations (Topic 805)* Clarifying the Definition of a Business. Substantially all of the fair value was concentrated in a single identifiable asset, a technology-based intangible asset. The purchased intangible is being amortized on a straight-line basis over an estimated useful life of five years. The Company’s results of operations for the year ended December 31, 2020 included the operating results of Sugarmate since the date of acquisition, the amounts of which were not material.

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is provided over their estimated useful lives on a straight-line basis. We review our finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company has not recognized any impairment losses through December 31, 2020.

***Research and Development Costs***

All research and development costs are charged to expense as incurred. Such costs include personnel-related costs, including stock-based compensation, supplies, license fees, development prototypes, outside design and testing services, depreciation, allocated facilities and information services, clinical trial costs, milestone payments under the Company's development and commercialization agreements and other indirect costs.

***Income Taxes***

The Company uses the asset and liability method of accounting for income taxes. Deferred income tax assets or liabilities are recognized based on the temporary differences between financial statement and income tax bases of assets and liabilities using enacted tax rates in effect for the years in which the differences are expected to reverse. Tax law and rate changes are reflected in income in the period such changes are enacted. A valuation allowance is recorded when it is more likely than not that some of the deferred tax assets will not be realized. The Company includes interest and penalties related to income taxes, including unrecognized tax benefits, within income tax expense.

The Company's income tax returns are based on calculations and assumptions that are subject to examination by the Internal Revenue Service and other tax authorities. In addition, the calculation of the Company's tax liabilities involves dealing with uncertainties in the application of complex tax regulations. The Company recognizes liabilities for uncertain tax positions based on a two-step process. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon settlement. While the Company believes it has appropriate support for the positions taken on its tax returns, the Company regularly assesses the potential outcomes of examinations by tax authorities in determining the adequacy of its provision for income taxes. The Company continually assesses the likelihood and amount of potential revisions and adjusts the income tax provision, income taxes payable and deferred taxes in the period in which the facts that give rise to a revision become known.

Significant judgment is required in determining the Company's provision for income taxes, deferred tax assets and liabilities and the valuation allowance recorded against net deferred tax assets. Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not the future realization of all or some of the deferred tax assets will not be achieved. The evaluation of the need for a valuation allowance is performed on a jurisdiction-by-jurisdiction basis, and includes a review of all available positive and negative evidence. Factors reviewed include projections of pre-tax book income for the foreseeable future, determination of cumulative pre-tax book income after permanent differences, earnings history, and reliability of forecasting. The Company will continue to assess the need for a valuation allowance on its deferred tax assets by evaluating both positive and negative evidence that may exist. Any adjustment to the net deferred tax asset valuation allowance would be recorded in the statement of operations for the period that the adjustment is determined to be required.

The Company is required to file federal and state income tax returns in the United States and various other state jurisdictions and, starting with 2018, a corporation income tax return in Canada. The preparation of these income tax returns requires the Company to interpret the applicable tax laws and regulations in effect in such jurisdictions, which could affect the amount of tax paid by the Company. An amount is accrued for the estimate of additional tax liability, including interest and penalties, for any uncertain tax positions taken or expected to be taken in an income tax return. The Company reviews and updates the accrual for uncertain tax positions as more definitive information becomes available. For further information, see Note 8, "Income Taxes."

***Convertible Senior Notes***

In accounting for the issuance of the convertible senior notes, the Company separated the notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of similar debt instruments that do not have associated convertible features. The carrying amount of the equity component representing the conversion option was determined by deducting the fair value of the liability component from the par value of the respective notes. The equity component is not remeasured as long as it continues to meet the condition for equity classification. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense over the term of the notes.

The Company allocated the issuance costs incurred to the liability and equity components of the notes based on their relative fair values. Issuance costs attributable to the liability component were recorded as a reduction to the liability portion of the notes and are being amortized to interest expense over the term of the notes. Issuance costs attributable to the equity component, representing the conversion option, were netted with the equity component in stockholders' equity.

***Revenue Recognition***

Revenue is generated primarily from sales of insulin pumps, disposable cartridges and infusion sets to individual customers with third-party insurance coverage and through a network of distributors that resell the products to insulin-dependent diabetes customers. The Company recognizes revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services.

*Revenue Recognition for Arrangements with Multiple Performance Obligations*

The Company considers the individual deliverables in its product offering as separate performance obligations. The transaction price is determined based on the consideration expected to be received, based either on the stated value in contractual arrangements or the estimated cash to be collected in non-contracted arrangements. The Company allocates the consideration to the individual performance obligations and recognizes the consideration based on when the performance obligation is satisfied, considering whether or not this occurs at a point in time or over time. Generally, insulin pumps, cartridges, infusion sets and accessories are deemed performance obligations that are satisfied at a point in time when the customer obtains control of the promised good, which is upon delivery for our distributor arrangements and upon receipt for sales directly to individual customers. Complementary products, such as t:connect and the Tandem Device Updater, are considered performance obligations that are satisfied over time, as access and support for these products is provided throughout the typical four-year warranty period of the insulin pumps. Accordingly, revenue related to the complementary products is deferred and recognized ratably over a four-year period. Where there is no standalone value for the complementary product, the Company determines their value by applying the expected cost plus a margin approach and then allocates the residual to the insulin pumps. Deferred revenue related to these performance obligations that are satisfied over time was included in the following consolidated balance sheet accounts in the amounts shown as of December 31, 2020 and 2019 (in thousands):

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Deferred revenue | $ 5,508 | $ 3,465 |
| Other long-term liabilities | 10,426 | 5,656 |
| Total | $ 15,934 | $ 9,121 |

*Sales Returns*

The Company offers a 30-day right of return to customers in the U.S. and Canada from the date of shipment of its insulin pumps, provided a physician's confirmation of the medical reason for the return is received. Estimated allowances for sales returns are based on historical returned quantities as compared to pump shipments in those same periods of return, adjusted for known or expected changes in the marketplace when appropriate. The amount recorded in deferred revenue on the Company's consolidated balance sheets for allowances for sales returns was $0.6 million and $0.4 million at December 31, 2020 and 2019, respectively. Actual product returns have not differed materially from estimated amounts recorded in the accompanying consolidated financial statements.

***Warranty Reserve***

The Company generally provides a four-year warranty on its insulin pumps to end user customers and may replace any pumps that do not function in accordance with the product specifications. Insulin pumps returned to the Company may be refurbished and redeployed. Additionally, the Company offers a six-month warranty on disposable cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment. The Company evaluates the reserve quarterly. Warranty costs are primarily estimated based on the current expected product replacement cost and expected replacement rates utilizing historical experience. Recently released versions of the pump may not incur warranty costs in a manner similar to previously released pumps, on which the Company initially bases its warranty estimate of newer pumps. The Company may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to length of time the pump version has been in the field and future expectations of performance based on new features and capabilities that may become available through Tandem Device Updater.

The following table provides a reconciliation of the changes in product warranty liabilities for the years ended December 31, 2020, 2019 and 2018:

| | Year Ended December 31, | | |
|---|---|---|---|
| (in thousands) | 2020 | 2019 | 2018 |
| Balance at beginning of the year | $ 16,724 | $ 9,138 | $ 5,640 |
| Provision for warranties issued during the period | 21,135 | 18,335 | 9,617 |
| Settlements made during the period | (13,736) | (10,167) | (7,797) |
| (Decrease) increase in warranty estimates | (2,048) | (582) | 1,678 |
| Balance at end of the year | $ 22,075 | $ 16,724 | $ 9,138 |

As of December 31, 2020 and December 31, 2019, total product warranty reserves of $22.1 million and $16.7 million, respectively, were included in the following consolidated balance sheet accounts:

| | December 31, | |
|---|---|---|
| (in thousands) | 2020 | 2019 |
| Other current liabilities | $ 8,409 | $ 4,707 |
| Other long-term liabilities | 13,666 | 12,017 |
| Total warranty reserve | $ 22,075 | $ 16,724 |

***Stock-Based Compensation***

Stock-based compensation cost is measured at the grant date based on the estimated fair value of the award, and the portion that is ultimately expected to vest is recognized as compensation expense over the requisite service period on a straight-line basis. The Company estimates the fair value of stock options issued under the Company's Amended and Restated 2013 Stock Incentive Plan (2013 Plan) and the fair value of the employees' purchase rights under the Company's 2013 Employee Stock Purchase Plan (ESPP) using the Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model requires the use of assumptions about a number of variables, including stock price volatility, expected term, dividend yield and risk-free interest rate. The fair value of restricted stock unit (RSU) awards issued under the Company's 2013 Plan that vest solely based on service is estimated based on the fair market value of the underlying stock on the date of grant.

***Common Stock Warrant Liabilities***

The Company accounts for certain stock warrants as a liability in the consolidated financial statements when they contain a provision within the warrant contracts that could require cash settlement in the event the Company did not have an active registration statement. The fair value of these common stock warrants is remeasured at each financial reporting period with any changes in fair value being recognized as a component of other income (expense) in the accompanying statements of operations and comprehensive loss.

***Shipping and Handling Expenses***

Shipping and handling expenses associated with product delivery are included within cost of sales in the Company's statements of operations. Amounts billed to a customer for shipping and handling are reported as revenues.

***Comprehensive Loss***

All components of comprehensive loss, including net loss, are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive loss is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources, including unrealized gains and losses on marketable securities and foreign currency translation adjustments.

***Net Loss Per Share***

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares that were outstanding for the period, without consideration for common stock equivalents. Diluted loss per share reflects the potential dilution that would occur if securities exercisable for or convertible into common stock were exercised for or converted into common stock. Dilutive common share equivalents are comprised of warrants, stock options outstanding under the Company's equity incentive plans, unvested RSUs, and potential awards granted pursuant to the ESPP, each calculated using the treasury stock method; and shares issuable upon conversion of the senior convertible notes using the if-converted method. For warrants that are recorded as a liability in the accompanying condensed consolidated balance sheets, the calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of the warrants is dilutive to loss per share for the period, an adjustment is made to net loss used in the calculation to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method. For the annual periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position (see Note 12, "Selected Quarterly Financial Data (Unaudited)" for quarterly details).

Potentially dilutive securities outstanding and not included in the calculation of diluted net loss per share (because inclusion would be anti-dilutive) are as follows (in thousands, in common stock equivalent shares):

| | Year Ended December 31, | | |
|---|---|---|---|
| | **2020** | **2019** | **2018** |
| Warrants to purchase common stock | 379 | 611 | 705 |
| Options to purchase common stock | 5,021 | 5,619 | 3,477 |
| Unvested restricted stock units | 78 | N/A | N/A |
| Awards granted under the ESPP | 3 | 5 | 4 |
| Convertible senior notes (if-converted) | 1,605 | N/A | N/A |
| | 7,086 | 6,235 | 4,186 |

***Recent Accounting Pronouncements***

In June 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments,* which modifies the measurement and recognition of credit losses for most financial assets and certain other instruments. The new standard requires the use of forward-looking expected credit loss models based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount, which may result in earlier recognition of credit losses under the new standard. The new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income (loss) rather than reducing the carrying amount under the prior, other-than-temporary-impairment model. The new standard must be adopted using the modified retrospective approach and was effective for the Company starting in the first quarter of 2020. The Company determined there was no cumulative-effect transition adjustment to the opening balance of accumulated deficit for recognition of additional credit losses upon adoption of this standard as of January 1, 2020 based on its outstanding accounts receivable, the composition and credit quality of its short-term investments, and current economic conditions as of that date.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. The updated guidance was effective for the Company starting in the first quarter of 2020. As a result, the Company modified certain fair value measurement disclosures primarily related to its Level 3 liabilities (see Note 4, "Fair Value Measurements").

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects of the income tax accounting guidance, including requirements such as tax basis step-up in goodwill obtained in a transaction that is not a business combination, ownership changes in investments, and interim-period accounting for enacted changes in tax law. ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. The Company early adopted the new guidance in the second quarter of 2020. As a result, the Company recognized, on a prospective basis, $13,000 of income tax expense in the second quarter of 2020 upon the reversal of tax benefits recorded in the first quarter of 2020 related to unrealized gains on short-term investments.

In June 2020, the FASB issued ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which is intended to simplify the accounting for convertible instruments. This new guidance eliminates certain models that require separate accounting for embedded conversion features, and eliminates certain of the conditions for equity classification for contracts in an entity's own equity. Accordingly, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance can be adopted through either a modified retrospective method of transition or a fully retrospective method of transition. ASU 2020-06 is effective for public business entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company is in the process of determining the impact of the adoption of the standard on its consolidated financial statements as well as whether to early adopt the new standard.

## 3. Financial Statement Information

### *Short-Term Investments*

The Company invests in marketable securities, principally debt instruments of the U.S. Government, financial institutions and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at December 31, 2020 and 2019 (in thousands):

| At December 31, 2020 | Maturity (in years) | Amortized Cost | Gross Unrealized Gain | Gross Unrealized Loss | Estimated Fair Value |
|---|---|---|---|---|---|
| Available-for-sale securities: | | | | | |
| Commercial paper | Less than 1 | $ 108,892 | $ 5 | $ (1) | $ 108,896 |
| U.S. Government-sponsored enterprise | Less than 2 | 52,330 | 21 | (1) | 52,350 |
| U.S. Treasury securities | Less than 2 | 143,244 | 12 | (2) | 143,254 |
| Corporate debt securities | Less than 2 | 85,788 | 48 | (13) | 85,823 |
| Total | | $ 390,254 | $ 86 | $ (17) | $ 390,323 |

| At December 31, 2019 | Maturity (in years) | Amortized Cost | Gross Unrealized Gain | Gross Unrealized Loss | Estimated Fair Value |
|---|---|---|---|---|---|
| Available-for-sale securities: | | | | | |
| Commercial paper | Less than 1 | $ 24,147 | $ 10 | $ — | $ 24,157 |
| U.S. Government-sponsored enterprise | Less than 2 | 33,073 | 26 | — | 33,099 |
| U.S. Treasury securities | Less than 2 | 17,963 | 17 | (1) | 17,979 |
| Corporate debt securities | Less than 2 | 50,011 | 42 | (5) | 50,048 |
| Total | | $ 125,194 | $ 95 | $ (6) | $ 125,283 |

The Company has classified all marketable securities, regardless of maturity, as short-term investments based upon the Company's ability and intent to use any of those marketable securities to satisfy the Company's liquidity requirements.

The Company periodically reviews the portfolio of available-for-sale debt securities to determine if any investment is other-than-temporarily impaired due to changes in credit risk or other potential valuation concerns. Unrealized losses on available-for-sale debt securities at that date were not significant and were due to changes in interest rates, including credit spreads, from perceived increased credit risks as a result of the COVID-19 global pandemic. The Company does not intend to sell the available-for-sale debt securities that are in an unrealized loss position, and it is not more likely than not that the Company will be required to sell these debt securities before recovery of their amortized cost bases, which may be at maturity. Based on the credit quality of the available-for-sale debt securities that are in an unrealized loss position, and the Company's estimates of future cash flows to be collected from those securities, the Company believes the unrealized losses are not credit losses. Accordingly, the Company has not recognized any impairment losses related to its available-for-sale debt securities at December 31, 2020.

***Accounts Receivable***

Accounts receivable consisted of the following (in thousands):

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Accounts receivable | $ 86,052 | $ 49,889 |
| Less: allowance for credit losses | (3,857) | (3,304) |
| Accounts receivable, net | $ 82,195 | $ 46,585 |

***Allowance for Credit Losses***

The following table provides a reconciliation of the changes in the estimated allowance for expected accounts receivable credit losses (formerly the allowance for doubtful accounts) for the years ended December 31, 2020, 2019 and 2018 (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Balance at beginning of the year | $ 3,304 | $ 1,837 | $ 1,035 |
| Provision for expected credit losses | 3,016 | 2,322 | 1,448 |
| Write-offs and adjustments, net of recoveries | (2,463) | (855) | (646) |
| Balance at end of the year | $ 3,857 | $ 3,304 | $ 1,837 |

***Inventories***

Inventories consisted of the following at (in thousands):

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Raw materials | $ 30,880 | $ 20,699 |
| Work-in-process | 15,664 | 16,532 |
| Finished goods | 17,177 | 11,842 |
| Total inventories | $ 63,721 | $ 49,073 |

***Property and Equipment***

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

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Leasehold improvements | $ 22,834 | $ 13,100 |
| Computer equipment and software | 12,219 | 9,899 |
| Office furniture and equipment | 9,876 | 6,367 |
| Manufacturing and scientific equipment | 44,026 | 33,422 |
| Total cost | 88,955 | 62,788 |
| Less: accumulated depreciation and amortization | (38,933) | (29,865) |
| Total property and equipment, net | $ 50,022 | $ 32,923 |

Depreciation and amortization expense related to property and equipment was $9.2 million, $5.7 million, and $5.5 million for the years ended December 31, 2020, 2019, and 2018, respectively.

***Intangible Assets Subject to Amortization***

Intangible assets subject to amortization consist of technology-based intangibles related to the Company's acquisition of Sugarmate, as well as patents purchased or licensed that are related to the Company's commercialized products. Intangible assets at December 31, 2020 and 2019, which were included in other long-term assets on the consolidated balance sheets, were as follows (in thousands):

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Intangible assets, gross amount | $ 12,502 | $ 3,247 |
| Accumulated amortization | (3,697) | (2,470) |
| Intangible assets, net | $ 8,805 | $ 777 |
| Weighted average remaining amortization period (in months) | 52 | 30 |

Amortization expense related to intangible assets subject to amortization amounted to $1.2 million, $0.3 million and $0.3 million for the years ended December 31, 2020, 2019, and 2018, respectively. The amortization expense is recorded in cost of sales and selling, general and administrative expense in the consolidated statement of operations. The estimated aggregate amortization expense for each of the five succeeding years is $2.2 million for 2021, $2.0 million for 2022, $1.9 million for each of 2023 and 2024, and $0.9 million for 2025.

**4. Fair Value Measurements**

Authoritative guidance on fair value measurements defines fair value, and provides a consistent framework for measuring fair value and for disclosures of each major asset and liability category measured at fair value on either a recurring or a nonrecurring basis. Fair value is intended to reflect an assumed exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or

liability. As a basis for considering such assumptions, the authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

| | |
|---|---|
| Level 1: | Observable inputs such as unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities. |
| Level 2: | Inputs, other than quoted prices in active markets, that are observable either directly or indirectly for substantially the full term of the asset or liability. |
| Level 3: | Unobservable inputs in which there is little or no market data and that are significant to the fair value of the assets or liabilities, which require the reporting entity to develop its own valuation techniques that require input assumptions. |

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2020 and 2019, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands):

| | | Fair Value Measurements at December 31, 2020 | | |
|---|---|---|---|---|
| | December 31, 2020 | Level 1 | Level 2 | Level 3 |
| **Assets** | | | | |
| Cash equivalents [1] | $ 87,300 | $ 87,300 | $ — | $ — |
| Commercial paper | 108,896 | — | 108,896 | — |
| U.S. Government-sponsored enterprise | 52,350 | — | 52,350 | — |
| U.S. Treasury securities | 143,254 | 143,254 | — | — |
| Corporate debt securities | 85,823 | — | 85,823 | — |
| Total assets | $ 477,623 | $ 230,554 | $ 247,069 | $ — |
| **Liabilities** | | | | |
| Common stock warrants | $ 14,261 | $ — | $ — | $ 14,261 |
| Total liabilities | $ 14,261 | $ — | $ — | $ 14,261 |

| | | Fair Value Measurements at December 31, 2019 | | |
|---|---|---|---|---|
| | December 31, 2019 | Level 1 | Level 2 | Level 3 |
| **Assets** | | | | |
| Cash equivalents [1] | $ 43,520 | $ 43,520 | $ — | $ — |
| Commercial paper | 24,157 | — | 24,157 | — |
| U.S. Government-sponsored enterprise | 33,099 | — | 33,099 | — |
| U.S. Treasury securities | 17,979 | 17,979 | — | — |
| Corporate debt securities | 50,048 | — | 50,048 | — |
| Total assets | $ 168,803 | $ 61,499 | $ 107,304 | $ — |
| **Liabilities** | | | | |
| Common stock warrants | $ 23,509 | $ — | $ — | $ 23,509 |
| Total liabilities | $ 23,509 | $ — | $ — | $ 23,509 |

(1) Generally, cash equivalents include money market funds and investments with a maturity of three months or less from the date of purchase.

The Company's Level 2 financial instruments are valued using market prices on less active markets with observable valuation inputs such as interest rates and yield curves. The Company obtains the fair value of Level 2 financial instruments from quoted market prices, calculated prices or quotes from third-party pricing services. The Company validates these prices through independent valuation testing and review of portfolio valuations provided by the Company's investment managers.

The Company's Level 3 liabilities at December 31, 2020 and 2019 included the remaining Series A warrants issued by the Company in connection with the public offering of common stock in October 2017. The Series A warrants, which expire in October 2022, initially provided holders the right to purchase 4,630,000 shares of the Company's common stock at an exercise price of $3.50 per share. The Series A warrants were initially valued in the aggregate amount of $5.2 million on the date of issuance utilizing a Black-Scholes pricing model.

During the years ended December 31, 2020 and 2019, the Company issued 262,615 shares and 93,470 shares of common stock, respectively, upon the exercise of Series A warrants. As of December 31, 2020 and 2019, there were Series A warrants outstanding to purchase 154,700 shares and 417,315 shares, respectively, of the Company's common stock (see Note 7, "Stockholders' Equity").

The Company reassesses the fair value of the outstanding Series A warrants at each reporting date utilizing a Black-Scholes pricing model. Variables used in the pricing model include the closing market price of the Company's common stock at the balance sheet date, and estimates of stock price volatility, dividend yield, expected warrant term and risk-free interest rate. The Company develops its estimates based on publicly available historical data. A significant increase (decrease) in any of these inputs in isolation, particularly the market price of the Company's common stock, would have resulted in a significantly higher (lower) fair value measurement. The assumptions used to estimate the fair values of the outstanding Series A warrants at December 31, 2020 and 2019 are presented below:

| | Series A Warrants | |
|---|---|---|
| | December 31, 2020 | December 31, 2019 |
| Risk-free interest rate | 0.1 % | 1.6 % |
| Expected dividend yield | 0.0% | 0.0% |
| Expected volatility | 55.3 % | 77.2 % |
| Expected term (in years) | 1.8 | 2.8 |

The following table presents a summary of changes in fair value of the Company's total Level 3 financial liabilities for the years ended December 31, 2020 and 2019:

| | 2020 | 2019 |
|---|---|---|
| Balance at beginning of year | $ 23,509 | $ 17,926 |
| Loss recognized from the change in fair value of common stock warrants | 17,087 | 11,075 |
| Decrease in fair value from warrants exercised during the period | (26,335) | (5,492) |
| Balance at end of year | $ 14,261 | $ 23,509 |

Of the loss recognized from the change in fair value of common stock warrants for the years ended December 31, 2020 and 2019, $5.5 million and $8.9 million, respectively, was attributable to warrants outstanding as of December 31, 2020 and 2019.

**5. Leases**

The Company's leases consist of operating leases for general office space, laboratory, manufacturing and warehouse facilities, and equipment. These noncancellable operating leases have initial lease terms from one year to seven years. Leases with an initial term of 12 months or less are expensed as incurred and are not recorded as right-of-use assets on the consolidated balance sheets. Certain leases include an option to renew, with renewal terms that can extend the lease term for additional periods. The exercise of lease renewal options is at the Company's sole discretion. The depreciable life of assets and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option that is reasonably certain to be exercised.

The Company recognizes lease expense for operating leases on a straight-line basis over the lease term. Because the Company's leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on the information available at the lease Commencement Date in determining the present value of future lease payments. The Company used the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date.

In January 2019, the Company entered into a lease agreement for approximately 25,332 square feet of additional general administrative office space (Initial Premises) located on Vista Sorrento Parkway, in San Diego, California (Vista Sorrento Lease). The lease term for the Initial Premises commenced in March 2019 and expires in September 2022. In May 2019, the Company entered into a First Amendment to the Vista Sorrento Lease (First Amendment) to expand the leased premises by adding approximately 33,681 square feet of additional general administrative office space (Expansion Space), and to extend the lease term for the Initial Premises through January 2023. The lease term for the Expansion Space commenced in May 2019 and expires in January 2023. The Company has a one-time option to extend the term of the Vista Sorrento Lease, covering both the Initial Premises and the Expansion Space, for a period of four years. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of $3.1 million on the consolidated balance sheet in the first quarter of 2019 related to the Initial Premises, and $4.7 million related to the First Amendment.

In March 2019, the Company entered into a lease agreement for approximately 40,490 square feet of space located on Marindustry Place, San Diego, California to house additional operations functions, including warehousing and shipping (Marindustry Place Lease). The lease term commenced in May 2019 and expires in April 2026. The Company has a one-time option to extend the term of the Marindustry Place Lease for a period of no less than three years and no more than five years. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of $3.4 million on the consolidated balance sheet on the Commencement Date in the second quarter of 2019.

In November 2019, the Company entered into a lease agreement for approximately 94,562 square feet of additional general office space located on Shoreline Drive, in Boise, Idaho (Shoreline Lease). The lease term commenced on July 1, 2020, and expires in June 2027. The Company has a one-time option to extend the term of the Shoreline Lease for a period of three years. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of approximately $6.5 million on the consolidated balance sheet on the Commencement Date in the first quarter of 2020.

In January 2020, the Company entered into a sub-lease agreement for approximately 30,703 square feet of general office space located on High Bluff Drive, in San Diego, California. The lease term began in April 2020 and expires in March 2022. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of approximately $2.3 million on the consolidated balance sheet on the Commencement Date in the first quarter of 2020.

In September 2020, the Company amended certain leases covering approximately 77,000 square feet of general office and laboratory space located on Roselle Street in San Diego, California (Roselle Street Leases). The lease amendments extended the term of each lease for an additional period of one year, and included a rent increase during the additional lease term. The Roselle Street Leases, which would have expired in May 2022, are now scheduled to expire in May 2023. The Company recognized additional right-of-use leased assets and corresponding operating lease liabilities of $2.2 million on the consolidated balance sheet in the third quarter of 2020 related to the amendment of the Roselle Street Leases.

The Company's lease cost recorded in the consolidated statements of operations was as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Operating lease cost | $ 7,514 | $ 4,542 | $ 2,557 |
| Short-term lease cost | 219 | 165 | 46 |
| Total lease cost | $ 7,733 | $ 4,707 | $ 2,603 |

Maturities of operating lease liabilities at December 31, 2020 were as follows (in thousands):

| **Year Ending December 31,** | | |
|---|---|---|
| 2021 | $ | 9,421 |
| 2022 | | 8,710 |
| 2023 | | 4,386 |
| 2024 | | 1,881 |
| 2025 | | 1,876 |
| Thereafter | | 2,099 |
| Total undiscounted lease payments | | 28,373 |
| Less: amount representing interest | | (3,038) |
| Present value of operating lease liabilities | | 25,335 |
| Less: current portion of operating lease liabilities | | (9,421) |
| Operating lease liabilities - long-term | $ | 15,914 |

The weighted-average remaining lease term and weighted-average discount rate for operating leases were as follows:

| | **December 31, 2020** | **December 31, 2019** |
|---|---|---|
| Weighted-average remaining lease term (in years) | 3.7 | 3.6 |
| Weighted-average discount rate used to determine operating lease liabilities | 5.9 % | 6.6 % |

Cash paid for amounts included in the measurement of lease liabilities, representing operating cash flows from operating leases, was $8.2 million and $4.4 million for the years ended December 31, 2020 and 2019, respectively.

**6. Debt**

***Convertible Senior Notes***

In May 2020, the Company entered into a purchase agreement with certain counterparties for the sale of an aggregate of $287.5 million principal amount of 1.50% Convertible Senior Notes due 2025 in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The Notes were issued pursuant to an Indenture, dated May 15, 2020, between the Company and U.S. Bank National Association, as trustee (Indenture). The net proceeds from the issuance of the Notes were $244.6 million, net of debt issuance costs and cash used to purchase the capped call transactions (Capped Call Transactions) discussed below.

The Notes are the Company's senior unsecured obligations. Interest is payable in cash semi-annually in arrears beginning on November 1, 2020 at a rate of 1.50% per year. The Notes mature on May 1, 2025 unless repurchased, redeemed, or converted in accordance with their terms prior to the maturity date.

The Notes are convertible into cash, shares of the Company's common stock, or a combination of cash and shares of the Company's common stock, at the Company's election, at an initial conversion rate of 8.8836 shares of common stock per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of approximately $112.57 (Conversion Price) per share of the Company's common stock. The conversion rate is subject to customary adjustments for certain events as described in the Indenture.

The Company may not redeem the Notes prior to May 6, 2023. The Company has the option to redeem for cash all or any portion of the Notes on or after May 6, 2023 if the last reported sale price of the Company's common stock has been at least 130% of the Conversion Price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which the Company provides notice of redemption, during any 30 consecutive trading day period, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest. No sinking fund is provided for the Notes.

Holders of the Notes may convert all or a portion of their Notes at their option prior to November 1, 2024, in multiples of $1,000 principal amounts, only under the following circumstances:

- if the last reported sale price of the Company's common stock for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the applicable conversion price of the Notes on each such trading day;

- during the five business day period after any five consecutive trading day period in which the trading price per $1,000 principal amount of the Notes for each day of that five consecutive trading day period was less than 98% of the product of the last reported sale price of the Company's common stock and the applicable conversion rate of the Notes on such trading day;

- if the Company calls any or all of the Notes for redemption, at any time prior to the close of business on the scheduled trading day immediately preceding the redemption date; or

- on the occurrence of specified corporate events.

On or after November 1, 2024, until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert their Notes at any time, regardless of the foregoing circumstances.

Holders of the Notes who convert in connection with a make-whole fundamental change, as defined in the Indenture, or in connection with a redemption are entitled to an increase in the conversion rate. Additionally, in the event of a fundamental change, as defined in the Indenture, holders of the Notes may require us to repurchase all or a portion of the Notes at a price equal to 100% of the principal amount of the Notes, plus any accrued and unpaid interest.

In accounting for the issuance of the Notes, the Company separated the Notes into liability and equity components. The carrying amount of the liability component was calculated by measuring the fair value of similar debt instruments, which do not have an associated convertible feature. The amount of the equity component representing the conversion option for the Notes was $88.5 million and was recorded as a debt discount, which is amortized to interest expense at an effective interest rate of 9.9%. The Company allocated $2.7 million of debt issuance costs to the equity component and the remaining debt issuance costs of $6.1 million were allocated to the liability component, which are amortized to interest expense under the effective interest rate method. The equity component of the Notes will not be remeasured as long as it continues to meet the conditions for equity classification. It is the Company's intent and policy to settle conversions through combination settlement, which essentially involves payment in cash equal to the principal portion and delivery of shares of common stock for the excess of the conversion value over the principal portion.

The liability and equity components of the Notes consisted of the following (in thousands):

| | December 31, 2020 |
|---|---|
| Liability: | |
| Principal | $ 287,500 |
| Unamortized debt discount and debt issuance costs | (84,516) |
| Net carrying amount | $ 202,984 |
| Carrying amount of the equity component | $ 85,803 |

As of December 31, 2020, the debt discount and debt issuance costs associated with the Notes will be amortized over the remaining period of approximately 4.3 years using the effective interest method.

The following table details interest expense recognized related to the Notes for the year ended December 31, 2020 (in thousands):

| | Year Ended December 31, 2020 |
|---|---|
| Contractual interest expense | $ 2,707 |
| Amortization of debt issuance costs | 652 |
| Amortization of debt discount | 9,446 |
| Total interest expense | $ 12,805 |

The Notes will have a dilutive effect to the extent the average market price per share of common stock for a given reporting period exceeds the conversion price of $112.57. As of December 31, 2020, the “if-converted value” did not exceed the principal amount of the Notes.

***Capped Call Transactions***

In connection with the issuance of the Notes, the Company entered into Capped Call Transactions with certain counterparties at a net cost of $34.1 million. The Capped Call Transactions are intended to reduce potential dilution to holders of the Company’s common stock beyond the conversion price of $112.57, up to a conversion price of $173.18 on any conversion of the Notes, or to offset any cash payments the Company is required to make in excess of the principal amount of such converted Notes, as the case may be, with such reduction or offset subject to a cap. The cap price of the Capped Call Transactions is initially $173.18 per share of the Company’s common stock, representing a premium of 100% above the last reported sale price of $86.59 per share of the Company’s common stock on May 12, 2020, and is subject to certain adjustments under the terms of the Capped Call Transactions. Conditions that cause adjustments to the initial strike price of the Capped Call Transactions mirror conditions that result in corresponding adjustments for the Notes.

For accounting purposes, the Capped Calls are separate transactions, and not part of the terms of the Notes. As these transactions meet certain criteria under the applicable accounting guidance, the Capped Calls are recorded in stockholders' equity and are not accounted for as derivatives. The cost of the Capped Call Transactions was recorded as a reduction of the Company’s additional paid-in capital in the Company’s consolidated balance sheet and will not be remeasured.

***Term Loan Agreement***

In August 2018, the Company fully repaid the term loan made by Capital Royalty Partners II, L.P. and its affiliated funds (CRG) pursuant to the Amended and Restated Term Loan Agreement (Term Loan Agreement). The balance of the outstanding debt during 2018 up until the time of repayment was $82.7 million, and was included in Notes payable long-term in the consolidated balance sheet, offset by the debt discount associated with financing fees and certain debt issuance costs. At the time of repayment, the remaining unamortized debt discount of $5.3 million was accelerated and recognized as a loss on extinguishment of debt in the consolidated statement of operations for the year ended December 31, 2018. The total repayment amount of $88.8 million included approximately $1.1 million in accrued interest, and approximately $5.0 million in associated financing fees that became due.

Under the Term Loan Agreement, interest was payable at the Company’s option, (i) in cash at a rate of 11.5% per annum, or (ii) at a rate of 9.5% of the 11.5% per annum in cash and 2.0% of the 11.5% per annum (PIK Loan) to be added to the principal of the loan and subject to accruing interest.

**7. Stockholders’ Equity (Deficit)**

***Public Offerings***

In the first quarter of 2018, the Company completed a registered public offering of 34,500,000 shares of common stock at a public offering price of $2.00 per share. The gross proceeds from the offering were approximately $69.0 million, before deducting underwriting discounts and commissions and other offering expenses.

In the third quarter of 2018, the Company completed a public offering of 4,035,085 shares of common stock at a public offering price of $28.50 per share. The gross proceeds to the Company from the offering were $115.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

***Shares Reserved for Future Issuance***

The following shares of the Company's common stock were reserved for future issuance at December 31, 2020 (in thousands):

| | |
|---|---|
| Shares reserved for issuance upon conversion of Convertible Senior Notes | 2,554 |
| Shares underlying outstanding warrants | 379 |
| Shares underlying outstanding stock options | 5,804 |
| Shares underlying unvested restricted stock units | 133 |
| Shares authorized for issuance pursuant to awards granted under the ESPP | 1,389 |
| Shares authorized for future equity award grants | 2,039 |
| | 12,298 |

***Common Stock Warrants***

Warrants outstanding to purchase shares of the Company's common stock as of December 31, 2020 were as follows:

| Issue Date | Exercise Price Per Share | Warrants Outstanding | Expiration Date |
|---|---|---|---|
| October 2017 | $3.50 | 154,700 | October 2022 |
| March 2017 | $23.50 | 193,788 | March 2027 |
| August 2011 - August 2012 | $73.73 | 30,861 | August 2021 - August 2022 |
| | | 379,349 | |

Each warrant allows the holder to purchase one share of the Company's common stock at the exercise price per share of the respective warrant. The Company issued 295,526 and 93,470 shares of its common stock upon the exercise of warrants during the years ended December 31, 2020 and 2019, respectively.

***Stock Plans***

In September 2006, the Company adopted the Company’s 2006 Stock Incentive Plan (2006 Plan), under which, as amended, 268,561 shares of common stock were reserved for issuance to employees, non-employee directors and consultants of the Company. The 2006 Plan was closed in 2013 with the approval of the 2013 Plan and no further options will be granted under the 2006 Plan.

The Company’s Amended and Restated 2013 Stock Incentive Plan (2013 Plan) was originally approved by the Company’s board of directors in October 2013. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock and restricted stock units to individuals who are then employees, officers, directors or consultants of the Company. In June 2018, the Company received approval from its stockholders to increase the number of shares of common stock reserved under the 2013 Plan by 5,500,000 shares. In June 2019, the Company received approval from its stockholders to increase the number of shares of its common stock reserved for issuance under the 2013 Plan by an additional 5,000,000 shares.

The Company issued 2,339,467 and 1,418,953 shares of its common stock, respectively, upon the exercise of stock options during the years ended December 31, 2020 and 2019. During the year ended December 31, 2020, the Company issued 1,892 shares of its common stock upon the vesting of RSUs.

*Common Stock Options*

The maximum term of stock options granted under the 2006 Plan and 2013 Plan is ten years. Common stock options have an exercise price equal to the closing price of the Company's common stock on the applicable award date, and generally vest over a four year period as to 25% of the underlying shares on the first anniversary of the award, with the balance of the options vesting monthly over the following three years.

The following table summarizes stock option activities for the 2006 Plan and 2013 Plan:

| | Total Options | Weighted-Average Exercise Price Per Share | Weighted-Average Remaining Contractual Life (in years) | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|---|
| Outstanding at December 31, 2018 | 5,763,192 | $ 23.61 | 8.94 | $ 116,988 |
| Granted | 3,026,511 | $ 54.62 | | |
| Exercised | (1,418,953) | $ 12.46 | | $ 71,808 |
| Canceled/forfeited/expired | (195,823) | $ 42.93 | | $ 4,190 |
| Outstanding at December 31, 2019 | 7,174,927 | $ 38.40 | 8.45 | $ 181,408 |
| Granted | 1,130,040 | $ 83.55 | | |
| Exercised | (2,339,467) | $ 24.69 | | $ 161,688 |
| Canceled/forfeited/expired | (161,995) | $ 27.00 | | $ 4,516 |
| Outstanding at December 31, 2020 | 5,803,505 | $ 52.08 | 7.90 | $ 268,649 |
| Vested and expected to vest at December 31, 2020 | 5,732,927 | $ 51.93 | 7.89 | $ 266,396 |
| Exercisable at December 31, 2020 | 2,980,386 | $ 40.30 | 7.17 | $ 178,540 |

*Restricted Stock Units (RSUs)*

RSUs have a grant price equal to the closing price of the Company's common stock on the award date, and generally vest over a four year period based only on service as to 25% of the underlying shares on the first anniversary of the award, with the balance of the RSUs vesting quarterly over the following three years. A summary of RSU activity for the year ended December 31, 2020 is as follows:

| | Total RSUs | Weighted-Average Grant Date Fair Value | Aggregate Intrinsic Value (in thousands) |
|---|---|---|---|
| Unvested awards outstanding at December 31, 2019 | — | $ — | $ — |
| Granted | 134,694 | $ 82.82 | |
| Vested | (1,892) | $ 95.68 | |
| Unvested awards outstanding at December 31, 2020 | 132,802 | $ 82.82 | $ 12,706 |

*Employee Stock Purchase Plan*

In October 2013, the Company adopted the ESPP, which enables eligible employees to purchase shares of the Company's common stock using their after-tax payroll deductions, subject to certain conditions. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code. Eligible employees may contribute, through payroll deductions, up to 15% of their earnings for the purchase of common stock under the ESPP. The purchase price of common stock under the ESPP is the lesser of: (a) 85% of the fair market value of a share of the Company's common stock on the first date of an offering or (b) 85% of the fair market value of a share of the Company's common stock on the date of purchase. Generally, the ESPP consists of a two-year offering period with four six-month purchase periods.

In June 2018, the Company received approval from its stockholders to increase the number of shares reserved for issuance under the ESPP by 2,000,000 shares.

During the years ended December 31, 2020 and 2019, 302,509 shares and 329,072 shares of our common stock, respectively, were purchased under the ESPP for proceeds of $9.1 million and $6.2 million, respectively.

*Stock-Based Compensation*

During the year ended December 31, 2019, the Company granted options to purchase 3,026,511 shares of common stock under the 2013 Plan, of which 1,644,715 options were originally awarded between February 2019 and June 2019, subject to and conditioned upon the approval by its stockholders of an increase in the number of shares of common stock reserved for issuance under the 2013 Plan. Stock-based compensation expense was not recognized for the contingent stock option grants prior to the approval by the Company's stockholders of the increase in the number of shares of common stock reserved for issuance under the 2013 Plan, which occurred in June 2019.

During the year ended December 31, 2018, the Company granted options to purchase 4,730,956 shares of common stock under the 2013 Plan, of which 811,800 options were originally awarded in December 2017, subject to and conditioned upon the approval by its stockholders of an increase in the number of shares of common stock authorized under the 2013 Plan. Stock-based compensation expense was not recognized for the contingent stock option grants prior to the approval by the Company's stockholders of the increase in the number of shares of common stock reserved for issuance under the 2013 Plan, which occurred in June 2018. Of the total options granted, options to purchase 4,201,100 shares of common stock, granted in June 2018, vested over a two year period with 50% of the underlying shares on the first anniversary of the award and the balance of the options vesting monthly over the following year.

The following table summarizes the allocation of stock-based compensation expense included in the consolidated statements of operations for all stock-based compensation arrangements (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Cost of sales | $ 8,210 | $ 6,415 | $ 2,581 |
| Selling, general & administrative | 41,563 | 42,857 | 16,824 |
| Research and development | 8,658 | 8,799 | 4,331 |
| Total stock-based compensation expense | $ 58,431 | $ 58,071 | $ 23,736 |

The total stock-based compensation capitalized as part of the cost of the Company's inventories was $0.6 million and $1.3 million at December 31, 2020 and 2019, respectively.

At December 31, 2020, the total unamortized stock-based compensation expense of approximately $120.7 million will be recognized over the remaining weighted average vesting term of approximately 2.8 years.

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

| | Stock Options | | |
|---|---|---|---|
| | Year Ended December 31, | | |
| | 2020 | 2019 | 2018 |
| Weighted average grant date fair value (per share) | $ 54.20 | $ 39.06 | $ 12.94 |
| Risk-free interest rate | 0.6 % | 2.1 % | 2.8 % |
| Expected dividend yield | 0.0 % | 0.0 % | 0.0 % |
| Expected volatility | 74.6 % | 71.8 % | 71.4 % |
| Expected term (in years) | 6.1 | 6.0 | 5.7 |

| | ESPP | | |
|---|---|---|---|
| | Year Ended December 31, | | |
| | 2020 | 2019 | 2018 |
| Weighted average grant date fair value (per share) | $ 36.83 | $ 30.32 | $ 13.48 |
| Risk-free interest rate | 0.2 % | 1.9 % | 2.5 % |
| Expected dividend yield | 0.0 % | 0.0 % | 0.0 % |
| Expected volatility | 60.3 % | 69.9 % | 81.2 % |
| Expected term (in years) | 1.3 | 1.3 | 1.3 |

*Risk-free Interest Rate*. The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued.

*Expected Dividend Yield*. The expected dividend yield is zero because the Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future.

*Expected Volatility*. The expected volatility is estimated based on a weighted-average volatility of the Company's actual historical volatility since its initial public offering in November 2013, and the historical stock volatilities of a peer group of similar companies whose share prices are publicly available. The peer group consisted of publicly traded companies in the same industry and in a similar stage of development. During 2020, the Company transitioned to solely using the expected volatility of its own common stock.

*Expected Term*. The Company utilized the simplified method for estimating the expected term of stock option grants. Under this approach, the weighted-average expected term is presumed to be the average of the vesting term and the contractual term of the option. The Company estimates the expected term of the ESPP using expected life for each tranche during the two-year offering period.

The Company also estimates forfeitures at the time of grant, and revises those estimates in subsequent periods if actual forfeitures differ from its estimates. Historical data was used to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest.

**8. Income Taxes**

The loss before provision for income taxes for the Company's domestic and international operations was as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| U.S. | $ (36,667) | $ (24,888) | $ (122,560) |
| Foreign | 385 | 284 | — |
| Loss before provision for income taxes | $ (36,282) | $ (24,604) | $ (122,560) |

The components of income tax expense (benefit) were as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Current: | | | |
| Federal | $ — | $ — | $ — |
| State | 75 | 86 | 51 |
| Foreign | 151 | 88 | — |
| Total current tax expense | 226 | 174 | 51 |
| Deferred: | | | |
| Federal | (1,760) | (21) | — |
| State | (366) | (4) | — |
| Foreign | — | — | — |
| Total deferred income tax benefit | (2,126) | (25) | — |
| Income tax expense (benefit) | $ (1,900) | $ 149 | $ 51 |

The expense (benefit) for income taxes reconciles to the amount computed by applying the federal statutory rate to loss before taxes as follows (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Income tax benefit at federal statutory rate (1) | $ (7,619) | $ (5,167) | $ (25,738) |
| State income tax, net of federal benefit | (2,792) | (1,174) | (1,649) |
| Warrants revaluation | 3,588 | 2,326 | 13,964 |
| Research and development credits | (5,330) | (2,091) | (1,425) |
| Section 382 limitation | 1,021 | 25,043 | — |
| Stock-based compensation | (18,309) | (8,974) | 1,362 |
| Officers' compensation | 2,612 | 3,133 | — |
| Other | 479 | 972 | 681 |
| Change in valuation allowance | 24,450 | (13,919) | 12,856 |
| Income tax expense (benefit) | $ (1,900) | $ 149 | $ 51 |

(1) For the years ended December 31, 2020, 2019 and 2018, the federal statutory tax rate was 21%.

Significant components of the Company's net deferred income tax assets at December 31, 2020 and 2019 are shown below (in thousands). The Company assesses all available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative book loss incurred over the three-year period ended December 31, 2020. Such objective evidence limits the ability to consider other subjective evidence, such as projections for future growth. On the basis of this analysis, a valuation allowance of $121.6 million and $109.6 million at December 31, 2020 and 2019, respectively, has been recorded to offset the net deferred tax asset as realization of such asset is uncertain. The amount of the deferred tax asset considered realizable, however, could be adjusted if estimates of future taxable income during the carryforward period are increased, or if objective negative evidence in the form of cumulative losses is no longer present and additional weight is given to subjective evidence such as the Company's projections for future growth.

| | December 31, | |
|---|---|---|
| | 2020 | 2019 |
| Deferred tax assets: | | |
| Net operating loss (NOL) carryforwards | $ 86,898 | $ 66,642 |
| Research and development tax credits carryforwards | 11,261 | 5,931 |
| Capitalized research and development expenses | 6,840 | 8,745 |
| Accrued compensation | 24,038 | 19,794 |
| Lease liabilities | 6,112 | 4,916 |
| Other | 12,096 | 9,350 |
| Total deferred tax assets | 147,245 | 115,378 |
| Deferred tax liabilities: | | |
| Convertible debt | (11,224) | — |
| Fixed assets | (7,675) | (2,026) |
| Other | (6,719) | (3,753) |
| Total deferred tax liabilities | (25,618) | (5,779) |
| Less valuation allowance | (121,627) | (109,599) |
| Net deferred tax assets | $ — | $ — |

As of December 31, 2020, the Company had accumulated federal and state NOL carryforwards of approximately $340.0 million, and $288.7 million, respectively, Of the total federal net operating loss carryforwards, approximately $131.5 million were generated after January 1, 2018, and therefore do not expire. NOL generated after January 1, 2018, is subject to 80% limitation in accordance with the Tax Cuts and Jobs Act of 2017. The remaining federal net operating loss carryforwards of $208.5 million will begin to expire in 2026, and state tax loss carryforwards begin to expire in 2021, unless previously utilized. The remaining California NOL carryforwards of $164.1 million will begin expiring in 2028. The Company has no foreign tax loss carryforwards as of December 31, 2020.

The Company also has federal and California research credit carryforwards of approximately $7.5 million and $11.4 million, respectively, as of December 31, 2020. The federal research credit carryforwards will begin expiring in 2028, unless previously utilized. The California research credit will carry forward indefinitely.

Utilization of the Company's net operating loss and research credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitations may result in the expiration of net operating loss carryforwards before utilization. The Company has completed analyses through December 31, 2020 to determine whether its net operating losses and credits are likely to be limited by Section 382. Based on the 2018 study completed in 2019, the Company determined that an ownership change, as defined under Section 382, occurred in 2018 and the resulting limitation significantly reduced the Company's ability to utilize its net operating loss and credit carryovers before they expire. As a result, in 2019 the Company reduced its deferred tax assets for the net operating loss and research credit carryforwards that were projected to expire unused with a corresponding offset to the valuation allowance recorded against such assets. Additionally, future ownership changes under Section 382 may also limit the Company's ability to fully utilize any remaining tax benefits.

The evaluation of uncertainty in a tax position is a two-step process. The first step involves recognition. The Company determines whether it is more likely than not that a tax position will be sustained upon tax examination, including resolution of any related appeals or litigation, based on only the technical merits of the position. The technical merits of a tax position are derived from both statutory and judicial authority (legislation and statutes, legislative intent, regulations, rulings, and case law) and their applicability to the facts and circumstances of the tax position. If a tax position does not meet the more-likely-than-not recognition threshold, the benefit of that position is not recognized in the financial statements. The second step is measurement. A tax position that meets the more-likely-than-not recognition threshold is measured to determine the amount of benefit to recognize in the financial statements. The tax position is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate resolution with a taxing authority.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits at the beginning and end of the years ended December 31, 2020, 2019 and 2018 (in thousands):

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2020 | 2019 | 2018 |
| Gross unrecognized tax benefits at the beginning of the year | 6,580 | $ 8,824 | $ 8,121 |
| Increases related to current year positions | 2,234 | 1,076 | 644 |
| Increases (decreases) related to prior year positions | 1,293 | (3,320) | 59 |
| Gross unrecognized tax benefits at the end of the year | $ 10,107 | $ 6,580 | $ 8,824 |

As of December 31, 2020, the Company had $8.6 million of unrecognized tax benefits that, if recognized and realized would impact the effective tax rate, subject to the valuation allowance.

The Company's practice is to recognize interest and penalties related to income tax matters in income tax expense. The Company had no accrual for interest and penalties on the Company's consolidated balance sheets and has not recognized interest and penalties in the consolidated statements of operations for the years ended December 31, 2020 and 2019. The Company does not expect any significant increases or decreases, other than the potential reduction as a result of the Section 382 limitation, to its unrecognized tax benefits within the next 12 months.

The Company is subject to taxation in the United States and various other state jurisdictions and, starting with 2018, Canada. Prior to 2018, the losses were all domestic. The Company's tax years from 2006 (inception) are subject to examination by the United States and state authorities due to the carry forward of unutilized NOLs and research and development credits.

**9. Employee Benefits**

***Employee 401(k) Plan***

The Company has a defined contribution 401(k) plan for employees in the United States who are at least 18 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar month following their date of hire. Unless they affirmatively elect otherwise, employees are automatically enrolled in the plan following 30 days from date of rehire or entry date. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation. The Company does not provide a matching contribution program.

**10. Commitments and Contingencies**

***Legal and Regulatory Matters***

In May 2020 the Company was named as a defendant in three California state court class action lawsuits arising from a data breach the Company experienced in January 2020. Collectively, these lawsuits seek statutory, compensatory, actual, and punitive damages; equitable relief, including restitution; pre- and post-judgment interest; injunctive relief; and attorney fees, costs, and expenses from the Company. On July 24, 2020, these three pending lawsuits were consolidated into a single case in the Superior Court of the State of California in the County of San Bernardino entitled *Joseph Deluna et al v. Tandem Diabetes Care, Inc.* The consolidated case alleges violations of the Confidentiality of Medical Information Act (CMIA), CCPA, California's Unfair Competition Law (UCL), and breach of contract. The Company filed a demurrer seeking dismissal of all claims, which was heard by the Court on October 27, 2020, and which resulted in the following outcome: (i) the demurrer of the CMIA claim was denied; and (ii) the demurrer of the CCPA, UCL, and contract claims were sustained with leave to amend the pending complaint. A second amended complaint was filed by the plaintiffs on November 25, 2020 and the Company filed a demurrer to such second amended complaint on December 28, 2020.

In September 2020, the Company was named as a defendant in a lawsuit entitled *Buck Walsh, individually and on behalf of others similarly situated v. Tandem Diabetes Care, Inc.*, which was filed in the Superior Court of the State of California in San Diego County. The alleged violations include business and professions code and labor code violations for failure to compensate wages, unpaid meal and rest periods, and failure to reimburse for necessary business-related expenses. The proposed class of plaintiffs includes hourly paid or non-exempt employees of the Company who were employed from April 6, 2016 through the date of adjudication.

Although the Company intends to vigorously defend against these claims, there is no guarantee that the Company will prevail. Accordingly, the Company is unable to determine the ultimate outcome of these lawsuits or determine the amount or range of potential losses associated with the lawsuits.

From time to time, the Company may be subject to other legal proceedings or regulatory matters arising in the ordinary course of business, including without limitation, actions with respect to intellectual property, employment, regulatory, product liability and contractual matters. In connection with these proceedings or matters, the Company regularly assesses the probability and amount (or range) of possible issues based on the developments in these proceedings or matters. A liability is recorded in the consolidated financial statements if it is determined that it is probable that a loss has been incurred, and that the amount (or range) of the loss can be reasonably estimated. Because of the uncertainties related to any pending proceedings or matters, the Company is currently unable to predict their ultimate outcome and, with respect to any legal proceeding or regulatory matter where no liability has been accrued, to make a reasonable estimate of the possible loss (or range of loss) that could result from an adverse outcome. At December 31, 2020 and 2019, there were no legal proceedings, regulatory matters, or other disputes or claims for which a material loss was considered probable or for which the amount (or range) of loss was reasonably estimable. However, regardless of the outcome, legal proceedings, regulatory matters, and other disputes and claims can have an adverse impact on the Company because of legal costs, diversion of management time and resources, and other factors.

***Operating Leases***

The Company leases general office space, laboratory, manufacturing and warehouse facilities, and equipment under noncancelable operating leases. Future minimum payments due under noncancelable operating leases were $28.4 million as of December 31, 2020 (see Note 5, "Leases" for further details).

In connection with one of the operating leases, the Company has a $0.5 million unsecured standby letter of credit arrangement with a bank under which the landlord of the building is the beneficiary. The expiration of the standby letter of credit is July 15, 2022.

***Purchase Obligations***

The Company has agreements with suppliers and other parties to purchase inventory, other goods and services and long-lived assets. Product inventory obligations primarily consist of purchase commitments for raw materials used in the production of insulin pumps and cartridges, and finished goods infusion sets. Cancellation of outstanding purchase commitments is generally allowed but requires payment of certain costs incurred through the date of cancellation. At December 31, 2020, obligations under our purchase agreements totaled $90.8 million, of which approximately $85.0 million is due within one-year.

**11. Business Segment and Geographic Information**

***Segment Reporting***

Operating segments are identified as components of an enterprise about which discrete financial information is available for evaluation by the chief operating decision-maker (CODM) in making decisions regarding resource allocation and assessing performance. The Company is organized based on its current product portfolio, which consists primarily of insulin pumps, disposable cartridges and infusion sets for the storage and delivery of insulin. The Company views its operations and manages its business as one segment and a single reporting unit because key operating decisions and resource allocations are made by the CODM using consolidated financial data.

***Disaggregation of Revenue***

The Company primarily sells its products through national and regional distributors in the United States on a non-exclusive basis, and through distribution partners outside the United States, including in select European countries, Canada, Australia, New Zealand, and South Africa. In the United States and Canada, the Company utilizes a direct sales force. The Company disaggregates its revenue by geography and by major sales channel as management believes these categories best depict how the nature, amount and timing of revenues and cash flows are affected by economic factors.

***Revenues by Geographic Region and Customer Sales Channel***

During the years ended December 31, 2020, 2019 and 2018, no individual country outside the United States generated revenue that represented more than 10% of total revenue. The table below sets forth revenues for the Company's two primary geographical markets, based on the geographic location to which our products are shipped.

| | For the Year Ended December 31, | | |
|---|---|---|---|
| (in thousands) | **2020** | **2019** | **2018** |
| United States | $ 415,680 | $ 302,084 | $ 174,188 |
| International | 83,150 | 60,221 | 9,678 |
| Total Sales | $ 498,830 | $ 362,305 | $ 183,866 |

Sales to distributors accounted for 70%, 73%, and 78% of the Company's total domestic sales for the years ended December 31, 2020, 2019 and 2018, respectively. Sales to distributors accounted for 94%, 92%, and 100% of the Company's total international sales for the years ended December 31, 2020, 2019 and 2018, respectively.

**12. Selected Quarterly Financial Data (Unaudited)**

The following financial information reflects all normal recurring adjustments that are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Quarterly financial information for the years ended December 31, 2020 and 2019 is presented in the following table (in thousands, except per share data):

| | For the Quarter Ended | | | |
|---|---|---|---|---|
| | March 31 | June 30 | September 30 | December 31 |
| **2020** | | | | |
| Sales | $ 97,926 | $ 109,236 | $ 123,603 | $ 168,065 |
| Gross profit | $ 50,261 | $ 54,390 | $ 65,313 | $ 90,556 |
| Operating expenses | $ 63,834 | $ 66,427 | $ 66,322 | $ 71,894 |
| Operating income (loss) | $ (13,573) | $ (12,037) | $ (1,009) | $ 18,662 |
| Net income (loss) | $ (14,867) | $ (27,107) | $ (9,408) | $ 17,000 |
| Basic net income (loss) per share [1] | $ (0.25) | $ (0.45) | $ (0.15) | $ 0.27 |
| Diluted net income (loss) per share [1][2] | $ (0.25) | $ (0.45) | $ (0.15) | $ 0.22 |
| | | | | |
| **2019** | | | | |
| Sales | $ 65,995 | $ 93,255 | $ 94,657 | $ 108,398 |
| Gross profit | $ 33,353 | $ 49,904 | $ 50,683 | $ 60,272 |
| Operating expenses | $ 44,350 | $ 51,769 | $ 56,687 | $ 58,128 |
| Operating income (loss) | $ (10,997) | $ (1,865) | $ (6,004) | $ 2,144 |
| Net income (loss) | $ (22,992) | $ (1,512) | $ (2,901) | $ 2,652 |
| Basic net income (loss) per share [1] | $ (0.40) | $ (0.03) | $ (0.05) | $ 0.04 |
| Diluted net income (loss) per share [1][2] | $ (0.40) | $ (0.03) | $ (0.09) | $ 0.04 |

(1) Net income (loss) per share is computed independently for each quarter and the full year based upon the respective average shares outstanding in each period. Therefore, the sum of the quarterly per-share calculations may not equal the reported annual per share amounts.

(2) With the exception of the fourth quarter of 2020, and the third and fourth quarters of 2019, there is no difference in the weighted average shares used to compute basic and diluted net income (loss) per share. (see Note 2, "Summary of Significant Accounting Policies" for further details). The numerator and denominator of the basic and diluted net income (loss) per share computations are calculated as follows for the respective quarters of 2020 and 2019 where basic and diluted net income (loss) per share differ:

| | For the Quarter Ended | | |
|---|---|---|---|
| (in thousands) | December 31, 2020 | December 31, 2019 | September 30, 2019 |
| Net income (loss) | $ 17,000 | $ 2,652 | $ (2,901) |
| Less: change in fair value of common stock warrants | (2,819) | — | (2,321) |
| Net income (loss) - diluted | $ 14,181 | $ 2,652 | $ (5,222) |
| | | | |
| Weighted average shares outstanding - basic | 62,249 | 59,219 | 58,801 |
| Dilutive common share equivalents: | | | |
| Warrants to purchase common stock | 308 | 514 | 394 |
| Options to purchase common stock | 2,984 | 3,140 | — |
| Unvested restricted stock units | 133 | N/A | N/A |
| Awards granted under the ESPP | 4 | 11 | — |
| Convertible senior notes (if-converted) | — | N/A | N/A |
| Weighted average shares - diluted | 65,678 | 62,884 | 59,195 |

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

Not applicable.

**Item 9A. Controls and Procedures.**

**Disclosure Controls and Procedures**

We maintain disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports we file with the SEC under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

As of December 31, 2020, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2020.

**Internal Control over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Internal control over financial reporting is a process designed by or under the supervision of our management, including our principal executive officer and principle financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

As of December 31, 2020, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework. Based on this assessment, our management concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

Ernst & Young LLP, an independent registered public accounting firm, has issued an attestation report on the effectiveness of our internal control over financial reporting as of December 31, 2020 as stated in its report, which is included herein.

**Changes in Internal Control over Financial Reporting**

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during our last fiscal quarter that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Limitation on Effectiveness of Controls**

In designing and evaluating our controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As discussed above, Mr. Sheridan, our principal executive officer, and Ms. Vosseller, our principal financial and accounting officer, are involved in a personal relationship and share a primary residence. While our board of directors is informed of the relationship and appropriate actions have been taken to ensure compliance with our policies and procedures, the existence of this relationship may create additional risk, or the perception of additional risk, that our controls and procedures may not be effective.

**Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors of Tandem Diabetes Care, Inc.

**Opinion on Internal Control over Financial Reporting**

We have audited Tandem Diabetes Care, Inc.'s internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, Tandem Diabetes Care, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows, for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 24, 2021 expressed an unqualified opinion thereon.

**Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

**Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Diego, California
February 24, 2021

**Item 9B. Other Information.**

Not applicable.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance.

Certain information regarding our executive officers and family relationships is set forth in the section of this Annual Report entitled "Business" in Part I, Item 1.

We have adopted a code of business conduct and ethics that applies to our Chief Executive Officer and other senior financial officers (our Chief Financial Officer, Vice President of Finance, Controller and other senior financial officers performing similar functions), which we refer to as the Code of Ethics (Senior Financial Officers). Our Code of Ethics (Senior Financial Officers) is designed to meet the requirements of Section 406 of Regulation S-K and the rules promulgated thereunder. We will promptly disclose on our website (i) the nature of any amendment to this Code of Ethics (Senior Financial Officers) that applies to any covered person, and (ii) the nature of any waiver, including an implicit waiver, from a provision of this Code of Ethics (Senior Financial Officers) that is granted to one of the covered persons. We have also adopted a code of business conduct and ethics that applies to all of our directors and employees, which we refer to as the Code of Ethics (Directors and Employees). The Code of Ethics (Senior Financial Officers) and the Code of Ethics (Directors and Employees) are available on our website at www.tandemdiabetes.com under the Investor Center section of the website. However, the information contained on or accessed through our website does not constitute part of this Annual Report, and references to our website address in this Annual Report are inactive textual references only.

The information required by this item that is not referenced or set forth above, will be set forth in our definitive Proxy Statement for our 2021 Annual Meeting of Stockholders, or our Proxy Statement, or in an amendment to this Annual Report, to be filed with the SEC not later than 120 days after the end of the fiscal year ended December 31, 2020, and is incorporated herein by reference.

### Item 11. Executive Compensation.

The information required by this item will be set forth in our Proxy Statement, or in an amendment to this Annual Report, and is incorporated herein by reference.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in our Proxy Statement, or in an amendment to this Annual Report, and is incorporated herein by reference.

### Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in our Proxy Statement, or in an amendment to this Annual Report, and is incorporated herein by reference.

### Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in our Proxy Statement, or in an amendment to this Annual Report, and is incorporated herein by reference.

## PART IV

**Item 15. Exhibits and Financial Statement Schedules**

(a) The following documents are filed as part of this Annual Report:

1. *Financial Statements.* The following documents are included in Part II, Item 8 of this Annual Report and are incorporated by reference herein:



2. *Financial Statement Schedules.* Financial statement schedules have been omitted because they are not required or are not applicable, or the required information is shown in the consolidated financial statements or notes thereto.

3. *Exhibits.*

| | | Incorporated by Reference | | | | |
|---|---|---|---|---|---|---|
| Exhibit Number | Exhibit Description | Form | File No. | Date of First Filing | Exhibit Number | Provided Herewith |
| 3.1 | Amended and Restated Certificate of Incorporation (as amended through August 17, 2018 and currently in effect). | 10-Q | 001-36189 | 1-Nov-18 | 3.1 | |
| 3.2 | Amended and Restated Bylaws (as amended through February 4, 2021 and currently in effect). | | | | | X |
| 4.1 | Description of Capital Stock. | 10-K | 001-36189 | 24-Feb-20 | 4.1 | |
| 4.2 | Form of Common Stock Certificate. | S-1/A | 333-191601 | 1-Nov-13 | 4.1 | |
| 4.3 | Third Amended and Restated Investors' Rights Agreement, dated August 30, 2012. | S-1 | 333-191601 | 7-Oct-13 | 4.2 | |
| 4.4 | Form of Warrant to Purchase Stock. | S-1 | 333-216531 | 8-Mar-17 | 4.3 | |
| 4.5 | Form of Preferred Stock Warrant. | S-1 | 333-191601 | 7-Oct-13 | 4.4 | |
| 4.6 | Form of Series A Warrant to Purchase Common Stock. | 8-K | 001-36189 | 13-Oct-17 | 4.1 | |
| 4.7 | Indenture between Tandem Diabetes Care, Inc. and U.S. Bank National Association. | 8-K | 001-36189 | 15-May-20 | 4.1 | |
| 4.8 | Form of Global Note, representing Tandem Diabetes Care, Inc.'s 1.50% Convertible Senior Notes due 2025 (included as Exhibit A to the Indenture filed as Exhibit 4.1). | 8-K | 001-36189 | 15-May-20 | 4.2 | |
| 10.1* | Tandem Diabetes Care, Inc. 2006 Stock Incentive Plan. | S-1 | 333-191601 | 7-Oct-13 | 10.3 | |
| 10.2* | Form of Stock Option Agreement under 2006 Plan. | S-1 | 333-191601 | 7-Oct-13 | 10.4 | |

| | | | | | |
|---|---|---|---|---|---|
| 10.3* | Form of Restricted Stock Purchase Agreement under 2006 Plan. | S-1 | 333-191601 | 7-Oct-13 | 10.5 |
| 10.4* | Tandem Diabetes Care, Inc. Amended and Restated 2013 Stock Incentive Plan. | DEF 14A | 001-36189 | 26-Apr-18 | Appendix B |
| 10.5* | Tandem Diabetes Care, Inc. Amended and Restated 2013 Stock Incentive Plan. | 10-Q | 001-36189 | 30-Jul-2020 | 10.2 |
| 10.6* | Form of Restricted Stock Unit Agreement under the 2013 Plan. | 10-Q | 001-36189 | 30-Jul-2020 | 10.1 |
| 10.7* | Form of Stock Option Agreement under 2013 Plan. | S-1/A | 333-191601 | 1-Nov-13 | 10.7 |
| 10.8* | Form of Stock Option Agreement under 2013 Plan (Non-Employee Directors). | S-1/A | 333-191601 | 1-Nov-13 | 10.8 |
| 10.9* | Tandem Diabetes Care, Inc. Amended and Restated 2013 Employee Stock Purchase Plan. | DEF 14A | 001-36189 | 26-Apr-18 | Appendix C |
| 10.10* | Tandem Diabetes Care, Inc. 2020 Senior Management Cash Bonus Plan. | 10-Q | 001-36189 | 30-Apr-2020 | 10.2 |
| 10.11* | Employee Offer Letter, dated July 8, 2013, by and between Tandem Diabetes Care, Inc. and David B. Berger. | S-1 | 333-191601 | 7-Oct-13 | 10.12 |
| 10.12* | Employee Offer Letter, dated February 1, 2013, by and between Tandem Diabetes Care, Inc. and John F. Sheridan. | S-1 | 333-191601 | 7-Oct-13 | 10.13 |
| 10.13* | Employee Offer Letter, dated January 12, 2016, by and between Tandem Diabetes Care, Inc. and Brian B. Hansen. | 8-K | 001-36189 | 2-Feb-16 | 10.1 |
| 10.14* | Employment Severance Agreement, dated February 1, 2016, by and between Tandem Diabetes Care, Inc. and Brian B. Hansen. | 8-K | 001-36189 | 2-Feb-16 | 10.2 |
| 10.15* | Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and John F. Sheridan. | S-1/A | 333-191601 | 8-Nov-13 | 10.17 |
| 10.16* | Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and David B. Berger. | S-1/A | 333-191601 | 8-Nov-13 | 10.18 |
| 10.17* | Amended and Restated Employment Severance Agreement, dated November 4, 2013, by and between Tandem Diabetes Care, Inc. and Susan M. Morrison. | S-1/A | 333-191601 | 8-Nov-13 | 10.19 |
| 10.18* | Amended and Restated Employment Severance Agreement dated August 2, 2017, by and between the Company and Leigh A. Vosseller. | S-1 | 333-222553 | 16-Jan-18 | 10.25 |
| 10.19* | Form of Indemnification Agreement. | S-1 | 333-191601 | 7-Oct-13 | 10.11 |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10.20 | Confidential Intellectual Property Agreement, dated July 10, 2012, by and between Tandem Diabetes Care, Inc. and Smiths Medical ASD, Inc. | S-1/A | 333-191601 | 8-Nov-13 | 10.20 | |
| 10.21** | Amended and Restated Development and Commercialization Agreement, dated January 4, 2013, by and between Tandem Diabetes Care, Inc. and DexCom, Inc. | 10-Q | 001-36189 | 29-Oct-15 | 10.1 | |
| 10.22** | Amendment No. 1 to Amended and Restated Development and Commercialization Agreement, dated September 24, 2015, by and between Tandem Diabetes Care, Inc. and DexCom, Inc. | 10-Q | 001-36189 | 29-Oct-15 | 10.2 | |
| 10.23** | Development Agreement, dated June 4, 2015 by and between Tandem Diabetes Care, Inc. and DexCom, Inc. | 10-Q/A | 001-36189 | 9-Nov-18 | 10.5 | |
| 10.24† | Development Agreement, dated November 20, 2020, by and between Tandem Diabetes Care, Inc. and DexCom, Inc. | | | | | X |
| 10.25† | Commercialization Agreement, dated November 20, 2020, by and between Tandem Diabetes Care, Inc. and DexCom, Inc. | | | | | X |
| 10.26 | Lease Agreement, dated March 7, 2012, as amended through November 5, 2013, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC. | S-1/A | 333-191601 | 8-Nov-13 | 10.1 | |
| 10.27 | Fourth Amendment to Lease, dated December 27, 2017, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC | 8-K | 001-36189 | 3-Jan-18 | 10.2 | |
| 10.28 | Lease Agreement, dated November 5, 2013, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC. | S-1/A | 333-191601 | 8-Nov-13 | 10.21 | |
| 10.29 | First Amendment to Lease, dated December 27, 2017, by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 Roselle Street, LLC | 8-K | 001-36189 | 3-Jan-18 | 10.1 | |
| 10.30 | Lease Agreement, dated June 30, 2016, by and between Tandem Diabetes Care, Inc. and ARE-SD REGION NO. 36, LLC. | 10-Q | 001-36189 | 28-Jul-16 | 10.3 | |
| 10.31 | Lease Agreement, dated November 14, 2019, by and between Tandem Diabetes Care, Inc. and Ameri Shore LLC. | 10-K | 001-36189 | 24-Feb-20 | 10.36 | |
| 10.32 | Second Amendment to Lease Agreement by and Between ARE-11025/11075 ROSELLE STREET, LLC, and Tandem Diabetes Care, Inc. | 10-Q | 001-36189 | 5-Nov-2020 | 10.1 | |

| | | | | | | |
|---|---|---|---|---|---|---|
| 10.33 | Fifth Amendment to Lease Agreement by and Between ARE-11025/11075 ROSELLE STREET, LLC, and Tandem Diabetes Care, Inc. | 10-Q | 001-36189 | 5-Nov-2020 | 10.2 | |
| 10.34† | License Agreement, dated July 14, 2016, by and between Tandem Diabetes Care, Inc. and TypeZero Technologies, LLC | 10-Q | 001-36189 | 30-Apr-2020 | 10.1 | |
| 21.1 | Subsidiaries of the Registrant | | | | | X |
| 23.1 | Consent of Independent Registered Public Accounting Firm. | | | | | X |
| 24.1 | Power of Attorney (included on the signature page). | | | | | X |
| 31.1 | Certification of John F. Sheridan, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | | X |
| 31.2 | Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | | X |
| 32.1*** | Certification of John F. Sheridan, Chief Executive Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | | X |
| 32.2*** | Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | | X |
| 101.INS | Inline XBRL Instance Document. | | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. | | | | | X |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. | | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | | X |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | | X |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document. | | | | | X |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). | | | | | X |

† Certain confidential portions of this exhibit have been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K. The Company has determined that such omitted information is (i) not material, and (ii) would likely cause competitive harm to the Company if publicly disclosed.

* Indicates management contract or compensatory plan.

** Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to an application for confidential treatment sent to the Securities and Exchange Commission. Such portions are omitted from this filing and have been filed separately with the Securities and Exchange Commission.

*** This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the registrant specifically incorporates it by reference.

**Item 16. Form 10-K Summary.**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Tandem Diabetes Care, Inc.

By: /s/ John F. Sheridan
John F. Sheridan
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: February 24, 2021

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints John F. Sheridan and Leigh A. Vosseller, and each of them individually, his and her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and her and in his and her name, place, and stead, in any and all capacities, to sign any and all amendments to this Annual Report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

| Signature | Title | Date |
|---|---|---|
| /s/ JOHN F. SHERIDAN<br>John F. Sheridan | President, Chief Executive Officer and Director (Principal Executive Officer) | February 24, 2021 |
| /s/ LEIGH A. VOSSELLER<br>Leigh A. Vosseller | Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer) | February 24, 2021 |
| /s/ DICK P. ALLEN<br>Dick P. Allen | Lead Independent Director | February 24, 2021 |
| /s/ KIM D. BLICKENSTAFF<br>Kim D. Blickenstaff | Chairman of the Board | February 24, 2021 |
| /s/ PEYTON R. HOWELL<br>Peyton R. Howell | Director | February 24, 2021 |
| /s/ KATHLEEN MCGRODDY-GOETZ<br>Kathleen McGroddy-Goetz | Director | February 24, 2021 |
| /s/ REBECCA B. ROBERTSON<br>Rebecca B. Robertson | Director | February 24, 2021 |
| /s/ DOUGLAS A. ROEDER<br>Douglas A. Roeder | Director | February 24, 2021 |
| /s/ RAJWANT S. SODHI<br>Rajwant S. Sodhi | Director | February 24, 2021 |
| /s/ CHRISTOPHER J. TWOMEY<br>Christopher J. Twomey | Director | February 24, 2021 |

# AMENDED AND RESTATED

# BYLAWS

# OF

# TANDEM DIABETES CARE, INC.,

**a Delaware corporation**

**As Updated Through February 4, 2021**

## ARTICLE I

## OFFICES

**Section 1. Registered Office**. The registered office of Tandem Diabetes Care, Inc. (the "Corporation") shall be fixed in the Corporation's Certificate of Incorporation, as the same may be amended and/or restated from time to time (as so amended and/or restated, the "Certificate").

**Section 2. Other Offices**. The Corporation may also have offices at such other places both within and without the State of Delaware as the Board of Directors may from time to time determine or the business of the Corporation may require.

**Section 3. Books**. The books of the Corporation may be kept within or without the State of Delaware as the Board of Directors may from time to time determine or the business of the Corporation may require. Any such records maintained by the Corporation may be kept on, or by means of, or be in the form of, any information storage device or method, provided that the records so kept can be converted into clearly legible paper form within a reasonable time. The Corporation shall so convert any records so kept upon the request of any person entitled to inspect such records pursuant to the provisions of these Bylaws or the Delaware General Corporation Law (the "DGCL"). When records are kept in such manner, a clearly legible paper form produced from or by means of the information storage device or method shall be admissible in evidence, and accepted for all other purposes, to the same extent as an original paper form accurately portrays the record.

## ARTICLE I.

## MEETINGS OF STOCKHOLDERS

**Section 1. Place of Meetings**. Meetings of stockholders may be held at any place within or outside the State of Delaware as designated by the Board of Directors. The Board of Directors may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as provided by the DGCL.

**Section 2. Annual Meetings**.

a. The annual meeting of the stockholders of the Corporation, for the purpose of election of directors and for such other business as may properly come before it, shall be held on such date and at such time as may be designated from time to time by the Board of Directors. Nominations of persons for election to the Board of Directors of the Corporation and the proposal of business to be

considered by the stockholders may be made at an annual meeting of stockholders: (i) pursuant to the Corporation's notice of meeting of stockholders (with respect to business other than nominations); (ii) brought specifically by or at the direction of the Board of Directors; or (iii) by any stockholder of the Corporation who was a stockholder of record at the time of giving the stockholder's notice provided for in Section 2(b) of this Article II of these Bylaws, who is entitled to vote at the meeting and who complied with the notice procedures set forth in this Section 2. For the avoidance of doubt, clause (iii) above shall be the exclusive means for a stockholder to make nominations and submit other business (other than matters properly included in the Corporation's notice of meeting of stockholders and proxy statement under Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (the "1934 Act")) before an annual meeting of stockholders.

b. At an annual meeting of the stockholders, only such business shall be conducted as is a proper matter for stockholder action under Delaware law and as shall have been properly brought before the meeting.

i. For nominations for the election to the Board of Directors to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 2(a) of this Article II, the stockholder must deliver written notice to the Secretary at the principal executive offices of the Corporation on a timely basis as set forth in Section 2(b)(iii) of this Article II and must update and supplement such written notice on a timely basis as set forth in Section 2(c) of this Article II. Such stockholder's notice shall set forth: (A) as to each nominee such stockholder proposes to nominate at the meeting: (1) the name, age, business address and residence address of such nominee; (2) the principal occupation or employment of such nominee; (3) the class and number of shares of each class of capital stock of the Corporation which are owned of record and beneficially by such nominee; (4) the date or dates on which such shares were acquired and the investment intent of such acquisition; (5) with respect to each nominee for election or re-election to the Board of Directors, include a completed and signed questionnaire, representation and agreement required by Section 2(e) of this Article II; and (6) such other information concerning such nominee as would be required to be disclosed in a proxy statement soliciting proxies for the election of such nominee as a director in an election contest (even if an election contest is not involved), or that is otherwise required to be disclosed pursuant to Section 14 of the 1934 Act and the rules and regulations promulgated thereunder (including such person's written consent to being named as a nominee and to serving as a director if elected); and (B) the information required by Section 2(b)(iv) of this Article II. The Corporation may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as an independent director of the Corporation or that could be material to a reasonable stockholder's understanding of the independence, or lack thereof, of such proposed nominee.

ii. Other than proposals sought to be included in the Corporation's proxy materials pursuant to Rule 14(a)-8 under the 1934 Act, for business other than nominations for the election to the Board of Directors to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of Section 2(a) of this Article II, the stockholder must deliver written notice to the Secretary at the principal executive offices of the Corporation on a timely basis as set forth in Section 2(b)(iii) of this Article II, and must update and supplement such written notice on a timely basis as set forth in Section 2(c) of this Article II. Such stockholder's notice shall set forth: (A) as to each matter such stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the reasons for conducting such business at the meeting, and any material interest (including any anticipated benefit of such business to any Proponent (as defined below) other than solely as a result of its ownership of the Corporation's capital stock, that is material to any Proponent

individually, or to the Proponents in the aggregate) in such business of any Proponent; and (B) the information required by Section 2(b)(iv) of this Article II.

iii. To be timely, the written notice required by Section 2(b)(i) or 2(b)(ii) of this Article II must be received by the Secretary at the principal executive offices of the Corporation not later than the close of business on the 90th day nor earlier than the close of business on the 120th day prior to the first anniversary of the preceding year's annual meeting; *provided, however,* that, subject to the last sentence of this Section 2(b)(iii), in the event that the date of the annual meeting is advanced more than 30 days prior to or delayed by more than 30 days after the anniversary of the preceding year's annual meeting, notice by the stockholder to be timely must be so received not earlier than the close of business on the 120th day prior to such annual meeting and not later than the close of business on the later of the 90th day prior to such annual meeting or the 10th day following the day on which public announcement of the date of such meeting is first made. In no event shall an adjournment or a postponement of an annual meeting for which notice has been given, or the public announcement thereof has been made, commence a new time period for the giving of a stockholder's notice as described above.

iv. The written notice required by Section 2(b)(i) or 2(b)(ii) of this Article II shall also set forth, as of the date of the notice and as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (each, a "Proponent" and collectively, the "Proponents"): (A) the name and address of each Proponent, as they appear on the Corporation's books; (B) the class, series and number of shares of the Corporation that are owned beneficially and of record by each Proponent; (C) a description of any agreement, arrangement or understanding (whether oral or in writing) with respect to such nomination or proposal between or among any Proponent and any of its affiliates or associates, and any others (including their names) acting in concert, or otherwise under the agreement, arrangement or understanding, with any of the foregoing; (D) a representation that the Proponents are holders of record or beneficial owners, as the case may be, of shares of the corporation entitled to vote at the meeting and intend to appear in person or by proxy at the meeting to nominate the person or persons specified in the notice (with respect to a notice under Section 2(b)(i) of this Article II) or to propose the business that is specified in the notice (with respect to a notice under Section 2(b)(ii) of this Article II); (E) a representation as to whether the Proponents intend to deliver a proxy statement and form of proxy to holders of a sufficient number of holders of the Corporation's voting shares to elect such nominee or nominees (with respect to a notice under Section 2(b)(i) of this Article II) or to carry such proposal (with respect to a notice under Section 2(b)(ii) of this Article II); (F) to the extent known by any Proponent, the name and address of any other stockholder supporting the proposal on the date of such stockholder's notice; and (G) a description of all Derivative Transactions (as defined below) by each Proponent during the previous 12-month period, including the date of the transactions and the class, series and number of securities involved in, and the material economic terms of, such Derivative Transactions.

For purposes of Sections 2 and 3 of this Article II, a "Derivative Transaction" means any agreement, arrangement, interest or understanding entered into by, or on behalf or for the benefit of, any Proponent or any of its affiliates or associates, whether record or beneficial:

A. the value of which is derived in whole or in part from the value of any class or series of shares or other securities of the Corporation;

B. which otherwise provides any direct or indirect opportunity to gain or share in any gain derived from a change in the value of securities of the Corporation;

C. the effect or intent of which is to mitigate loss, manage risk or benefit of security value or price changes; or

D. which provides the right to vote or increase or decrease the voting power of, such Proponent, or any of its affiliates or associates, with respect to any securities of the Corporation,

which agreement, arrangement, interest or understanding may include, without limitation, any option, warrant, debt position, note, bond, convertible security, swap, stock appreciation right, short position, profit interest, hedge, right to dividends, voting agreement, performance-related fee or arrangement to borrow or lend shares (whether or not subject to payment, settlement, exercise or conversion in any such class or series), and any proportionate interest of such Proponent in the securities of the corporation held by any general or limited partnership, or any limited liability company, of which such Proponent is, directly or indirectly, a general partner or managing member.

c. A stockholder providing written notice required by Section 2(b)(i) or (ii) of this Article II shall update and supplement such notice in writing, if necessary, so that the information provided or required to be provided in such notice is true and correct in all material respects as of (i) the record date for the meeting and (ii) the date that is five business days prior to the meeting and, in the event of any adjournment or postponement thereof, five business days prior to such adjourned or postponed meeting. In the case of an update and supplement pursuant to clause (i) of this Section 2(c), such update and supplement shall be received by the Secretary at the principal executive offices of the Corporation not later than five business days after the record date for the meeting. In the case of an update and supplement pursuant to clause (ii) of this Section 2(c), such update and supplement shall be received by the Secretary at the principal executive offices of the Corporation not later than two business days prior to the date for the meeting, and, in the event of any adjournment or postponement thereof, two business days prior to such adjourned or postponed meeting.

d. Notwithstanding anything in Section 2(b)(iii) of this Article II to the contrary, in the event that the number of directors in an Expiring Class (as defined below) is increased and there is no public announcement of the appointment of a director to such class, or, if no appointment was made, of the vacancy in such class, made by the Corporation at least 10 days before the last day a stockholder may deliver a notice of nomination in accordance with Section 2(b)(iii) of this Article II, a stockholder's notice required by this Section 2 and which complies with the requirements in Section 2(b)(i) of this Article II, other than the timing requirements in Section 2(b)(iii) of this Article II, shall also be considered timely, but only with respect to nominees for any new positions in such Expiring Class created by such increase, if it shall be received by the Secretary at the principal executive offices of the Corporation not later than the close of business on the 10th day following the day on which such public announcement is first made by the Corporation. For purposes of this Section 2, an "Expiring Class" shall mean a class of directors whose term shall expire at the next annual meeting of stockholders.

e. To be eligible to be a nominee for election or re-election as a director of the Corporation pursuant to a nomination under clause (iii) of Section 2(a) of this Article II, such proposed nominee or a person on such proposed nominee's behalf must deliver (in accordance with the time periods prescribed for delivery of notice under Section 2(b)(iii) or 2(d) of this Article II, as applicable) to the Secretary at the principal executive offices of the Corporation a written questionnaire with respect to the background and qualification of such proposed nominee and the background of any other person or entity on whose behalf the nomination is being made (which questionnaire shall be provided by the Secretary upon written request) and a written representation and agreement (in the form provided by the

Secretary upon written request) that such person: (i) is not and will not become a party to (A) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such person, if elected as a director of the corporation, will act or vote on any issue or question (a "Voting Commitment") that has not been disclosed to the Corporation in the questionnaire or (B) any Voting Commitment that could limit or interfere with such person's ability to comply, if elected as a director of the Corporation, with such person's fiduciary duties under applicable law; (ii) is not and will not become a party to any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with service or action as a director of the Corporation that has not been disclosed therein; and (iii) in such person's individual capacity and on behalf of any person or entity on whose behalf the nomination is being made, would be in compliance, if elected as a director of the Corporation, and will comply with, all applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation.

f. A person shall not be eligible for election or re-election as a director unless the person is nominated either in accordance with clause (ii) of Section 2(a) of this Article II, or in accordance with clause (iii) of Section 2(a) of this Article II. Except as otherwise required by law, the chairman of the meeting shall have the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made, or proposed, as the case may be, in accordance with the procedures set forth in these Bylaws and, if any proposed nomination or business is not in compliance with these Bylaws, or the Proponent does not act in accordance with the representations in Sections 2(b)(iv)(D) and 2(b)(iv)(E) of this Article II, to declare that such proposal or nomination shall not be presented for stockholder action at the meeting and shall be disregarded, notwithstanding that proxies in respect of such nominations or such business may have been solicited or received.

g. Notwithstanding the foregoing provisions of this Section 2, in order to include information with respect to a stockholder proposal in the proxy statement and form of proxy for a stockholders' meeting, a stockholder must also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act; *provided, however,* that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to proposals and/or nominations to be considered pursuant to Section 2(a)(iii) of this Article II.

h. For purposes of Sections 2 and 3 of this Article II,

i. "public announcement" shall mean disclosure in a press release reported by the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the 1934 Act; and

ii. "affiliates" and "associates" shall have the meanings set forth in Rule 405 under the Securities Act of 1933, as amended.

**Section 3. Special Meetings**.

a. Special meetings of the stockholders of the Corporation may be called, for any purpose as is a proper matter for stockholder action under Delaware law, by (i) the Chairman of the Board

of Directors, (ii) the Chief Executive Officer, or (iii) the Board of Directors pursuant to a resolution adopted by a majority of the total number of authorized directors (whether or not there exist any vacancies in previously authorized directorships at the time any such resolution is presented to the Board of Directors for adoption).

b. The Board of Directors shall determine the time and place, if any, of such special meeting. Upon determination of the time and place, if any, of the meeting, the Secretary shall cause a notice of meeting to be given to the stockholders entitled to vote, in accordance with the provisions of Section 4 of this Article II. No business may be transacted at such special meeting otherwise than specified in the notice of meeting.

c. Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders at which directors are to be elected (i) by or at the direction of the Board of Directors or (ii) by any stockholder of the Corporation who is a stockholder of record at the time of giving notice provided for in this paragraph, who shall be entitled to vote at the meeting and who delivers written notice to the Secretary of the Corporation setting forth the information required by Section 2(b)(i) of this Article II. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any such stockholder of record may nominate a person or persons (as the case may be), for election to such position(s) as specified in the Corporation's notice of meeting, if written notice setting forth the information required by Section 2(b)(i) of this Article II shall be received by the Secretary at the principal executive offices of the Corporation not later than the close of business on the later of the 90th day prior to such meeting or the 10th day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board of Directors to be elected at such meeting. The stockholder shall also update and supplement such information as required under Section 2(c) of this Article II. In no event shall an adjournment or a postponement of a special meeting for which notice has been given, or the public announcement thereof has been made, commence a new time period for the giving of a stockholder's notice as described above.

d. Notwithstanding the foregoing provisions of this Section 3, a stockholder must also comply with all applicable requirements of the 1934 Act and the rules and regulations thereunder with respect to matters set forth in this Section 3. Nothing in these Bylaws shall be deemed to affect any rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the 1934 Act; *provided, however,* that any references in these Bylaws to the 1934 Act or the rules and regulations thereunder are not intended to and shall not limit the requirements applicable to nominations for the election to the Board of Directors to be considered pursuant to Section 3(c) of this Article II.

**Section 4. Notice of Meetings.** Except as otherwise provided by law, notice, given in writing or by electronic transmission, of each meeting of stockholders shall be given not less than 10 nor more than 60 days before the date of the meeting to each stockholder entitled to vote at such meeting, such notice to specify the place, if any, date and hour, in the case of special meetings, the purpose or purposes of the meeting, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at any such meeting. If mailed, notice is deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the Corporation. If sent via electronic transmission, notice is deemed given as of the sending time recorded at the time of transmission. Notice of the time, place, if any, and purpose of any meeting of stockholders may be waived in writing, signed by the person entitled to notice thereof, or by electronic transmission by such person, either before or after

such meeting, and will be waived by any stockholder by his attendance thereat in person, by remote communication, if applicable, or by proxy, except when the stockholder attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of such meeting shall be bound by the proceedings of any such meeting in all respects as if due notice thereof had been given.

**Section 5. Quorum**.

a. Except as otherwise required by law or by applicable stock exchange rules, or provided by the Certificate or these Bylaws, the holders of a majority of the capital stock issued and outstanding and entitled to vote thereat, present in person, by remote communication, if applicable, or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. In the absence of a quorum, any meeting of stockholders may be adjourned, from time to time, either by the chairman of the meeting or by vote of the holders of a majority of the shares represented thereat, but no other business shall be transacted at such meeting. The stockholders present at a duly called or convened meeting, at which a quorum is present, may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum.

b. Except as otherwise required by law or by applicable stock exchange rules, or provided by the Certificate or these Bylaws, in all matters other than the election of directors, the affirmative vote of the majority of shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the subject matter shall be the act of the stockholders. Except as otherwise required by law or by applicable stock exchange rules, or provided by the Certificate or these Bylaws, directors shall be elected by the affirmative vote of a majority of the votes cast by the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the election of directors; *provided*, *however*, that if the number of director nominees exceeds the number of directors to be elected at the meeting, directors shall be elected by a plurality of the votes cast by the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting and entitled to vote generally on the election of directors. For purposes of these Bylaws, a "majority of the votes cast" means that the number of shares voted "for" a director's election exceeds 50% of the number of votes cast with respect to that director's election. Votes cast shall include direction to withhold authority in each case and shall exclude "abstentions" and "broker non-votes" with respect to that director's election.

c. Following the certification of the stockholder vote in an election where the number of director nominees does not exceed the number of directors to be elected at the meeting, an incumbent director who received a greater number of votes "against" his or her election than votes "for" his or her election shall promptly tender his or her resignation to the Board of Directors. The Board of Directors shall act on the tendered resignation no later than 90 days following certification of the election results, and publicly disclose (by a press release, a filing with the Securities and Exchange Commission or other broadly disseminated means of communication) its decision regarding the tendered resignation and the rationale behind its decision. The director who tenders his or her resignation shall not participate in the decision of the Board of Directors with respect to his or her resignation. Such incumbent director shall continue to serve as a director after submitting his or her resignation pursuant to the provisions of this Section 5 unless and until the Board of Directors accepts such resignation, or until his or her earlier death, removal, or resignation made pursuant to Section 4 of Article III of these Bylaws. If such incumbent director's resignation is not accepted by the Board of Directors, such director shall continue to serve until his or her successor is duly elected, or his or her earlier resignation or removal. If a director's resignation is accepted by the Board of Directors pursuant to these Bylaws, or if a nominee for director is not elected

and the nominee is not an incumbent director, then the Board of Directors, in its sole discretion, may fill any resulting vacancy or decrease the size of the Board of Directors pursuant to the provisions of Article III of these Bylaws.

d. Where a separate vote by a class or classes or series is required, except where otherwise required by law or applicable stock exchange rules, or provided by the Certificate or these Bylaws, a majority of the outstanding shares of such class or classes or series, present in person, by remote communication, if applicable, or represented by proxy, shall constitute a quorum entitled to take action with respect to that vote on that matter. Except where otherwise provided by statute or by the Certificate or these Bylaws, the affirmative vote of the majority of shares of such class or classes or series present in person, by remote communication, if applicable, or represented by proxy at the meeting shall be the act of such class or classes or series.

**Section 6. Adjournment**. Any meeting of stockholders, whether annual or special, may be adjourned from time to time either by the chairman of the meeting or by the vote of a majority of the shares present in person, by remote communication, if applicable, or represented by proxy at the meeting. When a meeting is adjourned to another time or place, if any, notice need not be given of the adjourned meeting if the time and place, if any, thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 30 days or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

**Section 7. Voting**. For the purpose of determining those stockholders entitled to vote at any meeting of the stockholders, except as otherwise provided by law, only persons in whose names shares stand on the stock records of the corporation on the record date, as provided in Section 9 of this Article II, shall be entitled to vote at any meeting of stockholders. Every person entitled to vote shall have the right to do so either in person, by remote communication, if applicable, or by an agent or agents authorized by a proxy granted in accordance with Delaware law. An agent so appointed need not be a stockholder. No proxy shall be voted after three years from its date of creation unless the proxy provides for a longer period. Elections of directors need not be by ballot unless the chairman of the meeting so directs or unless a stockholder demands election by ballot at the meeting and before the voting begins.

**Section 8. Joint Owners of Stock**. If shares or other securities having voting power stand of record in the names of two or more persons, whether fiduciaries, members of a partnership, joint tenants, tenants in common, tenants by the entirety, or otherwise, or if two or more persons have the same fiduciary relationship respecting the same shares, unless the Secretary is given written notice to the contrary and is furnished with a copy of the instrument or order appointing them or creating the relationship wherein it is so provided, their acts with respect to voting shall have the following effect: (a) if only one votes, his act binds all; (b) if more than one votes, the act of the majority so voting binds all; or (c) if more than one votes, but the vote is evenly split on any particular matter, each faction may vote the securities in question proportionally, or may apply to the Delaware Court of Chancery for relief as provided in the DGCL, Section 217(b). If the instrument filed with the Secretary shows that any such tenancy is held in unequal interests, a majority or even-split for the purpose of clause (c) of this Section 8 shall be a majority or even-split in interest.

**Section 9. List of Stockholders Entitled to Vote**. The officer who has charge of the stock ledger of the Corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical

order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the Corporation's principal place of business. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

**Section 10. Stockholder Action by Written Consent Without a Meeting**. No action shall be taken by the stockholders except at an annual or special meeting of stockholders called in accordance with these Bylaws, and no action shall be taken by the stockholders by written consent or electronic transmission.

**Section 11. Organization**. At each meeting of stockholders, the Chairman of the Board of Directors, if one shall have been elected, (or in his absence or if one shall not have been elected, the Chief Executive Officer) shall act as chairman of the meeting. The Secretary (or in his absence or inability to act, the person acting as the chairman of the meeting shall appoint a secretary of the meeting) shall act as secretary of the meeting and keep the minutes thereof. The Board of Directors shall be entitled to make such rules or regulations for the conduct of meetings of stockholders as it shall deem necessary, appropriate or convenient. Subject to such rules and regulations of the Board of Directors, if any, the chairman of the meeting shall have the right and authority to prescribe such rules, regulations and procedures and to do all such acts as, in the judgment of such chairman, are necessary, appropriate or convenient for the proper conduct of the meeting, including, without limitation, establishing an agenda or order of business for the meeting, rules and procedures for maintaining order at the meeting and the safety of those present, limitations on participation in such meeting to stockholders of record of the Corporation and their duly authorized and constituted proxies and such other persons as the chairman shall permit, restrictions on entry to the meeting after the time fixed for the commencement thereof, limitations on the time allotted to questions or comments by participants and regulation of the opening and closing of the polls for balloting on matters which are to be voted on by ballot.

## DIRECTORS

**Section 1. Powers**. Except as otherwise required by law or provided by the Certificate, the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

**Section 2. Number and Qualification of Directors**. Subject to the rights of the holders of any series of Preferred Stock to elect directors under specified circumstances, if any, the authorized number of directors shall be determined from time to time by resolution of the Board of Directors, provided the Board of Directors shall consist of at least one (1) member. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires. Directors need not be stockholders unless so required by the Certificate or these Bylaws. The Certificate or these Bylaws may prescribe other qualifications for directors.

**Section 3. Classes of Directors**. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided into three classes designated as Class I, Class II and Class III, respectively. Initially, directors shall be assigned to each class in accordance with a resolution or resolutions adopted by the Board of Directors. At the first annual meeting of stockholders following the initial classification of the Board of Directors, the term of office of the Class I directors shall expire and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following such initial classification, the term of office of the Class II directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following such initial classification, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting. During such time or times that applicable law prohibits a classified Board of Directors as described in this Section 3, all directors shall be elected at each annual meeting of stockholders to hold office until the next annual meeting. If for any cause, the directors shall not have been elected at an annual meeting, they may be elected as soon thereafter as convenient at a special meeting of the stockholders called for that purpose in the manner provided in these Bylaws.

Notwithstanding the foregoing provisions of this Section 3, each director shall serve until his successor is duly elected and qualified or until his earlier death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

**Section 4. Resignation; Vacancies**.

(1) Any director may resign at any time upon written notice or by electronic transmission to the Secretary of the Corporation, such resignation to specify whether it will be effective at a particular time. If no such specification is made, it shall be deemed effective at the time of delivery to the Secretary.

(2) Unless otherwise provided in the Certificate, and subject to the rights of the holders of any series of Preferred Stock, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director, and not by the stockholders, *provided, however*, that whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the Certificate, vacancies and newly created directorships of such class or classes or series shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board of Directors shall be deemed to exist under this Bylaw in the case of the death, removal or resignation of any director.

**Section 5. Removal**. Unless otherwise restricted by statute, the Certificate or these Bylaws, any director, or all of the directors, may be removed from the Board, but only for cause, and only by the

affirmative vote of the holders of a majority of the voting power of all the then outstanding shares of capital stock of the Corporation then entitled to vote at the election of directors, voting together as a single class.

**Section 6. Regular Meetings**. Unless otherwise restricted by the Certificate, regular meetings of the Board of Directors may be held at such places within or without the State of Delaware and at such date and time as the Board of Directors may by resolution from time to time determine and publicize among all directors by means of reasonable notice given to any director who is not present at the meeting at which such resolution is adopted. No further notice shall be required for regular meetings of the Board of Directors.

**Section 7. Special Meetings**. Unless otherwise restricted by the Certificate, special meetings of the Board of Directors may be called by a majority of the authorized directors. The person(s) calling any such special meeting of the Board of Directors may fix the hour, date and place thereof. Notice of the date, time and place of all special meetings of the Board of Directors shall be delivered to each director by the Secretary or Assistant Secretary, or in the case of death, absence, incapacity or refusal of such persons, by the Chairman of the Board, if one is elected, or the Chief Executive Officer or such other officer designated by the Chairman of the Board, if one is elected, or the Chief Executive Officer, personally or by telephone, facsimile, electronic mail or other form of electronic communication, to each director or sent by first-class mail, charges prepaid, addressed to each director at the director's address as it is shown on the records of the Corporation. In case the notice is mailed, it shall be deposited in the United States mail at least three (3) days before the time of the holding of the meeting. In case the notice is delivered personally or by telephone, facsimile, electronic mail or other form of electronic communication, it shall be so delivered at least twenty-four (24) hours before the time of the holding of the meeting. Except as otherwise required by law, by the Certificate of by these Bylaws, neither the business to be transacted at, nor the purpose of, any meeting of the Board of Directors need be specified in the notice or waiver of notice of such meeting. A written waiver of any such notice signed by the person entitled thereto, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends the meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

**Section 8. Quorum; Vote Required for Action; Adjournment**. Except as otherwise required by law, or provided in the Certificate or these Bylaws, a majority of the total number of directors shall constitute a quorum for the transaction of business at all meetings of the Board of Directors and the affirmative vote of not less than a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board of Directors. If a quorum shall not be present at any meeting of the Board of Directors, the directors present thereat may adjourn the meeting, from time to time, without notice other than announcement at the meeting, until a quorum shall be present. Any business which might have been transacted at the meeting as originally noticed may be transacted at such adjourned meeting at which a quorum is present. For purposes of this Section, the total number of directors includes any unfilled vacancies on the Board of Directors.

**Section 9. Action by Written Consent**. Unless otherwise restricted by the Certificate, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting if all the members of the Board of Directors or committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or electronic transmissions are filed with the minutes of proceedings of the Board

of Directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

**Section 10. Manner of Participation**. Unless otherwise restricted by the Certificate, members of the Board of Directors, or any committee thereof, may participate in a meeting of the Board of Directors or such committee, as the case may be, by conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other. Participation in a meeting pursuant to this Section 10 shall constitute presence in person at such meeting.

**Section 11. Committees**. The Board of Directors, by vote of a majority of the directors then in office, may elect one or more committees, including, without limitation, an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee, and may delegate thereto some or all of its powers except those which by law, by the Certificate or these Bylaws may not be delegated. Except as the Board of Directors may otherwise determine, any such committee may make rules for the conduct of its business, but unless otherwise provided by the Board of Directors or in such rules, its business shall be conducted so far as possible in the same manner as is provided by these Bylaws for the Board of Directors. All members of such committees shall hold such offices at the pleasure of the Board of Directors. The Board of Directors may abolish any such committee at any time. Any committee to which the Board of Directors delegates any of its powers or duties shall keep records of its meetings and shall report its actions to the Board of Directors.

**Section 12. Compensation**. Members of the Board of Directors, as such, may receive, pursuant to a resolution of the Board of Directors, fees and other compensation for their services as directors, including without limitation their services as members of committees of the Board of Directors.

**Section 13. Duties of Chairman of the Board of Directors**. The Chairman of the Board of Directors, if appointed and when present, shall preside at all meetings of the stockholders and the Board of Directors. The Chairman of the Board of Directors shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

## ARTICLE IV

## OFFICERS

**Section 1. Officers**. The officers of the Corporation shall be, if and when designated by the Board of Directors, a Chief Executive Officer, a Secretary and a Chief Financial Officer. The Corporation may also have, at the discretion of the Board of Directors, a Chairman of the Board, a President, one or more Vice Presidents, one or more Assistant Financial Officers, one or more Assistant Secretaries and such other officers as may be appointed in accordance with the provisions of this Article IV. Any number of offices may be held by the same person.

**Section 2. Tenure of Officers**. All officers shall hold office at the pleasure of the Board of Directors and until their successors shall have been duly elected and qualified, unless sooner removed. Any officer elected or appointed by the Board of Directors may be removed at any time by the Board of Directors. Any officer may resign at any time by giving notice in writing or by electronic transmission to the Board of Directors or to the Chief Executive Officer or to the Secretary, and such resignation shall be effective upon receipt, unless the resignation otherwise provides. If the office of any officer becomes vacant for any reason, the vacancy may be filled by the Board of Directors.

**Section 3. Duties of Chief Executive Officer**. The Chief Executive Officer shall preside at all meetings of the stockholders and at all meetings of the Board of Directors, unless the Chairman of the Board of Directors has been appointed and is present. Unless an officer has been appointed Chief Executive Officer of the Corporation, the President shall be the chief executive officer of the Corporation and shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the Corporation. To the extent that a Chief Executive Officer has been appointed and no President has been appointed, all references in these Bylaws to the President shall be deemed references to the Chief Executive Officer. The Chief Executive Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

**Section 4. Duties of President.** The President shall preside at all meetings of the stockholders and at all meetings of the Board of Directors, unless the Chairman of the Board of Directors or the Chief Executive Officer has been appointed and is present. Unless another officer has been appointed Chief Executive Officer of the Corporation, the President shall be the chief executive officer of the Corporation and shall, subject to the control of the Board of Directors, have general supervision, direction and control of the business and officers of the Corporation. The President shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time.

**Section 5. Duties of Vice Presidents.** The Vice Presidents may assume and perform the duties of the President in the absence or disability of the President or whenever the office of President is vacant. The Vice Presidents shall perform other duties commonly incident to their office and shall also perform such other duties and have such other powers as the Board of Directors or the Chief Executive Officer, or, if the Chief Executive Officer has not been appointed or is absent, the President shall designate from time to time.

**Section 6. Duties of Secretary.** The Secretary shall attend all meetings of the stockholders and of the Board of Directors and shall record all acts and proceedings thereof in the minute book of the Corporation. The Secretary shall give notice in conformity with these Bylaws of all meetings of the stockholders and of all meetings of the Board of Directors and any committee thereof requiring notice. The Secretary shall perform all other duties provided for in these Bylaws and other duties commonly incident to the office and shall also perform such other duties and have such other powers, as the Board of Directors shall designate from time to time. The President may direct any Assistant Secretary or other officer to assume and perform the duties of the Secretary in the absence or disability of the Secretary, and each Assistant Secretary shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

**Section 7. Duties of Chief Financial Officer.** The Chief Financial Officer shall keep or cause to be kept the books of account of the Corporation in a thorough and proper manner and shall render statements of the financial affairs of the Corporation in such form and as often as required by the Board of Directors or the President. The Chief Financial Officer, subject to the order of the Board of Directors, shall have the custody of all funds and securities of the Corporation. The Chief Financial Officer shall perform other duties commonly incident to the office and shall also perform such other duties and have such other powers as the Board of Directors or the President shall designate from time to time.

**Section 8. Delegation of Authority**. The Board of Directors may from time to time delegate the powers or duties of any officer to any other officer or agent, notwithstanding any provision hereof.

## ARTICLE V

## STOCK

**Section 1. Stock Certificates**. The shares of the Corporation shall be represented by certificates, provided that the Board of Directors may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the Corporation. Every holder of stock represented by certificates and upon request every holder of uncertificated shares shall be entitled to have a certificate signed by, or in the name of the Corporation by the Chairman of the Board, Chief Executive Officer or the President, and by Chief Financial Officer, or the Secretary or an Assistant Secretary of the Corporation representing the number of shares registered in certificate form.

**Section 2. Signatures**. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue.

**Section 3. Lost Certificates**. A new certificate or certificates shall be issued in place of any certificate or certificates theretofore issued by the Corporation alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. The Corporation may, as a condition precedent to the issuance of such new certificate, require the owner of such lost, stolen, or destroyed certificate, or his legal representative, to agree to indemnify the Corporation in such manner as it shall require or to give the Corporation a bond (or other security) sufficient to indemnify it against any claim that may be made against the Corporation (including any expense or liability) on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate.

**Section 4. Transfers**. Subject to any restrictions on transfer and unless otherwise provided by the Board of Directors, shares of stock that are represented by a certificate may be transferred on the books of the Corporation by the surrender to the Corporation or its transfer agent of the certificate theretofore properly endorsed or accompanied by a written assignment or power of attorney properly executed, with transfer stamps (if necessary) affixed, and with such proof of the authenticity of signature as the Corporation or its transfer agent may reasonably require. Shares of stock that are not represented by a certificate may be transferred on the books of the Corporation by submitting to the Corporation or its transfer agent such evidence of transfer and following such other procedures as the Corporation or its transfer agent may require.

**Section 5. Record Holders**. The Corporation shall be entitled to recognize the exclusive right of a person registered on its books as the record holder of shares to receive dividends, and to vote as such record holder, and to hold liable for calls and assessments a person registered on its books as the record holder of shares, and shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of any other person, whether or not it shall have express or other notice thereof, except as otherwise required by law.

**Section 6. Record Dates**. In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board of Directors, and which record date: (a) in the case of determination of stockholders entitled to vote at any meeting of stockholders, shall, unless otherwise required by law, not be more than 60 nor less than 10 days before the date of such meeting and (b) in the case of any other action, shall not be more than 60 days prior to such other action. If no record date is fixed: (i) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held; and (ii) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

## ARTICLE VI

## INDEMNIFICATION

**Section 1. Indemnification of Directors, Officers, Employees and Other Agents**.

a. **Directors and Officers.** The Corporation shall indemnify its directors and officers to the extent not prohibited by the DGCL or any other applicable law; *provided, however,* that the Corporation may modify the extent of such indemnification by individual contracts with its directors and officers; and, *provided, further,* that the Corporation shall not be required to indemnify any director or officer in connection with any proceeding (or part thereof) initiated by such person unless (i) such indemnification is expressly required to be made by law, (ii) the proceeding was authorized by the Board of Directors of the Corporation, (iii) such indemnification is provided by the Corporation, in its sole discretion, pursuant to the powers vested in the Corporation under the DGCL or any other applicable law or (iv) such indemnification is required to be made under subsection (d) of Section 1 of this Article VI.

b. **Employees and Other Agents.** The Corporation shall have power to indemnify its employees and other agents as set forth in the DGCL or any other applicable law. The Board of Directors shall have the power to delegate the determination of whether to indemnify any such employee or other agent to such officers or other persons as the Board of Directors so determines.

c. **Expenses.** The Corporation shall advance to any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was a director or officer, of the Corporation, or is or was serving at the request of the Corporation as a director or officer of another corporation, partnership, joint venture, trust or other enterprise, prior to the final disposition of the proceeding, promptly following request therefor, all expenses incurred by any director or officer in connection with such proceeding provided, however, that if the DGCL requires, an advancement of expenses incurred by a director or officer in his or her capacity as a director or officer (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made only upon delivery to the Corporation of an undertaking, by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal that such indemnitee is not entitled to be indemnified for such expenses under this Section 1 or otherwise.

Notwithstanding the foregoing, unless otherwise determined pursuant to subsection (e) of this Section 1, no advance shall be made by the Corporation to an officer of the Corporation (except by reason of the fact that such officer is or was a director of the Corporation in which event this paragraph shall not apply) in any action, suit or proceeding, whether civil, criminal, administrative or investigative, if a determination is reasonably and promptly made (i) by a majority vote of directors who were not parties to the proceeding, even if not a quorum, or (ii) by a committee of such directors designated by a majority vote of such directors, even though less than a quorum, or (iii) if there are no such directors, or such directors so direct, by independent legal counsel in a written opinion, that the facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the Corporation.

d. **Enforcement.** Without the necessity of entering into an express contract, all rights to indemnification and advances to directors and officers under this Section 1 shall be deemed to be contractual rights and be effective to the same extent and as if provided for in a contract between the Corporation and the director or officer. Any right to indemnification or advances granted by this Section 1 to a director or officer shall be enforceable by or on behalf of the person holding such right in any court of competent jurisdiction if (i) the claim for indemnification or advances is denied, in whole or in part, or (ii) no disposition of such claim is made within 90 days of request therefor. To the extent permitted by law, the claimant in such enforcement action, if successful in whole or in part, shall be entitled to be paid also the expense of prosecuting the claim. In connection with any claim for indemnification, the Corporation shall be entitled to raise as a defense to any such action that the claimant has not met the standards of conduct that make it permissible under the DGCL or any other applicable law for the Corporation to indemnify the claimant for the amount claimed. In connection with any claim by an officer of the Corporation (except in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that such officer is or was a director of the Corporation) for advances, the Corporation shall be entitled to raise a defense as to any such action clear and convincing evidence that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to the best interests of the Corporation, or with respect to any criminal action or proceeding that such person acted without reasonable cause to believe that his conduct was lawful. Neither the failure of the Corporation (including its Board of Directors, independent legal counsel or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because he has met the applicable standard of conduct set forth in the DGCL or any other applicable law, nor an actual determination by the Corporation (including its Board of Directors, independent legal counsel or its stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that claimant has not met the applicable standard of conduct. In any suit brought by a director or officer to enforce a right to indemnification or to an advancement of expenses hereunder, the burden of proving that the director or officer is not entitled to be indemnified, or to such advancement of expenses, under this Section 1 or otherwise shall be on the Corporation.

e. **Non-Exclusivity of Rights.** The rights conferred on any person by this Bylaw shall not be exclusive of any other right which such person may have or hereafter acquire under any applicable statute, provision of the Certificate, Bylaws, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding office. The Corporation is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advances, to the fullest extent not prohibited by the DGCL, or by any other applicable law.

f. **Survival of Rights.** The rights conferred on any person by this Bylaw shall continue as to a person who has ceased to be a director or officer, or, if applicable, employee or other agent, and shall inure to the benefit of the heirs, executors and administrators of such a person.

g. **Insurance.** To the fullest extent permitted by the DGCL or any other applicable law, the Corporation, upon approval by the Board of Directors, may purchase insurance on behalf of any person required or permitted to be indemnified pursuant to this Section 1.

h. **Amendments.** Any repeal or modification of this Section 1 shall only be prospective and shall not affect the rights under this Bylaw in effect at the time of the alleged occurrence of any action or omission to act that is the cause of any proceeding against any agent of the Corporation.

i. **Saving Clause.** If this Bylaw or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each director and officer to the full extent not prohibited by any applicable portion of this Section 1 that shall not have been invalidated, or by any other applicable law. If this Section 1 shall be invalid due to the application of the indemnification provisions of another jurisdiction, then the Corporation shall indemnify each director and officer to the full extent under any other applicable law.

j. **Certain Definitions.** For the purposes of this Bylaw, the following definitions shall apply:

i. The term "proceeding" shall be broadly construed and shall include, without limitation, the investigation, preparation, prosecution, defense, settlement, arbitration and appeal of, and the giving of testimony in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative.

ii. The term "expenses" shall be broadly construed and shall include, without limitation, court costs, attorneys' fees, witness fees, fines, amounts paid in settlement or judgment and any other costs and expenses of any nature or kind incurred in connection with any proceeding.

iii. The term the "corporation" shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had power and authority to indemnify its directors, officers, and employees or agents, so that any person who is or was a director, officer, employee or agent of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, shall stand in the same position under the provisions of this Section 1 with respect to the resulting or surviving corporation as he would have with respect to such constituent corporation if its separate existence had continued.

iv. References to a "director," "officer," "employee," or "agent" of the corporation shall include, without limitation, situations where such person is serving at the request of the corporation as, respectively, a director, officer, employee, trustee or agent of another corporation, partnership, joint venture, trust or other enterprise.

v. References to "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to "serving at the request of the corporation" shall include any service as a director, officer, employee or agent of the corporation which imposes duties on, or involves services by,

such director, officer, employee, or agent with respect to an employee benefit plan, its participants, or beneficiaries; and a person who acted in good faith and in a manner such person reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "not opposed to the best interests of the corporation" as referred to in this Section 1.

## ARTICLE VII

## NOTICES

**Section 1. Notices**.

a. **Notice to Stockholders.** Written notice to stockholders of stockholder meetings shall be given as provided in Section 4 of Article II of these Bylaws. Without limiting the manner by which notice may otherwise be given effectively to stockholders under any agreement or contract with such stockholder, and except as otherwise required by law, written notice to stockholders for purposes other than stockholder meetings may be sent by U.S. mail or nationally recognized overnight courier, or by facsimile, telegraph or telex or by electronic mail or other electronic means.

b. **Notice to Directors.** Any notice required to be given to any director may be given by the method stated in subsection (a), as otherwise provided in these Bylaws, or by overnight delivery service, facsimile, telex or telegram, except that such notice other than one which is delivered personally shall be sent to such address as such director shall have filed in writing with the Secretary, or, in the absence of such filing, to the last known post office address of such director.

c. **Affidavit of Mailing.** An affidavit of mailing, executed by a duly authorized and competent employee of the corporation or its transfer agent appointed with respect to the class of stock affected, or other agent, specifying the name and address or the names and addresses of the stockholder or stockholders, or director or directors, to whom any such notice or notices was or were given, and the time and method of giving the same, shall in the absence of fraud, be prima facie evidence of the facts therein contained.

d. **Methods of Notice.** It shall not be necessary that the same method of giving notice be employed in respect of all recipients of notice, but one permissible method may be employed in respect of any one or more, and any other permissible method or methods may be employed in respect of any other or others.

e. **Notice to Person With Whom Communication is Unlawful.** Whenever notice is required to be given, under any provision of law or of the Certificate or Bylaws of the Corporation, to any person with whom communication is unlawful, the giving of such notice to such person shall not be required and there shall be no duty to apply to any governmental authority or agency for a license or permit to give such notice to such person. Any action or meeting which shall be taken or held without notice to any such person with whom communication is unlawful shall have the same force and effect as if such notice had been duly given. In the event that the action taken by the Corporation is such as to require the filing of a certificate under any provision of the DGCL, the certificate shall state, if such is the fact and if notice is required, that notice was given to all persons entitled to receive notice except such persons with whom communication is unlawful.

f. **Notice to Stockholders Sharing an Address.** Except as otherwise prohibited under the DGCL, any notice given under the provisions of the DGCL, the Certificate or the Bylaws shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Such consent shall have been deemed to have

been given if such stockholder fails to object in writing to the Corporation within 60 days of having been given notice by the Corporation of its intention to send the single notice. Any consent shall be revocable by the stockholder by written notice to the Corporation.

## ARTICLE VIII

## GENERAL PROVISIONS

**Section 1.** **Dividends**. Subject to limitations contained in the DGCL and the Certificate, the Board of Directors may declare and pay dividends upon the shares of capital stock of the Corporation, which dividends may be paid either in cash, securities of the Corporation or other property.

**Section 2.** **Disbursements**. All checks or demands for money and notes of the Corporation shall be signed by such officer or officers or such other person or persons as the Board of Directors may from time to time designate.

**Section 3.** **Fiscal Year**. The fiscal year of the Corporation shall be fixed by resolution of the Board of Directors.

**Section 4.** **Corporate Seal**. The Board of Directors shall have the power to adopt and alter the seal of the Corporation.

**Section 5.** **Voting of Stock Owned by the Corporation**. The Chairman of the Board, the Chief Executive Officer and any other officer of the Corporation authorized by the Board of Directors shall have power, on behalf of the Corporation, to attend, vote and grant proxies to be used at any meeting of stockholders of any Corporation (except this Corporation) in which the Corporation may hold stock.

**Section 6.** **Construction and Definitions**. Unless the context requires otherwise, the general provisions, rules of construction and definitions in the DGCL shall govern the construction of these Bylaws.

**Section 7.** **Provisions of Certificate Govern**. In the event of any inconsistency between the terms of these Bylaws and the Certificate, the terms of the Certificate will govern.

**Section 8.** **Amendments**. Subject to the limitations set forth in Section 1(h) of Article VI of these Bylaws or the provisions of the Certificate, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the Corporation. Any adoption, amendment or repeal of the Bylaws of the Corporation by the Board of Directors shall require the approval of a majority of the authorized number of directors. The stockholders also shall have power to adopt, amend or repeal the Bylaws of the Corporation; *provided*, ho*wever,* that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by the Certificate, such action by stockholders shall require the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of the capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class.

## ARTICLE IX

## FORUM SELECTION

**Section 1.** **Exclusive Forum**. Unless the Corporation consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the exclusive forum for the resolution of any complaint asserting a cause of action

under the Securities Act of 1933, as amended. Any person or entity purchasing or otherwise acquiring any interest in any security of the Corporation shall be deemed to have notice of and consented to this provision.

# AMENDED AND RESTATED BYLAWS

# OF

# TANDEM DIABETES, CARE, INC.,
# a Delaware corporation

**As Updated Through February 4, 2021**

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# DEVELOPMENT AGREEMENT

This Development Agreement (this "**Agreement**") is made and entered into on November 20, 2020 (the "**Effective Date**") by and between Tandem Diabetes Care, Inc, having a principal place of business at 11075 Roselle St., San Diego, CA 92121 ("**Tandem**") and DexCom, Inc., a Delaware corporation having a principal place of business at 6340 Sequence Drive, San Diego, CA 92121 ("**DexCom**"). Tandem and DexCom may be referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**".

## RECITALS

A. DexCom is in the business of developing and commercializing continuous glucose monitoring systems;

B. Tandem is in the business of developing and commercializing insulin pump systems;

C. The Parties entered into that certain development agreement dated June 4, 2015, as amended, to enable the integration of Tandem's t:slim X2™ insulin pump with DexCom's G6® CGM device (the "**On-Market t-slim:G6 Implementation**" and such agreement, the "**Original G6 Development Agreement**");

D. On February 7, 2020, DexCom issued a notice of termination for (i) the development agreement dated January 4, 2013, which addressed the integration of Tandem's insulin pump with DexCom's G4® CGM device (the "**G4 Development Agreement**"), which termination became effective August 10, 2020 and (ii) the development agreement dated June 4, 2015, which addressed the integration of Tandem's insulin pump with DexCom's G5® CGM device (the "**G5 Development Agreement**" and collectively with the G4 Development Agreement, "**Legacy Development Agreements**"), which the Parties agreed will terminate on December 31, 2020 with respect to all countries other than Australia and will terminate on December 31, 2021 with respect to Australia; and

E. The Parties now wish to enter into an additional development agreement to enable the integration of Tandem's t:sport insulin pump with DexCom's G6® CGM device, and enable the integration of Tandem's t:slim X2™ and t:sport insulin pumps with DexCom's G7® CGM device; and

F. The Parties are also entering into a commercialization agreement of even date herewith (the "**Commercialization Agreement**") which sets forth the terms for the commercialization of both the integrated technology solutions developed hereunder and the integrated technology solutions developed under the Original G6 Development Agreement.

The Parties therefore agree as follows:

## 1. DEFINITIONS

1.1 "**Affiliate**" means any corporation or other entity that is directly or indirectly controlling, controlled by or under common control with a Party. For the purpose of this definition, "control" means: (i) the direct or indirect ownership of more than fifty percent (50%) of the capital stock of the subject entity; (ii) the direct or indirect control of more than fifty percent (50%) of the voting rights of the subject entity; or (iii) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of the subject entity (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.2 **"[***]"** means, (a) with respect to DexCom [***] and (b) with respect to Tandem [***].

1.3 "**Applicable Laws**" means all applicable laws, rules and regulations, including any rules, regulations, guidance or other requirements of any Regulatory Authority, that may be in effect from time to time and are applicable to a particular activity hereunder.

1.4 "**CGM**" means continuous glucose monitoring.

1.5 "**Change of Control**" means a transaction or a series of related transactions: (i) in which one or more related parties that did not previously own or control greater than a fifty percent (50%) equity interest in a Party obtains ownership or control of greater than a fifty percent (50%) equity interest in a Party; (ii) as a result of which one or more related parties that did not previously have the right or power to control the management or policies of a Party acquires such right or power; or (iii) in which a Party sells all or substantially all of its assets to a Third Party.

1.6 "**Clinical Study**" means any pre or post approval clinical study involving the administration of and/or use of a Combined System with a human subject, whether conducted before or after Regulatory Approval of a Combined System, including clinical studies to support such Regulatory Approval process or as otherwise required by a Regulatory Authority.

1.7 "**Combined System**" means an integrated technology solution comprised of the DexCom System and the Tandem System that enables [***]. The Parties agree that the integrated technology solution(s) developed by the Parties pursuant to the Legacy Development Agreements, and any improvements thereto, are not Combined Systems hereunder.

1.8 **"Combined System Implementation"** means, as applicable, an implementation of the Combined System, involving the integration of Tandem's t:sport insulin pump with DexCom's G6® CGM device, the integration of Tandem's t:slim X2™ insulin pump with DexCom's G7® CGM device and the integration of Tandem's t:sport insulin pump with DexCom's G7® CGM device, in each case as developed under this Agreement. The Parties agree that the On-Market t-slim:G6 Implementation, including any improvement thereto, is not a

Combined System Implementation. The initial architecture of the Combined System Implementation with respect to Tandem's t:sport Insulin Delivery Device and DexCom's G6® CGM Device is described in **Exhibit A**.

1.9 "**Commercially Reasonable Efforts**" means the carrying out of a Party's obligations under this Agreement with the exercise of prudent scientific and business judgment and a level of effort and resources consistent with the efforts and resources that the Party who bears the performance obligation, but in any event at least the level of effort and resources of a similarly sized comparable Third Party in the CGM or insulin delivery device industry, as applicable, would employ for products of similar strategic importance and commercial value that result from its own research efforts.

1.10 "**Committee**" means any of the Development Working Team, Commercial Working Team, Joint Steering Committee and any subordinate committee appointed by such Working Teams or the Joint Steering Committee.

1.11 "**Communication Protocol**" means a DexCom communication protocol that permits a DexCom CGM-Enabled Tandem Display Device to identify, receive and display DexCom CGM Data and to control the DexCom CGM Transmitter, which communication protocol will be developed by or on behalf of DexCom under the Development Plan, as may be amended or updated by DexCom from time to time in accordance with the Development Plan.

1.12 "**Development Plan**" means the written plan setting forth the activities and related obligations to be performed by the Parties with respect to the development and validation of the Combined System Implementations with respect to DexCom's G6® and G7® CGM devices, as such plan may be updated from time to time by the Development Working Team as set forth below, including the following:

1.12.1 Applicable specifications;

1.12.2 Applicable deliverables;

1.12.3 Assigned key personnel (which for clarity shall be for informational purposes only and each Party shall be free to change its key personnel at any time);

1.12.4 Applicable development milestones;

1.12.5 Applicable Regulatory Approvals; and

1.12.6 Any other matters related to the development of the Combined System Implementations that the Development Working Team deems material.

1.13 "**DexCom CGM App**" means any software (including any software application) of DexCom or its Affiliates designed to gather DexCom CGM Data in connection with a Combined System, which may include [***], depending on the configuration of such Combined System, as described in more detail in the Development Plan.

1.14 "**DexCom CGM Data**" means the continuous glucose monitoring data displayed on the receiver or other display device of a DexCom System (in each case solely to the extent such DexCom System is used as part of a Combined System in accordance with this Agreement or the Commercialization Agreement), as set forth in more detail in Exhibit B to the Commercialization Agreement**.** For clarity, DexCom CGM Data excludes any raw CGM sensor data.

1.15 "**DexCom CGM Device**" means DexCom's CGM devices known as DexCom G6® and DexCom G7®, including any Minor Release thereof.

1.16 "**DexCom CGM-Enabled Tandem Display Device**" means a Tandem Display Device comprising a receiver or other component of the Tandem Insulin Delivery Device configured to identify, Process and/or display DexCom CGM Data from a DexCom CGM Transmitter and control the DexCom CGM Transmitter, as described in more detail in the Development Plan. A DexCom CGM-Enabled Tandem Display Device will be independently developed by Tandem and is not, and will not be, a component of any DexCom System.

1.17 "**DexCom CGM Transmitter**" means the transmitter component of the DexCom System (which may be a standalone DexCom transmitter that operably couples to the DexCom Sensor or an embedded component of a DexCom Sensor) that is configured to transmit DexCom CGM Data from a DexCom Sensor to any receiver adapted to identify, receive, and display such information, and is also controlled from an authenticated receiver and the DexCom CGM App.

1.18 "**DexCom Sensor**" means the component of a DexCom System comprising a continuous glucose monitoring electrode sensor, adapted to (i) penetrate the patient's skin to come into contact with the patient's interstitial fluid, (ii) measure interstitial fluid glucose level, and (iii) be operably coupled to a DexCom CGM Transmitter to communicate the blood glucose value as measured by such sensor, to a separate receiver.

1.19 "**DexCom System**" means a CGM system comprised of a DexCom CGM Device and one or more DexCom CGM Apps, as described in more detail in the Development Plan.

1.20 "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.21 "**EU**" means those countries that are members of the European Union as of the date on which the relevant determination is being made.

1.22 "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.23 "**Governmental Authority**" means any (i) international, regional, national, federal, state, or local government entity, authority, agency, instrumentality, court, tribunal, regulatory commission or other body, either foreign or domestic, whether legislative,

judicial, administrative or executive; or (ii) arbitrator to whom a dispute has been presented under government rule or by agreement of the Parties with an interest in such dispute.

1.24 "**Intellectual Property**" means (collectively): any copyright, patent or patent application (including any foreign counterparts of any of the foregoing, as well as all continuations, continuations-in-part, divisionals, reissues, reexaminations, and all renewals and extensions thereof, regardless of whether such rights arise under the laws of the United States or any other state, country or jurisdiction), inventions, trade secrets, methods, know-how, technology, information, data and results (including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data and results), software, algorithms, rights of publicity, authors' rights, goodwill and all other intellectual property rights as may exist now and/or hereafter come into existence. Intellectual Property shall include Software and Copyrights, but shall exclude all Trademarks.

1.25 "**Internal Compliance Policies**" means a Party's internal policies and procedures intended to ensure that a Party complies with Applicable Laws, Party-Specific Regulations, and such Party's internal ethical, medical and similar standards.

1.26 "**Major Release**" means a new generation of a product (e.g., in the case of the DexCom System, G7® as compared to G6®) that adds material features and functionality improving overall performance, efficiency and/or usability, and designated by the provider as a replacement for a prior generation, excluding for clarity any Minor Release.

1.27 "**Minor Release**" means an intra-generational product release adding functionality in a backwards-compatible manner, or a patch version for such product making backwards-compatible bug fixes.

1.28 "**Party-Specific Regulations**" means all judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement.

1.29 "**Personal Data**" means any information or set of information relating to an identified or identifiable individual Processed by either Party through a Combined System or provided or shared by or on behalf of one Party to the other Party under this Agreement, regardless of the medium in which such information is displayed or contained, which shall include (a) all information that identifies that individual or could reasonably be used to identify such individual, (b) all "personal information," "personal data," and/or "protected health information" under applicable Privacy Laws (including, as applicable, HIPAA, CCPA, GDPR, and APPI), and (c) all information to which any applicable Privacy Laws apply and shall, at a minimum, include any information which relates to an identified or identifiable natural person.

1.30 "**PMA**" means premarket approval.

1.31 "**Privacy Laws**" means all applicable foreign, federal, state, and local laws and regulations governing the Processing, sharing, safeguarding, security, disclosure or transfer of Personal Data (including electronic transaction sets, medical code sets, provider identifier, employer identifier, and patient identifier), as amended from time to time, including, as applicable, (i) HIPAA and the HITECH Act and all amendments to and further regulations of HIPAA and the HITECH Act, (ii) the EU General Data Protection Regulation 2016/679 ("**GDPR**"), (iii) California Consumer Privacy Act ("**CCPA**"), (iv) Japan's Act on the Protection of Personal Information ("**APPI**"), and (v) the CAN-SPAM Act, Canada's Anti-Spam Legislation and other laws or regulations governing telemarketing, including any such laws or regulations prohibiting unsolicited telephone calls to persons or entities listed on "Do Not Call" registries or similar lists or prohibiting unsolicited e-mails, spam or faxes to any person.

1.32 "**Processing**" (including "**Process**" and "**Processed**") means any operation or set of operations that is performed on Personal Data, DexCom CGM Data or Tandem Insulin Data, within an entity that maintains such information, including receipt, use, collection, recording, maintaining, organization, storage, adaptation, modification, retrieval, consultation, retention, alteration, dissemination, transmission, access, transfer, combination, erasure, destruction, deidentification, or pseudonymization. Processing does not include the release, transfer, provision of, access to, or divulging in any other manner of Personal Data outside the Party maintaining such information (and its Affiliates) and not to the other Party or its Affiliates.

1.33 "**Regulatory Approval**" means, with respect to a country, any and all classifications, clearances, approvals, licenses, registrations or authorizations of any Regulatory Authority (including any required approvals for reimbursement) necessary to commercially distribute, sell or market a product in such country, including, as may be applicable, PMA, a premarket notification (510(k)) or a *de novo* application in the United States or analogous clearance or approval in other jurisdictions, including a CE marking approval in the EU.

1.34 "**Regulatory Authority**" means the FDA, the EMA or any supranational, national or local agency, authority, department, inspectorate, ministry official, parliament or public or statutory person of any government of any country, including a notified body, having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.

1.35 "**Regulatory Documentation**" means all (i) applications, registrations, licenses, authorizations and approvals (including Regulatory Approvals); and (ii) correspondence, reports and other submissions submitted to or received from Regulatory Authorities and all supporting documents with respect thereto, including all adverse event files and complaint files.

1.36 "**Representatives**" means a Party's and its Affiliates' employees, officers, directors, consultants and legal, technical and business advisors.

1.37 "**Software and Copyrights**" means software, code, works of authorship and copyrightable subject matter.

1.38 "**System**" means (i) with respect to DexCom, the DexCom System as used in a Combined System, and (ii) with respect to Tandem, the Tandem System as used in a Combined System.

1.39 "**Tandem Development Tools**" means those application program interfaces and developer tools that Tandem provides or otherwise makes available to DexCom for use in connection with the Development Plan.

1.40 "**Tandem Diabetes Management App**" means any diabetes management software (including any software application), of Tandem or its Affiliates for use in connection with the Tandem Insulin Delivery Device, and associated data management software, which may include [***], depending on the configuration of such Combined System, as described in more detail in the Development Plan.

1.41 "**Tandem Display Device**" means a device used in connection with, or component of the, Tandem Insulin Delivery Device that communicates with and controls (fully or partially) the Tandem Insulin Delivery Device and which also Processes data related to the Tandem System.

1.42 "**Tandem Insulin Data**" means any insulin data generated by a Tandem System (solely to the extent such Tandem System is used as part of a Combined System in accordance with this Agreement or the Commercialization Agreement) and made available to DexCom through the Tandem Partner CID, as set forth in more detail in Exhibit D to the Commercialization Agreement. For clarity, Tandem Insulin Data does not include any data not specified in the Tandem Partner CID.

1.43 "**Tandem Insulin Delivery Device**" means Tandem's pump products known as t:slim and t:sport, with or without a dedicated controller, including any Minor Release thereof.

1.44 "**Tandem Partner CID**" means the communication interface description ("**CID**") that defines the messaging protocol used to allow the Tandem System to communicate [***] Data to a DexCom CGM App.

1.45 "**Tandem Partner CID Documentation**" means written documentation, including any specifications, provided by or on behalf of Tandem to DexCom, sufficient to allow DexCom to build code such that [***] Data may be transferred into a DexCom CGM App from the Tandem System when a User uses the Tandem Partner CID.

1.46 "**Tandem System**" means a subcutaneous infusion system comprised of a Tandem Insulin Delivery Device, a Tandem Display Device and one or more Tandem Diabetes Management Apps, as described in more detail in the Development Plan.

1.47 "**Third Party**" means any entity or person other than DexCom or Tandem or their respective Affiliates.

1.48 "**Trademarks**" means all trade names, trademarks, service marks, logos and trade dress, including applications therefor, and all rights therein and thereto, together with all goodwill associated therewith.

1.49 "**Transaction Agreements**" means, collectively, this Agreement, the Commercialization Agreement and the Quality Agreement.

1.50 **Additional Definitions:** Any capitalized terms not defined in this Agreement have the meaning as defined in the Commercialization Agreement executed by the Parties on November 20, 2020. The following table identifies the location of definitions set forth in various Sections of this Agreement (or, where applicable, the Commercialization Agreement):

| Defined Term | Section Reference |
|---|---|
| "[***]" | [***] |
| "**Agreement**" | Preamble to this Agreement |
| "[***]" | [***] |
| "**Alliance Manager**" | Section 2.7 |
| **"Anti-Corruption Laws"** | Commercialization Agreement |
| "[***]" | [***] |
| "**Combined System Infringement Action**" | Section 7.4 |
| **"Commercial Working Team"** | Commercialization Agreement |
| "**Commercialization Agreement**" | Recitals to this Agreement |
| "**Commercialization Plan**" | Commercialization Agreement |
| "[***]" | [***] |
| "**Confidential Information**" | Section 6.1 |
| "**Development Working Team**" | Section 2.3.1 |
| "**DexCom**" | Preamble to this Agreement |
| "**DexCom Indemnitees**" | Section 7.2 |
| "[***]" | [***] |
| "**Disclosing Party**" | Section 6.1 |
| "**Effective Date**" | Preamble to this Agreement. |
| "[***]" | [***] |
| "**G4 Development Agreement**" | Recitals to this Agreement |
| "**G5 Development Agreement**" | Recitals to this Agreement |
| "**Indemnitee**" | Section 7.6 |
| "**Indemnitor**" | Section 7.6 |
| "**Joint Steering Committee**" | Section 2.4.1 |
| "**Legacy Development Agreements**" | Recitals to this Agreement |
| "**Losses**" | Section 7.1 |
| "**Notifying Party**" | Section 8.2.1 |
| "**On-Market t-slim:G6 Implementation**" | Recitals to this Agreement |
| **"Original G6 Development Agreement"** | Recitals to this Agreement |

| | |
|---|---|
| "**Party**" and "**Parties**" | Preamble to this Agreement |
| "**Publication**" | Section 6.7 |
| "**Quality Agreement**" | Commercialization Agreement |
| "**Receiving Party**" | Section 6.1 |
| "**Relevant DexCom Regulatory Meetings**" | Section 4.2.4 |
| "**Relevant Tandem Regulatory Meetings**" | Section 4.1.2 |
| "**Tandem**" | Preamble to this Agreement |
| "**Tandem Indemnitees**" | Section 7.1 |
| "**Term**" | Section 8.1 |
| "**Termination Support Services**" | Section 8.6.3 |
| "**TypeZero License Agreement**" | Section 3.1.2 |

## 2. DEVELOPMENT, DEVELOPMENT WORKING TEAM, JOINT STEERING COMMITTEE, AND PARTY RESPONSIBILITIES

2.1. Development Generally. As soon as reasonably practicable following the Effective Date, the Parties (through the Develop Working Team) will jointly develop and agree on the Development Plan, as set forth in Section 2.3.2(i). Each Party shall use Commercially Reasonable Efforts to perform its designated responsibilities and work under the Development Plan; provided, that each Party acknowledges that there is no guarantee of any successful results from the performance of such Development Plan. The current architecture for the Combined System Implementations is listed in **Exhibit A**.

2.2. Conduct of Development Plan; Compliance with Law. The Parties shall conduct the Development Plan, or cause the same to be done, (i) using reasonable and customary good scientific practices and in accordance with all Applicable Laws, the provisions of this Agreement (including the Development Plan), and (ii) in accordance with, in the case of Tandem, Tandem's Internal Compliance Policies, and in the case of DexCom, DexCom's Internal Compliance Policies, to the extent such Internal Compliance Policies do not conflict with the Applicable Laws.

2.3. Development Working Team.

1 Within [***] from the Effective Date, the Parties shall establish a management team for the implementation of the Development Plan that shall be comprised of three (3) members for each Party ("**Development Working Team**") (who shall be Representatives of the appointing Party and at least one of which shall be a member of the Joint Steering Committee). Each Party may replace its Development Working Team members at any time by notice to the other Party.

2 In accordance with the provisions and objectives of this Agreement and the Development Plan, the Development Working Team shall, subject to Section 2.5:

i. develop, review and approve the Development Plan;

ii. oversee, coordinate and manage the Parties' activities under, and implementation of, the Development Plan;

iii. ensure communication between the Parties concerning the implementation, status and results of the Development Plan;

iv. exercise decision-making authority over all Development Plan activities in accordance with this Section 2.3 and make all such decisions and take all such other actions as are delegated to it in this Agreement;

v. review and approve updates or amendments to the Development Plan as the Development Working Team determines is appropriate for the Parties to achieve the Development Plan objectives;

vi. coordinate continuous improvement and technology upgrades for the Combined System Implementations with the Commercial Working Team; and

vii. perform such other functions as are appropriate to further the purposes of this Agreement as mutually determined in writing by the Parties.

3 The Development Working Team shall meet as needed but not less than [***], except as may otherwise be agreed in writing by the Parties. Development Working Team meetings shall be held at times and places or in such form, such as by telephone or video conference, as the Development Working Team determines, except that in-person meetings of the Development Working Team will alternate between the Parties' offices, unless otherwise agreed in writing by the Parties. Any Development Working Team member may designate by notice to the other members (which may be provided by e-mail) a qualified Representative of its Party as a substitute to attend and perform the functions of that Development Working Team member at any Development Working Team meeting that such member cannot attend.

4 The Development Working Team shall appoint one (1) of the Development Working Team members to act as the initial Development Working Team chairperson during such period as the Development Working Team shall designate. At the end of each such designated period during the Term, the Parties shall alternate in appointing the chairperson for the next such defined period. Where the Development Working Team chairperson cannot attend a Development Working Team meeting, the other member having been previously designated by the same Party shall serve as the temporary Development Working Team chairperson for such meeting, unless neither of such Party's designated Development Working Team members can attend, in which case a qualified substitute designated by the Development Working Team chairperson for such purpose shall serve as the temporary Development Working Team chairperson for such meeting.

5 The Development Working Team chairperson shall be responsible for:

i. calling and presiding over each Development Working Team meeting during his or her tenure as chairperson;

ii. preparing and circulating the agenda for each such meeting; and

iii. preparing draft minutes of each such meeting and providing a copy of the draft minutes to each Development Working Team member within [***] after each such meeting for approval, which shall be deemed to have been given unless the Development Working Team member objects within [***] after receipt of the draft minutes.

6 Each Party shall collectively have one (1) vote in any matter requiring the Development Working Team's action or approval. All Development Working Team decisions shall be unanimous and no Development Working Team vote may be taken unless at least one Development Working Team member of each Party (or properly designated substitute) is present. The Development Working Team shall make all decisions and take other actions in good faith and with due care, after consideration of the information that is reasonably available to it, with the intention that the resulting decision or action shall maintain or increase the likelihood that the Parties will achieve the purposes and goals of the Development Plan.

7 If the Development Working Team cannot reach a unanimous decision on any matter within its authority at a scheduled Development Working Team meeting or within [***] thereafter, then either Party may, by notice to the other Party, refer such matter to the Joint Steering Committee for resolution by good faith discussions for a period of at least [***]. In the event that the Joint Steering Committee is unable to reach agreement with respect to such matter within such [***], then the following shall apply:

i. DexCom shall have the final decision-making authority with respect to (A) the technical specifications for the DexCom System and the Communication Protocol; provided, that such technical specifications are consistent with the general Combined System Implementation features and functionality set forth in the Development Plan and (B) DexCom's day-to-day implementation of its responsibilities under the Development Plan; and

ii. Tandem shall have the final decision-making authority with respect to (A) the technical specifications for the Tandem System; provided, that such technical specifications are consistent with the general Combined System Implementation features and functionality set forth in the Development Plan and (B) Tandem's day-to-day implementation of its responsibilities under the Development Plan;

Provided, further, that neither Party may exercise its final decision-making authority in a manner that (A) goes beyond the JSC's authority, as limited by Section 2.5, (B) would unilaterally impose any additional or different obligation on the other Party (including for the other Party to incur or share any additional cost), (C) would cause a Party to assume additional regulatory responsibilities, including reporting requirements or (D) would require changes to quality management practices.

8 The Development Working Team shall keep each Party fully informed of the status and progress of the Development Plan. Except as otherwise provided in this Agreement or in the Development Plan, the Parties will make available and disclose to one another all results of material work conducted pursuant to the Development Plan in the prior period at least [***] prior to and in preparation for the Development Working Team meetings, and in any particular form and format, that is designated by the Development Working Team. For avoidance of doubt, the Parties are under no obligation to disclose information relating to any other research efforts not related to the Development Plan.

2.4 Joint Steering Committee.

2.1 Within [***] from the Effective Date, the Parties shall establish a committee for oversight of the development and commercialization of the Combined Systems developed under this Agreement and the Original G6 Development Agreement that shall be comprised of two (2) Representatives of DexCom and two (2) Representatives of Tandem ("**Joint Steering Committee**"). Each Party may replace its Joint Steering Committee members at any time by notice to the other Party.

2.2 In accordance with the provisions and objectives of this Agreement, the Joint Steering Committee shall, subject to Section 2.5:

i. Establish strategic objectives and general direction for the Development Working Team and Commercial Working Team and the Combined System Implementations;

ii. monitor each Party's performance, progress and results with respect to the Development Plan and Commercialization Plan;

iii. appoint and oversee additional subordinate committees or working groups responsible for certain specific matters (e.g., an intellectual property committee, information security committee, etc.), as and to the extent necessary and appropriate;

iv. decide on changes to Agreed Markets under a Commercialization Plan as proposed by the Commercial Working Team;

v. resolve disputes referred to it by either the Development Working Team or the Commercial Working Team; and

vi. perform such other functions as are appropriate to further the purposes of this Agreement as mutually determined in writing by the Parties.

2.3 The Joint Steering Committee shall meet as needed but not less than [***], except as may otherwise be agreed in writing by the Parties. Joint Steering Committee meetings shall be held at times and places or in such form, such as by telephone or video conference, as the Joint Steering Committee determines, except that in-person meetings of the Joint Steering Committee will alternate between the Parties' offices, unless otherwise agreed

in writing by the Parties. Any Joint Steering Committee member may designate a qualified Representative of its Party as a substitute to attend and perform the functions of that Joint Steering Committee member at any Joint Steering Committee meeting.

2.4 Subject to such persons being bound by written agreement(s) or other legally enforceable obligations concerning confidentiality and proper assignment of Intellectual Property under the Development Plan consistent with the terms of this Agreement, each Party may invite additional Representatives to attend Joint Steering Committee meetings to make presentations, without any voting authority, on written notice to the other Party's members of the Development Working Team (including notice sent via e-mail) before the Development Working Team meeting that the Representative will attend.

2.5 Each Party shall collectively have one (1) vote in any matter requiring the Joint Steering Committee action or approval. All Joint Steering Committee decisions shall be unanimous and no Joint Steering Committee vote may be taken unless at least one Joint Steering Committee member of each Party (or properly designated substitute) is present. The Joint Steering Committee shall make all decisions and take other actions in good faith and with due care, after consideration of the information that is reasonably available to it.

2.6 If the Joint Steering Committee cannot reach a unanimous decision on any matter within its authority at a scheduled Joint Steering Committee, meeting or within [***] thereafter, then the matter shall be resolved in accordance with Section 2.3.7 of this Agreement if the dispute relates to the Development Plan (or activities thereunder or related thereto), or Section 2.3.7 of the Commercialization Agreement if the dispute relates to the Commercialization Plan (or activities thereunder or related under), or if not subject to dispute resolution in accordance with either of such Sections, then the status quo shall be maintained until a unanimous decision can be reached.

2.7.5 Governance Limitations. Each of the Joint Steering Committee and the Development Working Team has only the powers specifically delegated to it by this Agreement (or with respect to the Joint Steering Committee, the Commercialization Agreement) and has no authority to act on behalf of any Party in connection with any Third Party. Without limiting the foregoing, and notwithstanding anything in this Agreement to the contrary, neither the Joint Steering Committee nor the Development Working Team has any authority to, and shall not purport to or attempt to:

i. amend this Agreement or any other Transaction Agreement;

ii. approve or take any action that would breach or conflict with any provision of this Agreement or of any other Transaction Agreement;

iii. negotiate agreements on behalf of any Party;

iv. make representations or warranties on behalf of any Party;

v. determine compliance or non-compliance with any provision of this Agreement or of any other Transaction Agreement; provided, that the Joint Steering Committee shall have the right to discuss any such non-compliance;

vi. waive any rights of any Party;

vii. extend credit on behalf of any Party; or

viii. take or grant licenses of, transfer ownership or otherwise encumber Intellectual Property on behalf of any Party.

2.7.6 Governance [***]. Each Party shall [***] of its respective Joint Steering Committee and Development Working Team members, and their designated substitutes, related to their participation on the Joint Steering Committee and Development Working Team and attendance at Joint Steering Committee and Development Working Team meetings.

2.7.7 Alliance Managers. Each of Tandem and DexCom shall appoint one (1) Representative who possesses a general understanding of development and commercialization issues to act as it's alliance manager (each, an "**Alliance Manager**"). Each of Tandem and DexCom may change its designated Alliance Manager from time to time upon written notice to the other Party. Any Alliance Manager may designate another Representative of its Party as a substitute to temporarily perform the functions of that Alliance Manager upon written notice to the other Party's Alliance Manager. The Alliance Managers shall attend all meetings of the Joint Steering Committee, Development Working Team and Commercial Working Team (and each Alliance Manager may attend any other Committee meetings that he or she desires to attend) as non-voting participants and support the Committee members in the discharge of their responsibilities.

2.1 Responsibilities. In accordance with, and without limiting the terms of this Agreement and the Commercialization Agreement, each Alliance Manager shall:

i. identify and bring disagreements and issues that may result in disputes (including any asserted occurrence of a material breach by a Party) to the attention of the Joint Steering Committee, Development Working Team and/or Commercial Working Team, as applicable, in a timely manner, and function as the point of first referral in all matters of conflict resolution;

ii. provide a single point of communication for seeking consensus both internally within the Parties' respective organizations and between the Parties;

iii. plan and coordinate cooperative efforts, internal communications and external communications between the Parties with respect to this Agreement and the Commercialization Agreement; and

iv. take responsibility for ensuring that meetings and the production of meeting agendas and minutes occur as set forth in this Agreement and the Commercialization

Agreement, and that relevant action items resulting from such meetings are appropriately carried out or otherwise addressed.

The Alliance Managers shall jointly be responsible for:

A. calling each Joint Steering Committee meeting;

B. preparing and circulating the agenda for each Joint Steering Committee meeting; and

C. preparing draft minutes of each Joint Steering Committee meeting and providing a copy of the draft minutes to each Joint Steering Committee member within [***] after each such meeting for approval, which shall be deemed to have been given unless Joint Steering Committee member objects within [***] after receipt of the draft minutes. The Parties shall work in good faith to promptly resolve any dispute regarding such draft minutes.

2.8.8 Tandem's Development Related Responsibilities. Unless otherwise determined by the Development Working Team, or stated otherwise in the Development Plan, Tandem shall:

2.1 be solely responsible for all design and development activities associated with the development of the DexCom CGM-Enabled Tandem Display Devices and Tandem Diabetes Management Apps;

2.2 commit personnel and resources and formulate a plan to achieve the milestones set forth in the Development Plan. For the avoidance of doubt, such personnel may work on projects not related to the Combined System Implementations, provided they use Commercially Reasonable Efforts to achieve the milestones set forth in the Development Plan;

2.3 use Commercially Reasonable Efforts in the design and development of the Combined System Implementations to give such Combined Systems the ability to: (1) [***], (2) [***], in compliance with all Privacy Laws, and (3) operate using commercially reasonable cybersecurity measures.

2.9 DexCom Development Related Responsibilities. Unless otherwise determined by the Development Working Team, or stated otherwise in the Development Plan, DexCom shall:

2.1 be solely responsible for the design and development of the DexCom CGM Devices and DexCom CGM Apps;

2.2 commit personnel and resources and formulate a plan to achieve the milestones set forth in the Development Plan. For the avoidance of doubt, such personnel may work on projects not related to the Combined System Implementations, provided they use Commercially Reasonable Efforts to achieve the milestones set forth in the Development Plan;

2.3 use Commercially Reasonable Efforts to support the integration of DexCom CGM Data into the Combined System Implementations in accordance with the Development Plan; and

2.4 use Commercially Reasonable Efforts in the design and development of the Combined System Implementations to give such Combined Systems the ability to operate using commercially reasonable cybersecurity measures and in compliance with all Privacy Laws.

2.10 Costs. Unless otherwise mutually agreed by the Parties in the Development Plan, [***].

2.11 Clinical Studies.

2.11.1 Subject to this Section 2.11.1 and Section 2.11.2, Tandem shall have the sole right to (a) determine, in its sole discretion, the need for any Clinical Studies for the Combined System Implementations to the extent necessary or reasonably useful to obtain or maintain Regulatory Approval for such Combined System Implementations, and (b) to conduct, support or sponsor such Clinical Studies, provided that, in each instance in which Tandem conducts or is the sponsor (from a regulatory perspective) of any such Clinical Trial, [***]. Tandem shall keep DexCom reasonably informed of Clinical Studies conducted, supported or sponsored by Tandem through regular updates to the JSC, which updates shall (i) address the nature, anticipated timing and progress with each such Clinical Study, and (ii) identify any and all contract research organizations engaged by or on behalf of Tandem to provide services in connection with such Clinical Study, and with respect to any Clinical Study sponsored by Tandem, Tandem shall consider in good faith any input timely received from DexCom. Without limiting the foregoing, Tandem shall [***]. Upon request, DexCom will (i) provide reasonable assistance and reasonably cooperate with Tandem to [***], and (ii) [***]. Notwithstanding anything to the contrary contained in this Agreement or any other Transaction Agreements, any and all non-public information provided by DexCom to Tandem relating to (A) [***] or (B) the [***] constitute Confidential Information and trade secrets of DexCom, and shall be subject to the provisions of Section 6.

2.11.2 In no event shall a Party conduct any Clinical Studies that [***].

2.11.3 For clarity, nothing in this Agreement or the Commercialization Agreement shall prevent Tandem, as the sponsor of a Clinical Study hereunder, from undertaking in good faith any exigent action that it reasonably believes it is required to undertake as such sponsor to protect the safety of study subjects, to protect the integrity of study data or to comply with Applicable Laws.

2.12 Version Support. Beginning on the date of the first Regulatory Approval of each Combined System Implementation, each Party agrees, for the Term, to use Commercially Reasonable Efforts to conduct and support continuous development of such Combined System Implementation with respect to any Minor Release or Major Release of its System or component thereof, as set forth herein.

2.13 DexCom Discontinuation. Notwithstanding Section 2.12, DexCom may, in its sole discretion, (i) discontinue its support of the then-current DexCom CGM Device (a) in [***] any time commencing [***] subsequent to [***], or (b) in [***] any time commencing [***] subsequent to [***] and (ii) discontinue its support of features of its then current DexCom CGM Device [***] at any time commencing [***] after [***].

## 3. INTELLECTUAL PROPERTY OWNERSHIP AND LICENSES

3.1 Intellectual Property Ownership.

3.1.1 Except as set forth in Section 3.2 or as otherwise expressly set forth in herein, this Agreement does not comprise an assignment or license of any Intellectual Property by either Party to the other.

3.1.2 As between the Parties, DexCom (and/or its Affiliates) will solely own and retain all rights, title and interest to any Intellectual Property owned or controlled by DexCom (and/or its Affiliates) as of the Effective Date or developed or acquired by DexCom (and/or its Affiliates) during the Term independently from this Agreement and the Commercialization Agreement or developed solely by or on behalf of DexCom (and/or its Affiliates) pursuant to this Agreement or the Commercialization Agreement, including for clarity any such Intellectual Property related to the Communication Protocol. As between the Parties, Tandem (and/or its Affiliates) will own and retain all rights, title and interest to any Intellectual Property owned or controlled by Tandem (and/or its Affiliates) as of the Effective Date or developed or acquired by Tandem (and/or its Affiliates) during the Term independently from this Agreement and the Commercialization Agreement or solely developed by or on behalf of Tandem (and/or its Affiliates) pursuant to this Agreement or the Commercialization Agreement, including for clarity any such Intellectual Property related to the Tandem Partner CID or any Tandem Development Tool. This Agreement does not amend or modify the terms of the License Agreement between TypeZero Technologies LLC and Tandem dated July 14, 2016, as amended (the "**TypeZero License Agreement**").

3.1.3 The Parties do not intend for there to be any "joint inventions" under this Agreement. Notwithstanding the foregoing, to the extent any Intellectual Property is developed by employees or contractors of DexCom or its Affiliates jointly with employees or contractor of Tandem or its Affiliates in the course of their performance under this Agreement or the Commercialization Agreement, (i) such Intellectual Property shall be deemed to be both Parties' Confidential Information, such that each Party shall be deemed to be a Receiving Party with respect thereto; (ii) the Parties will jointly own such Intellectual Property, and each Party shall have the right to exploit such jointly owned Intellectual Property and freely grant licenses to Affiliates or Third Parties under its interest therein without the consent of or accounting to, the other Party, subject to Section 6; and (iii) at either Party's request, the Parties shall discuss in good faith whether and where to file any patent applications covering such jointly owned Intellectual Property.

3.2 DexCom Granted Licenses in Intellectual Property.

3.3.1 License Grant. Subject to the terms and conditions in this Agreement and any other applicable Transaction Agreement, DexCom hereby grants Tandem a [***] non-exclusive license to use the Communication Protocol solely for the purpose of developing and commercializing a DexCom CGM-Enabled Tandem Display Device, including the right to make, have made, use, sell, offer to sell, have sold and import the DexCom CGM-Enabled Tandem Display Device.

3.3.2 Limitations on Use. Tandem agrees not to distribute, license, sublicense or otherwise transfer the Communication Protocol to any Third Party other than, subject to Section 10.2, subcontractors that have entered into written agreements (or are otherwise subject to legally enforceable obligations) (i) whereby all ownership rights in any Intellectual Property made or developed through such distribution, license, sublicense or transfer will be duly vested in Tandem (or its Affiliate); and (ii) containing obligations of nonuse and nondisclosure of Confidential Information consistent with the terms of this Agreement. Tandem shall have no right under this Agreement to intercept, propagate, reverse engineer, disassemble, de-encrypt, or derive the source code for the software or bios included in any DexCom System, or any proprietary component thereof. Tandem is not granted any right to raw sensor data received or generated by any DexCom System and/or used by the DexCom System to produce the DexCom CGM Data or any other output beyond the data made available through the Communication Protocol, and will not try to derive, de-encrypt or intercept any of such data. Tandem shall not access or use any information within the DexCom System other than as set forth in this Agreement.

3.3.3 Tandem Granted Licenses in Intellectual Property.

3.1 License Grant. Subject to the terms and conditions in this Agreement and any other applicable Transaction Agreement, Tandem hereby grants DexCom a [***] non-exclusive license to use the Tandem Partner CID Documentation, Tandem Partner CID and Tandem Development Tools solely for the purpose of accessing Tandem Insulin Data in accordance with the Combined System Implementations contemplated by the Development Plan.

3.2 Limitations on Use. DexCom agrees not to distribute, license, sublicense or otherwise transfer the Tandem Partner CID Documentation, Tandem Partner CID or any Tandem Development Tool to any Third Party other than, Subject to Section 10.2, subcontractors that have entered into written agreements (or are otherwise subject to legally enforceable obligations) (i) whereby all ownership rights in any Intellectual Property made or developed through such distribution, license, sublicense or transfer will be duly vested in DexCom (or its Affiliate); and (ii) containing obligations of nonuse and nondisclosure of Confidential Information consistent with the terms of this Agreement. DexCom shall have no right under this Agreement to intercept, propagate, reverse engineer, disassemble, de-encrypt, or derive the source code for the software or bios included in any Tandem System, or any proprietary component thereof. DexCom is not granted any right to any data within the Tandem System beyond the data made available through the Tandem Partner CID, and will not try to derive, de-encrypt or intercept any of such data. DexCom shall not access or use any information within the Tandem System other than as set forth in this Agreement.

3.4 Agreements with Representatives. Each Party shall ensure that each Representative involved in any way with the development of the Combined System Implementations, including such Party's Alliance Manager and appointed members of the Joint Steering Committee and the Development Working Group, shall have entered into written agreements (or are otherwise subject to legally enforceable obligations) (i) whereby all ownership rights in any Intellectual Property made or developed by them under the Development Plan will be duly vested in such Party (or its Affiliate); and (ii) containing obligations of nonuse and nondisclosure of Confidential Information consistent with the terms of this Agreement.

3.5 Representations Regarding Licensed Intellectual Property. DexCom represents and warrants to Tandem that DexCom has the right to provide the Communication Protocol to Tandem for Tandem's use in accordance with the terms of this Agreement. Tandem represents and warrants to DexCom that Tandem has the right to provide the Tandem Partner CID, Tandem Partner CID Documentation, and Tandem Development Tools to DexCom for DexCom's use in accordance with the terms of this Agreement. Except as otherwise provided in this Agreement, all rights granted under this Section 3 are granted "as is" with no representations or warranties made regarding the validity, utility or performance of any Intellectual Property licensed hereunder.

3.6 All Rights Retained. Except as expressly set forth in this Agreement and any other applicable Transaction Agreement, neither Party grants to the other Party under this Agreement or any other applicable Transaction Agreement any rights or license in or to any Intellectual Property owned or controlled by such Party or any of its Affiliates, whether by implication, estoppel, or otherwise.

## 4. REGULATORY MATTERS

4.1 Tandem's Testing and Regulatory Responsibilities.

4.1.1 Tandem will be responsible for performing and leading all regulatory testing and related tasks, including all Clinical Studies and all regulatory filings, for Combined System Implementations, including, as applicable the Tandem Diabetes Management Apps, but excluding DexCom CGM Apps, including all necessary related translations and all Clinical Studies required for all Regulatory Approvals.

4.1.2 To the extent permitted by Applicable Laws and by the applicable Regulatory Authority, Tandem will, in the exercise of its commercially reasonable, good faith judgement and in a timely manner (and in any event with at least [***] [***] except where not reasonably feasible), [***] [***] with relevant Regulatory Authorities as necessary to support Regulatory Approval of the Combined System Implementations that are specific to [***] ("**Relevant Tandem Regulatory Meetings**"). At the request of Tandem, DexCom shall [***]. Where reasonably feasible with the Regulatory Authority, Tandem shall [***] reasonably in advance of such Relevant Tandem Regulatory Meeting. Tandem will endeavor to [***]. Furthermore, in any meeting or teleconference with Regulatory Authorities (or portion thereof) that [***], Tandem shall (i) [***], and (ii) promptly (and in any event within [five (5) days])

following the Relevant Tandem Regulatory Meeting, (a) [***] and (b) [***], to the extent pertaining to [***]. As soon as practicable following [***], the Parties shall [***].

4.2 DexCom's Testing and Regulatory Responsibilities.

4.2.1 DexCom will be responsible for performing and leading all regulatory testing and related tasks for the DexCom CGM Devices, and the DexCom CGM App, including all necessary related translations, and for the avoidance of doubt, the DexCom System.

4.2.2 DexCom will designate personnel to provide reasonable support for Tandem in testing of the Combined System Implementations as related to performance of the DexCom CGM Devices and the DexCom CGM App.

4.2.3 Without limiting Section 4.1.2, upon Tandem's request, DexCom will participate in joint meetings with Tandem with relevant Regulatory Authorities as reasonably necessary to support Regulatory Approval of Combined System Implementations, including, as applicable the Tandem Diabetes Management Apps, but excluding DexCom CGM Apps.

4.2.4 To the extent permitted by Applicable Laws and by the applicable Regulatory Authority, DexCom will, in the exercise of its commercially reasonable, good faith judgement and in a timely manner (and in any event with at least [***] prior notice to Tandem except where not reasonably feasible), [***] any and all meetings and teleconferences with DexCom with relevant Regulatory Authorities as necessary to support Regulatory Approval of the Combined Systems that are specific to [***] ("**Relevant DexCom Regulatory Meetings**"). At the request of DexCom, Tandem shall [***]. Where reasonably feasible with the Regulatory Authority, DexCom shall [***] reasonably in advance of such Relevant DexCom Regulatory Meeting. DexCom will endeavor to [***]. Furthermore, in any meeting or teleconference with Regulatory Authorities (or portion thereof) that [***], DexCom shall (i) [***], and (ii) promptly (and in any event within [***]) following the Relevant DexCom Regulatory Meeting, (a) [***] and (b) [***], to the extent pertaining to [***]. As soon as practicable following [***], the Parties shall [***].

4.3 Right to Reference. Each Party hereby has the right to cross reference, refer to, rely on, file, incorporate by reference, or otherwise use any regulatory submission or drug master file Controlled by the other Party or its Affiliates (and any data contained therein) for the Combined System Implementations or any component thereof, made in any country in the Agreed Markets (including all Regulatory Approvals); provided, that (i) Tandem's right to cross-reference, refer to, rely on, file, incorporate by reference or otherwise use shall be limited to doing so in order to support regulatory submissions that Tandem makes under this Agreement or any other Transaction Agreement for the Combined System Implementations in the Agreed Markets and to enable Tandem to fulfill its obligations, or exercise its rights, under this Agreement or any other Transaction Agreement to develop and/or to commercialize the Combined System Implementations in the Agreed Markets, including doing so in order to conduct, support or sponsor Clinical Studies utilizing such DexCom CGM-Enabled Tandem Display Device, and (ii) DexCom's right to cross-reference, refer to, rely on, file, incorporate by

reference or otherwise use shall be limited to doing so in order to support regulatory submissions that DexCom makes under this Agreement or any other Transaction Agreement for the DexCom System for use with the Combined System Implementations in the Agreed Markets. Each Party hereby agrees to promptly provide or have provided to the applicable Regulatory Authorities and/or the other Party or its designee a letter of consent to permit such referencing. In any case in which the Regulatory Authority for the applicable jurisdiction requires a Party to have copies of such filings in order to exercise its rights or perform its obligations hereunder, the other Party shall provide such copies to such requesting Party (provided that the requesting Party shall be responsible for any translation costs in connection therewith).

4.4 Regulatory Obligations and Expenses. In connection with obtaining or maintaining Regulatory Approvals, interacting with Regulatory Authorities, filing or maintaining Regulatory Documentation, or maintaining regulatory records (in each case in relation to its System or the Combined System Implementations), unless required to comply with Applicable Laws, in no instance shall either Party take any action or omit to take any action that, directly or indirectly, would be reasonably likely to result in the other Party incurring (i) additional responsibilities to Regulatory Authorities or otherwise under Applicable Laws that are not listed or described in the Development Plan or Commercialization Plan, or (ii) additional internal or out-of-pocket expenses (including expenses related to additional reporting obligations) that are not listed or described in the Development Plan or Commercialization Plan, in each case without prior written consent of such other Party; provided, that the foregoing shall not limit either Party's right to make any Minor Release or Major Release of its System or component thereof.

## 5. REPRESENTATIONS AND WARRANTIES

5.1 Each Party hereby represents, warrants and covenants, as applicable, to the other Party that:

i. it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation;

ii. it is duly authorized to execute and deliver this Agreement, the person or persons executing this Agreement on its behalf have been duly authorized to do so by all requisite corporate action, and this Agreement is legally binding upon it and enforceable in accordance with its terms;

iii. it has full corporate right, power and authority to perform its respective obligations under this Agreement, including the right to grant the rights and licenses granted to the other Party hereunder;

iv. it will obtain and maintain all licenses, permits and other authorizations necessary to perform its obligations hereunder, and will fully cooperate in obtaining and maintaining any approvals from Regulatory Authorities necessary to implement this Agreement;

v. it will perform its obligations hereunder in compliance with all Applicable Laws, and it has in place a compliance program and internal policies and procedures for its employees and agents to comply with Applicable Laws (including Anti-Corruption Laws and Privacy Laws) as contemplated by Section 6, including training on such policies and procedures and reporting obligations for non-compliance.

vi. it has not been:

A. Debarred by the United States Food and Drug Administration under any provision of the Generic Drug Enforcement Act; or

B. Excluded by the Office of the Inspector General of the United States Department of Health and Human Services, or by any other authority, from participating in any health care program (such as Medicare or Medicaid) funded by any Governmental Authority.

Each Party agrees that no person who has been debarred or excluded as described above will furnish any of the services or deliverables or perform any obligations on behalf of such Party under this Agreement. Neither Party shall subcontract any performance of this Agreement to any Party that is on the specialty designated nationals and blocked persons list maintained by the United States Department of the Treasury Office of Foreign Assets Control (available via http://www.ustreas.gov/offices/enforcement/ofac/ as of the Effective Date) or to any Party who is located in or has its principal place of business in a country subject to economic sanctions maintained by the United States Department of the Treasury Office of Foreign Assets Control. Each Party will promptly notify the other Party in writing (with a copy to legal counsel) of any formal actions taken or pending, of which the Party has knowledge, that could reasonably be construed to threaten or to confirm a debarment or exclusion of any person on the lists specified in Section 5.1(vi)(A) or (B).

5.2 Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 5 OR ELSEWHERE IN THIS AGREEMENT, NEITHER TANDEM NOR DEXCOM MAKES ANY REPRESENTATIONS OR WARRANTIES UNDER THIS AGREEMENT, AND EXPRESSLY DISCLAIMS ANY WARRANTIES WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR NON-INFRINGEMENT.

## 6. CONFIDENTIALITY

6.1 Confidential Information. Except as expressly provided in this Agreement or any other Transaction Agreement, during the Term and for [***], except with respect to Confidential Information constituting trade secrets (to the extent identified by the Disclosing Party in writing or to the extent reasonably identifiable as a trade secret based on the nature and content of the disclosure), which such obligations shall not expire, the Party receiving Confidential Information from the Disclosing Party (the "**Receiving Party**") will not publish or otherwise disclose and will not use such Confidential Information for any purpose other than

carrying out Receiving Party's obligations and exercising its rights under this Agreement and any other Transaction Agreement. For purposes of this Agreement, "**Confidential Information**" means any information furnished by or on behalf of a Party (the "**Disclosing Party**") in connection with this Agreement or any other Transaction Agreement (including in connection with the negotiation thereof) or either of the Legacy Development Agreements which is confidential or proprietary to the Disclosing Party, including research and development plans and results; processes; evaluation procedures (including clinical and field testing); manufacturing methods; applications to government authorities; pricing or cost information; construction plans; sales, marketing, and advertising studies and plans; customer lists; computer information and software; special techniques unique to a Party's business; information subject to a right of privacy in favor of a Third Party; information the Disclosing Party maintains under a system of protection against unauthorized access; and, subject to the rights and obligations with respect to disclosure and use thereof contained in the Transaction Agreements (including any rights that users have therein), DexCom CGM Data and Tandem Insulin Data. Notwithstanding the foregoing, the Disclosing Party's Confidential Information will not include information that the Receiving Party can demonstrate with competent evidence:

6.1.1 was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

6.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

6.1.3 became generally available to the public or otherwise part of the public domain after its disclosure hereunder and other than through any act or omission of the Receiving Party in breach of this Agreement; or

6.1.4 was subsequently lawfully disclosed to the Receiving Party by a person without breaching a duty of confidentiality or developed by or for the Receiving Party without use of, reliance on, or reference to any Confidential Information of the Disclosing Party.

6.2 Permitted Disclosures. Notwithstanding Section 6.1, a Receiving Party may use or disclose the Disclosing Party's Confidential Information solely to the extent such use or disclosure is reasonably necessary in complying with an order of a court of law, prosecuting or defending litigation, complying with applicable governmental regulations, submitting information to tax or other Governmental Authorities, or conducting Clinical Studies; provided that, subject to Section 6.5, if a Receiving Party is required to make any such disclosure of Confidential Information, it will give the other Party reasonable advanced notice of the disclosure, and use its reasonable efforts to secure confidential treatment of the information prior to its disclosure (whether through protective orders or otherwise).

6.3 Unauthorized Disclosure of Confidential Information. If a Party becomes aware of an unauthorized disclosure of the other Party's Confidential Information, then such Party shall notify the other Party promptly in writing.

6.4 Return of Confidential Information. Following any expiration or termination of this Agreement and all other Transaction Agreements, within [***] after receipt of the Disclosing Party's written request, the Receiving Party will return to the Disclosing Party (where practicable), or, at the Receiving Party's option, destroy and provide written certification of the destruction of, all tangible materials that contain the Disclosing Party's Confidential Information, other than such Confidential Information to which the Receiving Party retains a right to use under this Agreement or any other Transaction Agreement. Notwithstanding the foregoing, (i) the Receiving Party may retain one copy of the Disclosing Party's Confidential Information in the legal files of the Receiving Party for the sole purpose of determining the scope of obligations incurred under this Agreement or as otherwise required by Applicable Laws; (ii) the Receiving Party may retain any electronic copies of the Disclosing Party's Confidential Information held securely in the Receiving Party's electronic backup storage in accordance with its established document retention policies and (iii) the Receiving Party may retain the Disclosing Party's Confidential Information to the extent included in the Receiving Party's board of director or board committee materials or minutes or actions, quality systems, or regulatory history; subject in each case to the Receiving Party's continuing confidentiality and non-use obligations under this Agreement with respect to such Confidential Information.

6.5 Confidentiality Terms; Confidentiality of Agreement; Press Releases.

6.5.1 Except as explicitly permitted under this Section 6.5 or any other Transaction Agreement, neither Party will disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of this Agreement and any other Transaction Agreement: (i) on a confidential basis to its Representatives, members of the Party's board of directors in their capacity as such, to advisors (including financial advisors, attorneys and accountants), existing or potential investors (provided that such investors are not [***]) and others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement, providing that such Party shall be responsible for any disclosure of information by any of the persons referred to in the preceding sentence in contravention of the terms of this Agreement; or (ii) to the extent necessary to comply with Applicable Laws; provided that the Disclosing Party shall promptly notify the other Party (other than in the case where such disclosure is necessary, in the reasonable opinion of the Disclosing Party's legal counsel, to comply with Applicable Laws) and allow the other Party a reasonable opportunity to oppose with the Governmental Authority initiating the process and, to the extent allowable by Applicable Laws, to seek limitations on the portion of the Agreement that is required to be disclosed.

6.5.2 The Parties shall not issue a press release disclosing the existence of this Agreement or any other Transaction Agreement, any specific term hereof, or any specific transaction contemplated herein unless required by Applicable Laws or as agreed in writing by the Parties. Where such a press release or other public disclosure is so required, no Party shall issue a press release without first giving the other Party reasonable opportunity to review and approve the proposed public disclosure or press release, such approval not to be unreasonably withheld, delayed or conditioned. For clarity, no such review and approval shall be required for any public disclosure or press release that restates information that has been previously approved

for public disclosure or that is otherwise in the public domain without a breach of this Agreement or any Transaction Agreement, provided that such information remains accurate in all material respects.

6.6 Records. At its own expense, each Party will create and maintain and provide access to upon reasonable request all records that relate to this Agreement and to a Party's performance under this Agreement (i) to the extent required by this Agreement and Applicable Laws, (ii) sufficient to demonstrate that any and all amounts invoiced to a Party under this Agreement are accurate and proper in both kind and amount; (iii) sufficient to demonstrate the accuracy of reports submitted to either Party under this Agreement; and (iv) sufficient to enable a Party to comply with Applicable Laws and other legal obligations, to the extent that such Party has or reasonably should have knowledge of those Applicable Laws and other legal obligations. Each of the Parties will maintain all such records for the longer of (a) any period prescribed by Applicable Laws or stated expressly in this Agreement, (b) [***] after the term of this Agreement.

6.7 Publication. If a Party desires to publish or present, whether in writing or by oral presentation, any methods, findings, results, or other matters arising out of the Development Plan that relate specifically to the non-publishing Party's System or include the non-publishing Party's Confidential Information (a "**Publication**"), such Party shall provide the non-publishing Party with [***]. The non-publishing Party will have the right during such [***] period to [***]. If such non-publishing Party does not provide any comments during such period, it shall be [***]. In addition, the Publication may be delayed at the non-publishing Party's written request received during such period for an additional period of up to an additional [***] if it contains [***]. For clarity, this Section 6.7 shall not apply to any further disclosure of Results that have been previously publicly disclosed pursuant to this Section 6.7, provided that further disclosure remains accurate in all material respects.

6.8 Personal Data; DexCom CGM Data and Tandem Insulin Data. To the extent any Personal Data, DexCom CGM Data and/or Tandem Insulin Data is collected, received or shared by a Party or its Affiliates with or from the other Party or its Affiliates in connection with activities contemplated by this Agreement, the use of such data shall be governed solely by Section 8 of the Commercialization Agreement (and not this Section 6).

## 7. INDEMNIFICATION AND DEFENSE OF INFRINGEMENT

7.1 DexCom will defend and indemnify Tandem, its Affiliates, and each of their respective directors, officers, employees, agents, successors and assigns (collectively, "**Tandem Indemnitees**"), against all Third Party claims, suits and proceedings, and will hold the Tandem Indemnitees harmless against all judgments, settlements, costs, liabilities and expenses (including reasonable attorneys' fees and litigation costs) (collectively, "**Losses**") payable to Third Parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) DexCom's breach of its [***] under this Agreement, (ii) the [***], (iii) the [***], or (iv) physical injury (including death) and/or property damage [***].

7.2 Tandem will defend and indemnify DexCom, its Affiliates, and each of their respective directors, officers, employees, agents, successors and assigns (collectively, "**DexCom Indemnitees**"), against all Third Party claims, suits and proceedings, and will hold the DexCom Indemnitees harmless against all Losses payable to Third Parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) Tandem's breach of its [***] under this Agreement, (ii) [***], (iii) the [***], (iv) physical injury (including death) and/or property damage [***].

7.3 If the manufacture or use of the Combined System Implementations results in a claim, suit or proceeding in which DexCom and Tandem are both entitled to indemnification by the other Party pursuant to Sections 7.1 and 7.2, then the Parties will discuss in good faith their cooperation in connection with such matter, and shall [***].

7.4 If the manufacture or use of the Combined System Implementations results in a Third Party claim, suit, allegation, action or proceeding against Tandem or DexCom alleging infringement or misappropriation of the Intellectual Property of such Third Party and neither DexCom nor Tandem is entitled to indemnification pursuant to Sections 7.1 and 7.2 (a "**Combined System Infringement Action**"), such Party will promptly notify the other Party in writing. The Parties will [***] in connection with the Combined System Infringement Action and shall [***] of any Combined System Infringement Action. The Parties will [***] concerning any Combined System Infringement Action and, in the [***] that the [***], the Parties will [***].

7.5 At either Party's request, the Parties shall promptly enter into a common-interest agreement to protect any available attorney-client privileges and the like, on reasonable and customary terms.

7.6 A Party seeking indemnification hereunder (the "**Indemnitee**") will promptly notify the indemnifying Party (the "**Indemnitor**") of any claim, suit, proceeding, loss, or expense likely to lead to a claim for indemnification, along with all material related information in the Indemnitee's possession. The Indemnitor will have the right to manage the defense and settlement of any claim, except that [***]. The Indemnitee may not enter into any settlement of any such claim without the prior written consent of Indemnitor. The Indemnitee will [***]. The Indemnitee may [***]. In addition, the Indemnitee may [***].

7.7 Notwithstanding the foregoing in this Section 7, an Indemnitor under this Section 7 has no obligation for any Losses to the extent resulting from (i) [***], or (ii) [***].

7.8 In the event of any actual or alleged infringement of a valid claim of a patent or the actual or alleged infringement or misappropriation of any Third Party Intellectual Property by the Tandem System (or components thereof, including any DexCom CGM-Enabled Tandem Display Device, but excluding any Communication Protocol provided by DexCom), (a) Tandem shall have the right to [***] to render such Tandem System non-infringing or to be no longer misappropriating such Third Party Intellectual Property and (b) if Tandem cannot reasonably modify the Tandem System to be non-infringing or to no longer be misappropriating

such Third Party Intellectual Property, Tandem shall have the right to terminate this Agreement upon [***] written notice to DexCom.

7.9 In the event of any actual or alleged infringement of a valid claim of a patent or the actual or alleged infringement or misappropriation of any Third Party Intellectual Property by the DexCom System (or components thereof), (a) DexCom shall have the right to modify the DexCom System (including any components thereof) to render such DexCom System non-infringing or to be no longer misappropriating such Third Party Intellectual Property] and (b) if[DexCom cannot reasonably modify the DexCom System to be non-infringing or to no longer be misappropriating such Third Party Intellectual Property], DexCom shall have the right to terminate this Agreement upon [***] written notice to Tandem.

7.10 In the event that either Party is entitled to indemnification of any Third Party claim, suit or proceeding under both this Agreement and the Commercialization Agreement or the [***], then such Party shall only be entitled to seek indemnification for such claim, suit or proceeding (and only entitled to recover for a particular Loss) [***] under either this Agreement or the Commercialization Agreement or the [***] and in no event shall such Party be permitted to seek indemnification for such claim, suit or proceeding (or recover for any particular Loss) under both this Agreement and the Commercialization Agreement or under both this Agreement and the [***].

## 8. TERM AND TERMINATION

8.1 Term. The term of this Agreement will begin on the Effective Date and continue in effect for as long as the Commercialization Agreement continues in effect, unless this Agreement is terminated earlier pursuant to the other provisions of this Agreement (the "**Term**").

8.2 Termination for Material Breach.

8.2.1 Either Party (the "**Notifying Party**") shall be entitled to terminate this Agreement upon written notice to the other Party if such other Party materially breaches this Agreement and fails to cure such breach [***] following written notice from the Notifying Party specifying such breach in reasonable detail.

8.2.2 Notwithstanding the foregoing, if the allegedly breaching Party in good faith disputes such material breach or the failure to cure such material breach, then such Party shall provide the Notifying Party written notice of that dispute putting forward in reasonable detail the rationale for disputing the alleged breach or failure to cure to the Notifying Party. In such event, the Parties shall promptly undertake good faith efforts to resolve such dispute, in which case, such termination shall not be effective until [***] after the resolution as to whether such material breach has occurred (and, if it is determined that there was a material breach that remains uncured at the expiration of such [***]); provided, that, during the pendency of any such dispute resolution the Parties shall continue performing their respective obligations, and exercising their respective rights, under this Agreement. The Parties hereby agree to take such steps as may be reasonably necessary to complete such dispute resolution as expeditiously as possible given the circumstances.

8.3 Termination Without Cause. Either Party may terminate this Agreement at any time with [***] written notice to the other Party.

8.4 Termination for Change of Control. Each Party shall provide to the other Party written notice within the later of [***] after or as soon as permitted under Applicable Laws after undergoing a Change of Control. If such Change of Control is [***], then such other Party shall have the right (but not the obligation) to terminate this Agreement upon [***] prior written notice, provided that such notice is given within [***] following such other Party's receipt of the notice of such Change of Control. [***].

8.5 [***] If a Party [***] asserting that [***] then the [***] may, [***]. Notwithstanding the foregoing, the [***] shall not have the right to [***] to the extent [***].

8.6 Effect of Termination.

8.6.1 General. In the case of expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall cease immediately, unless otherwise stated in this Agreement.

8.6.2 Accrued Rights and Obligations. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accrued prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

8.6.3 Post-Termination Support. Upon any expiration or termination of this Agreement, the Parties will ensure continued provision of support services to the then-current customers for the applicable System, as set forth in the then-current warranty terms covering such System (or such longer period as may be required under Applicable Laws) (hereinafter the "**Termination Support Services**"). If required to perform the Termination Support Services, the license grants set forth in Section 3.2.1 and 3.2.2 relating to the Communication Protocol and the license grants set forth Sections 3.3.1 and 3.3.2 relating to the use of the Tandem Partner CID Documentation, Tandem Partner CID and Tandem Development Tools shall continue for the length of the Termination Support Services and shall be subject to the restrictions set forth therein, provided that upon any expiration or termination of this Agreement, the license grants set forth in Section 3.2.1 and 3.2.2 relating to the Communication Protocol and the license grants set forth Sections 3.3.1 and 3.3.2 relating to the use of the Tandem Partner CID Documentation, Tandem Partner CID and Tandem Development Tools will immediately and automatically be limited to the extent necessary to support the units of the Combined Systems for such then-current customers.

8.6.4 Survival. In addition, Sections 1, 3.1, 5.2, 6, 7, 8.6, 9 and 10, and the third sentence of Section 2.11.1 (but solely to the extent any relevant data results from such Clinical Studies commenced or initiated during the Term of this Agreement), will survive expiration or termination of this Agreement, provided that, in the event any Section identified

above expressly sets forth a limited period of time with respect to the duration or survival of such right or obligation beyond the expiration or termination of this Agreement, then such right or obligation shall survive only for such expressly identified period of time.

**9. LIMITATION OF LIABILITY**

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OTHER PERSON OR ENTITY FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, LOST PROFITS, OR ANY OTHER SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE. THESE LIMITATIONS SHALL APPLY WHETHER OR NOT THE BREACHING PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN. IF EITHER PARTY TERMINATES THIS AGREEMENT IN ACCORDANCE WITH ANY OF ITS PROVISIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER, BECAUSE OF SUCH TERMINATION, FOR COMPENSATION, REIMBURSEMENT OR DAMAGES ON ACCOUNT OF THE LOSS OF PROSPECTIVE PROFITS OR ANTICIPATED SALES OR ON ACCOUNT OF EXPENDITURES, INVENTORY, INVESTMENTS, LEASES OR COMMITMENTS IN CONNECTION WITH THE BUSINESS OR GOODWILL OF TANDEM OR DEXCOM.

THE FOREGOING EXCLUSION OF CERTAIN DAMAGES IN THIS SECTION DOES NOT APPLY TO DAMAGES FOR ANY OF THE FOLLOWING:

(I) BREACH OF AN OBLIGATION OF CONFIDENTIALITY UNDER SECTION 6 OR MISAPPROPRIATION OF INTELLECTUAL PROPERTY OR TRADE SECRETS; OR

(II) INDEMNIFICATION OBLIGATIONS UNDER SECTION 7, INCLUDING INDEMNIFICATION OBLIGATIONS UNDER SECTION 7 RELATED TO INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

**10. MISCELLANEOUS**

10.1 No Exclusivity. This Agreement shall be non-exclusive for both Tandem and DexCom, and, subject to compliance with the terms and conditions of this Agreement, shall in no way prohibit either Party from working with any Third Party, including other insulin pump or CGM and/or data management companies, or acquiring, licensing, designing, developing, marketing, selling and/or distributing products that compete, directly or indirectly, with the products contemplated by this Agreement. Each Party further acknowledges that the personnel assigned to the activities contemplated by this Agreement may also participate in other activities that may utilize technologies similar to or involve products competitive with those contemplated by this Agreement.

10.2 Subcontractors. Subject to the terms and conditions of this Agreement, either Party may subcontract the performance of its obligations under this Agreement to a Third Party [***], provided that (i) such subcontractor is bound by terms and conditions consistent, in all relevant respects, with this Agreement, including restrictions with respect to the protection and use of Confidential Information which are no less stringent than those set forth in this Agreement; (ii) such Party hereby expressly waives any requirement that the other Party exhaust any right or remedy (or otherwise proceed) against any such subcontractor for any obligation or performance hereunder prior to proceeding directly against such Party; and (iii) each Party shall be fully responsible for the performance of its subcontractors.

10.3 Contract Interpretation. The meaning of a provision of this Agreement will be considered in context with other provisions of the Agreement. The following principles apply to the construction of this Agreement unless the construction is plainly contrary to the intent of the Parties:

10.1 "Including" means "including but not limited to."

10.2 "Or" means "and/or."

10.3 "Will" and "shall" have the same meaning.

10.4 Language that has a generally prevailing meaning is given that meaning unless the Agreement expressly assigns a different one.

10.5 Technical terms used in the technical field of the subject of the Agreement are given their technical meaning.

10.6 Singular words may be treated as plural, and plural words may be treated as singular.

10.7 The masculine gender may be treated as feminine, and the feminine gender may be treated as masculine.

10.8 In computing any period of time under this Agreement, the day of the act, event, or default from which the designated period of time begins to run is not included. If the Agreement specifies that a period is to run for a certain number of business days, only business days are included in the count, and the period may not end on any day that is not a business day.

10.4 Force Majeure. Nonperformance of any Party will be excused to the extent that performance is prevented or delayed by strike, fire, earthquake, flood, governmental acts or orders or restrictions (other than due to a failure to comply with Applicable Laws), epidemic, pandemic, or any other reason where failure to perform is beyond the reasonable control of the nonperforming Party.

10.5 No Implied Waivers; Rights Cumulative. No failure on the part of DexCom or Tandem to exercise and no delay in exercising any right under this Agreement, or

provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, nor will any partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right.

10.6 Independent Contractors. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute DexCom or Tandem as partners in the legal sense. No Party hereto will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

10.7 Notices. All notices, requests and other communications hereunder will be in writing and will be personally delivered or sent by registered or certified mail, return receipt requested, postage prepaid, or via email (with delivery or receipt confirmation), in each case to the respective address specified below, or such other address as may be specified in writing to the other Parties hereto:

Tandem: Tandem Diabetes Care, Inc.
11075 Roselle St.
San Diego, CA 92121
Attn: CEO
[***]

With Copy to: Tandem Diabetes Care, Inc.
11075 Roselle St.
San Diego, CA 92121
Attn: General Counsel
[***]

DexCom: DexCom, Inc.
6340 Sequence Drive
San Diego, California 92121
Attn: Legal Department
[***]

10.8 Assignment. Except as otherwise expressly provided under this Agreement, neither Party may assign or otherwise transfer this Agreement or any right or obligation hereunder without the express prior written consent of the other Party; provided that: either Party shall be permitted to effect such an assignment or other transfer of this Agreement in its entirety, without the written consent of the other Party (i) to any of its then-existing Affiliates, or (ii) in connection with a merger or the transfer or sale of all or substantially all of its business or assets related to this Agreement, or (iii) subject to Section 8.4, in connection with a Change of Control.

10.9 Modifications. No amendment or modification of any provision of this Agreement will be effective unless in writing signed by each Party hereto. No provision of this

Agreement will be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by all Parties. In the event of a conflict between the provisions of the exhibits or the attachments to this Agreement and the provisions of this Agreement itself, the conflicting provision(s) of the Agreement shall control over the language in the exhibit or attachments, unless otherwise agreed by the Parties.

10.10 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

10.11 Governing Law.

10.11.1 This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with the laws of the State of California without regard for conflicts of laws principles. Disputes as to matters within the authority of the Development Working Team will be resolved as set forth in Section 2.3.7; provided that any dispute as to the application of such Section 2.3.7 shall be subject to this Section 10.11.

10.11.2 Notwithstanding any other provision of this Agreement, either Party may seek interim equitable relief in any court of competent jurisdiction in connection with any alleged breach or violation of Section 2.2, Section 6 or Intellectual Property rights.

10.12 Choice of Forum. The Parties hereby submit and consent to the exclusive jurisdiction of any state or federal court located in [***] and irrevocably agree that all actions or proceedings relating to this Agreement shall be litigated in such courts, and each of the Parties waives any objection which it may have based on improper venue or forum non conveniens to the conduct of any such action or proceeding in such court.

10.13 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same instrument.

10.14 Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

10.15 Entire Agreement. This Agreement (including the exhibits attached hereto which are hereby incorporated into this Agreement by reference), together with the Transaction Agreements, constitutes the entire agreement with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, whether written or oral, between DexCom and Tandem with respect to such subject matter. For clarity, (i) the G4 Development Agreement was terminated effective August 10, 2020, (ii) the G5 Development Agreement will terminate effective December 31, 2020 with respect to all countries other than

Australia and will terminate on December 31, 2021 with respect to Australia, (iii) the Original G6 Development Agreement shall remain in full force and effect subject to any amendments thereto and for clarity shall include the amendments in the Commercialization Agreement executed between the parties and (iv) the TypeZero License Agreement shall remain in full force and effect and shall not be amended or modified by this Agreement.

10.16 Performance by Affiliates. Either Party may discharge any obligation and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such first Party without any obligation to first proceed against such Affiliate.

10.17 Standstill.

10.17.1 Except as permitted by the last sentence of this Section 10.17, during the Term of this Agreement and for a period of[twelve (12) months thereafter, without the prior written consent of the Board of Directors of Tandem, DexCom and its officers, directors and Affiliates, will not directly or indirectly in any manner: (i) acquire, announce an intention to acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934 (the "Exchange Act")) or interest in any securities or direct or indirect rights, warrants or options to acquire, or securities convertible into or exchangeable for, any securities of Tandem (ii) make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the SEC promulgated pursuant to Section 14 of the Exchange Act) any securities of Tandem with respect to any business combination, restructuring, recapitalization or similar transaction; (iii) form, join or in any way participate in a "group" within the meaning of Section 13(d)(3) of the Exchange Act with respect to any voting securities of Tandem; (iv) acquire, announce an intention to acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, exchange or otherwise, (a) any of the assets, tangible or intangible, of Tandem or (b) direct or indirect rights, warrants or options to acquire any assets of Tandem, other than in the ordinary course of business; (v) enter into any arrangement or understanding with, or otherwise assist or encourage, others to do any of the actions restricted or prohibited under clauses (i), (ii), (iii) or (iv) of this Section 10.17; (vi) otherwise act in concert with others, to seek to offer to Tandem or any of its stockholders any business combination, restructuring, recapitalization or similar transaction to or with Tandem, or (vii) take any action to control the management, Board of Directors or policies of Tandem. Notwithstanding the above, cumulative acquisitions by DexCom, including any Affiliate of DexCom, of less than one percent (1%) of Tandem's outstanding common shares shall not be deemed a breach of this provision.

10.17.2 The standstill provisions of Section 10.17.1 shall not apply in the event that, without any violation of the standstill provision, (i) a Third Party unrelated to

DexCom shall have entered into a definitive agreement with Tandem to acquire more than 50% of the outstanding common stock of Tandem, or (ii) a Third Party unrelated to DexCom commences a tender offer for more than 50% of the outstanding common stock of Tandem that the board of directors of Tandem recommends. The standstill provisions of Section 10.17.1 shall automatically become applicable again if the Third Party announces its intent not to proceed with the acquisition or commenced tender offer.

10.17.3 DexCom recognizes that, if it fails to perform or breaches any of its obligations under this Section 10.17, any remedy at law may prove to be inadequate relief to Tandem. DexCom therefore agrees that Tandem is entitled to seek temporary and permanent injunctive relief or specific performance in any such case.

**[Signature Page Follows]**

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be signed by duly authorized officers or representatives as of the Effective Date.

**DEXCOM, INC.**
By:_____
Print Name:_____
Title:_____
Date:_____

**TANDEM DIABETES CARE, INC.**
By:_____
Print Name:_____
Title:_____
Date:_____

**Exhibit A: Initial Combined System Architecture DexCom G6®**

[***]

# COMMERCIALIZATION AGREEMENT

This Commercialization Agreement (this "**Agreement**") is made and entered into on November 20, 2020 (the "**Effective Date**") by and between Tandem Diabetes Care, Inc, having a principal place of business at 11075 Roselle St., San Diego, CA 92121 ("**Tandem**") and DexCom, Inc., a Delaware corporation having a principal place of business at 6340 Sequence Drive, San Diego, CA 92121 ("**DexCom**"). Tandem and DexCom may be referred to in this Agreement individually as a "**Party**" and collectively as the "**Parties**".

## RECITALS

A. DexCom is in the business of developing and commercializing continuous glucose monitoring systems;

B. Tandem is in the business of developing and commercializing insulin pump systems;

C. The Parties are entering into a development agreement of even date herewith, to enable the integration of Tandem's t:sport insulin pump with DexCom's G6® CGM device and enable the integration of Tandem's t:slim X2™ and t:sport insulin pumps with DexCom's G7® CGM device (the "**Development Agreement**");

D. The Parties have amended that certain development agreement, dated June 4, 2015, as amended, for the integration of Tandem's t:slim X2™ insulin pump with DexCom's G6® CGM device (the "**On-Market t-slim:G6 Implementation**" and such agreement, the "**Original G6 Development Agreement**" and, together with the Development Agreement, "**Current Development Agreements**"), such that commercialization activities relating to this implementation of the Combined System are governed by the terms of this Agreement;

E. On February 7, 2020, DexCom issued a notice of termination for (i) the development agreement dated January 4, 2013, which addressed the integration of Tandem's insulin pump with DexCom G4® CGM device (the "**G4 Development Agreement**"), which termination became effective August 10, 2020 and (ii) the development agreement dated June 4, 2015, which addressed the integration of Tandem's insulin pump with DexCom G5® CGM device (the "**G5 Development Agreement**" and collectively with the G4 Development Agreement, "**Legacy Development Agreements**"), which the Parties agreed will terminate on December 31, 2020 with respect to all countries other than Australia and will terminate on December 31, 2021 with respect to Australia; and

F. The Parties desire to commercialize the integrated solutions developed under the Current Development Agreements on the terms and conditions set forth herein.

Accordingly, the Parties therefore agree as follows:

## AGREEMENT

## 1. DEFINITIONS

1.1. "**Affiliates**" means any corporation or other entity that is directly or indirectly controlling, controlled by or under common control with a Party. For the purpose of this definition, "control" means: (i) the direct or indirect ownership of more than fifty percent (50%) of the capital stock of the subject entity; (ii) the direct or indirect control of more than fifty percent (50%) of the voting rights of the subject entity; or (iii) the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of the subject entity (whether through ownership of securities or other ownership interests, by contract or otherwise).

1.2. "**Agreed Markets**" means the countries or jurisdictions in which the Combined System will be commercialized in accordance with the Commercialization Plan and specifically including the countries where Tandem is currently commercializing the On-Market t-slim:G6 Implementation, as set forth on **Exhibit A**.

1.3. **"[***]"** means, (a) with respect to DexCom [***] and (b) with respect to Tandem [***].

1.4. "**Alliance Manager**" has the meaning set forth in the Development Agreement.

1.5. "**Anti-Corruption Laws**" means the United States Foreign Corrupt Practices Act, the United States Anti-Kickback Statute, the United Kingdom Bribery Act, and any other laws of a similar nature for the prevention of *inter alia*, fraud, corruption, racketeering, money laundering and terrorism, in each case as may be amended from time to time.

1.6. "**Applicable Laws**" means all applicable laws, rules and regulations, including any rules, regulations, guidance or other requirements of any Regulatory Authority, that may be in effect from time to time and are applicable to a particular activity hereunder, including, as applicable, (i) regulations and guidance documents of the FDA and EMA (and national implementations thereof) and, if and as appropriate under the circumstances, International Conference on Harmonization (ICH) guidance or other comparable regulation and guidance of any applicable Regulatory Authority in the Agreed Markets, (ii) Anti-Corruption Laws, (iii) Privacy Laws, (iv) Transparency Laws, (v) cGCP, (vi) cGDP, and (vii) cGMP.

1.7. "**cGCP**" means all applicable current Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of Clinical Studies, including, as applicable, (a) as set forth in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**") Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Agreed Markets, (b) the Declaration of Helsinki (2004) as last amended at the 52nd World Medical Association in October 2000 and any further amendments or clarifications thereto, (c) U.S. Code of Federal Regulations Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards) and 312 (Investigational New Drug Application), as may be amended from time to time, and (d) the equivalent applicable laws in any relevant country, each as may be amended

and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.8. "**cGDP**" means the then current standards for all good distribution practices relevant to any product hereunder, including, as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, (b) European Directive 2013/C 68/01 and Eudralex 4, (c) WHO TRS 957 Annex 5, (d) USP <1079>, (e) any state or other local laws or regulations governing the licensing of distributors or manufacturers of pharmaceutical products or medical devices, and (f) the equivalent applicable laws in any relevant country, each as may be amended and applicable from time to time.

1.9. "**CGM**" means continuous glucose monitoring.

1.10. "**cGMP**" means the then-current Good Manufacturing Practices that apply to the manufacture (including clinical or commercial supply) of any product hereunder, including, as applicable, (a) the United States regulations set forth under Title 21 of the United States Code of Federal Regulations, parts 4, 210, 211 and 820, (b) applicable guidance published from time-to-time by the FDA, (c) the International Conference on Harmonisation Guidelines ICH Q7A Good Manufacturing Practice Guidance for the principles, guidelines of Good Manufacturing Practices for Medicinal Products as defined with EC Directive 2003/94/EC and associated EC Guide to Good Manufacturing Practice, and (d) the equivalent applicable laws in any relevant country, each as may be amended and applicable from time to time.

1.11. "**Change of Control**" means a transaction or a series of related transactions: (i) in which one or more related parties that did not previously own or control greater than a fifty percent (50%) equity interest in a Party obtains ownership or control of greater than a fifty percent (50%) equity interest in a Party; (ii) as a result of which one or more related parties that did not previously have the right or power to control the management or policies of a Party acquires such right or power; or (iii) in which a Party sells all or substantially all of its assets to a Third Party.

1.12. "**Clinical Study**" means any pre or post approval clinical study involving the administration of and/or use of a Combined System with a human subject, whether conducted before or after Regulatory Approval of a Combined System, including clinical studies to support such Regulatory Approval process or as otherwise required by a Regulatory Authority.

1.13. "**Combined System**" means an integrated technology solution comprised of the DexCom System and the Tandem System that enables [***]. The Parties agree that the integrated technology solution(s) developed by the Parties pursuant to the Legacy Development Agreements, and any improvements thereto, are not Combined Systems hereunder.

1.14. **"Combined System Implementation"** means, as applicable, an implementation of the Combined System, involving the integration of Tandem's t:sport insulin pump with DexCom's G6® CGM device, the integration of Tandem's t:slim X2™ insulin pump with DexCom's G7® CGM device and the integration of Tandem's t:sport insulin pump with

DexCom's G7® CGM device, in each case as developed under the Development Agreement. The Parties agree that the On-Market t-slim:G6 Implementation, including any improvement thereto, is not a Combined System Implementation. The initial architecture of the Combined System Implementation with respect to Tandem's t:sport Insulin Delivery Device and DexCom's G6® CGM Device is described in Exhibit A to the Development Agreement.

1.15. "**Commercially Reasonable Efforts**" means the carrying out of a Party's obligations under this Agreement with the exercise of prudent scientific and business judgment and a level of effort and resources consistent with the efforts and resources that the Party who bears the performance obligation, but in any event at least the level of effort and resources of a similarly-sized comparable Third Party in the CGM or insulin delivery device industry, as applicable, would employ for products of similar strategic importance and commercial value that result from its own research efforts.

1.16. "**Communication Protocol**" means a DexCom communication protocol that permits a DexCom CGM-Enabled Tandem Display Device to identify, receive and display DexCom CGM Data and to control the DexCom CGM Transmitter, which communication protocol will be developed by or on behalf of DexCom under the Development Plan, as may be amended or updated by DexCom from time to time in accordance with the Development Plan.

1.17. "**Compliance**" means the adherence by the Parties in all material respects to all Applicable Laws and Party-Specific Regulations, in each case with respect to the activities to be conducted under this Agreement.

1.18. "**Control**", "**Controls**" **or "Controlled by**" means, with respect to any item of or right under Intellectual Property, the ability of the specified Party or any of its Affiliates, whether through ownership, license or other right (other than pursuant to this Agreement), to grant access to, license or sublicense such item or right without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding the foregoing, Intellectual Property held by a Third Party that is an acquirer in a Change of Control transaction of a Party or by any of such Third Party's Affiliates (such Third Party and Affiliates collectively, the "**Acquirer**") that exists immediately before the consummation of such Change of Control transaction or is or developed or acquired by the Acquirer after such consummation independently of this Agreement shall not be deemed to be Controlled by such Party.

1.19. "**Customer**" means a customer that has purchased a Combined System, or a DexCom CGM Device or Tandem Insulin Delivery Device in connection with a Combined System, whether an end user, a distributor, a payor or a healthcare professional, as applicable.

1.20. "**Development Plan**" has the meaning set forth in the Development Agreement.

1.21. "**DexCom CGM App**" means any software (including any software application) of DexCom or its Affiliates designed to gather DexCom CGM Data in connection with a Combined System, which may include software loaded onto a CGM device, cloud infrastructure, and/or Electronic Health Record (EHR) systems, depending on the configuration of such Combined System, as described in more detail in the Development Plan.

1.22. "**DexCom CGM Data**" means the continuous glucose monitoring data displayed on the receiver or other display device of a DexCom System (in each case solely to the extent such DexCom System is used as part of a Combined System in accordance with this Agreement or the Development Agreement), as set forth in more detail in **Exhibit B**. For clarity, DexCom CGM Data excludes any raw CGM sensor data.

1.23. "**DexCom CGM Device**" means DexCom's CGM devices known as DexCom G6® and DexCom G7®, including any Minor Release thereof.

1.24. "**DexCom CGM-Enabled Tandem Display Device**" means a Tandem Display Device comprising a receiver or other component of the Tandem Insulin Delivery Device configured to identify, Process and/or display DexCom CGM Data from a DexCom CGM Transmitter and control the DexCom CGM Transmitter, as described in more detail in the Development Plan. A DexCom CGM-Enabled Tandem Display Device will be independently developed by Tandem and is not, and will not be, a component of any DexCom System.

1.25. "**DexCom CGM Transmitter**" means the transmitter component of the DexCom System (which may be a standalone DexCom transmitter that operably couples to the DexCom Sensor or an embedded component of a DexCom Sensor) that is configured to transmit DexCom CGM Data from a DexCom Sensor to any receiver adapted to identify, receive, and display such information, and is also controlled from an authenticated receiver and the DexCom CGM App.

1.26. "**DexCom Sensor**" means the component of a DexCom System comprising a continuous glucose monitoring electrode sensor, adapted to (i) penetrate the patient's skin to come into contact with the patient's interstitial fluid, (ii) measure interstitial fluid glucose level, and (iii) be operably coupled to a DexCom CGM Transmitter to communicate the blood glucose value as measured by such sensor, to a separate receiver.

1.27. "**DexCom System**" means a CGM system comprised of a DexCom CGM Device and one or more DexCom CGM Apps, as described in more detail in the Development Plan.

1.28. "**DexCom Trademarks**" means the Trademarks set forth on **Exhibit C** and such other Trademarks as DexCom may designate in writing to Tandem from time to time.

1.29. "**EMA**" means the European Medicines Agency or any successor agency thereto.

1.30. "**EU**" means those countries that are members of the European Union as of the date on which the relevant determination is being made.

1.31. "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.32. "**First Commercial Launch**" means, with respect to each Combined System, the first date that such Combined System is (or was) made available for purchase by any Customer in any Agreed Market following Regulatory Approval in such Agreed Market.

1.33. "**Governmental Authority**" means any (i) international, regional, national, federal, state, or local government entity, authority, agency, instrumentality, court, tribunal, regulatory commission or other body, either foreign or domestic, whether legislative, judicial, administrative or executive; or (ii) arbitrator to whom a dispute has been presented under government rule or by agreement of the Parties with an interest in such dispute.

1.34. "**HIPAA**" means the Health Insurance Portability and Accountability Act of 1996, and the regulations thereunder, as they may be amended from time to time.

1.35. "**HITECH Act**" means the Health Information Technology for Economic and Clinical Health Act, and the regulations thereunder, as they may be amended from time to time.

1.36. "**Intellectual Property**" means (collectively): any copyright, patent or patent application (including any foreign counterparts of any of the foregoing, as well as all continuations, continuations-in-part, divisionals, reissues, reexaminations, and all renewals and extensions thereof, regardless of whether such rights arise under the laws of the United States or any other state, country or jurisdiction), inventions, trade secrets, methods, know-how, technology, information, data and results (including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data and results), software, algorithms, rights of publicity, authors' rights, goodwill and all other intellectual property rights as may exist now and/or hereafter come into existence. Intellectual Property shall include Software and Copyrights, but shall exclude all Trademarks.

1.37. "**Internal Compliance Policies**" means a Party's internal policies and procedures intended to ensure that a Party complies with Applicable Laws, Party-Specific Regulations, and such Party's internal ethical, medical and similar standards.

1.38. "**Joint Steering Committee**" means the Joint Steering Committee formed pursuant to the Development Agreement.

1.39. "**Major Release**" means a new generation of a product (e.g., in the case of the DexCom System, G7® as compared to G6®) that adds material features and functionality improving overall performance, efficiency and/or usability, and designated by the provider as a replacement for a prior generation, excluding for clarity any Minor Release.

1.40. "**Marketing Team**" has the meaning set forth in Section 6.1.2.

1.41. "**Minor Release**" means an intra-generational product release adding functionality in a backwards-compatible manner, or a patch version for such product making backwards-compatible bug fixes.

1.42. "**Party-Specific Regulations**" means all judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement.

1.43. "**Personal Data**" means any information or set of information relating to an identified or identifiable individual Processed by either Party through a Combined System or provided or shared by or on behalf of one Party to the other Party under this Agreement, regardless of the medium in which such information is displayed or contained, which shall include (a) all information that identifies that individual or could reasonably be used to identify such individual, (b) all "personal information," "personal data," and/or "protected health information" under applicable Privacy Laws (including, as applicable, HIPAA, CCPA, GDPR, and APPI), and (c) all information to which any applicable Privacy Laws apply and shall, at a minimum, include any information which relates to an identified or identifiable natural person. For the purposes of this Agreement, Personal Data includes DexCom CGM Data, and Tandem Insulin Data and specifically excludes any information that has been de-identified.

1.44. "**PMA**" means premarket approval.

1.45. "**Privacy Laws**" means all applicable foreign, federal, state, and local laws and regulations governing the Processing, sharing, safeguarding, security, disclosure or transfer of Personal Data (including electronic transaction sets, medical code sets, provider identifier, employer identifier, and patient identifier), as amended from time to time, including, as applicable, (i) HIPAA and the HITECH Act and all amendments to and further regulations of HIPAA and the HITECH Act, (ii) the EU General Data Protection Regulation 2016/679 ("**GDPR**"), (iii) California Consumer Privacy Act ("**CCPA**"), (iv) Japan's Act on the Protection of Personal Information ("**APPI**"), and (v) the CAN-SPAM Act, Canada's Anti-Spam Legislation and other laws or regulations governing telemarketing, including any such laws or regulations prohibiting unsolicited telephone calls to persons or entities listed on "Do Not Call" registries or similar lists or prohibiting unsolicited e-mails, spam or faxes to any person.

1.46. "**Processing**" (including "Process" and "Processed") means any operation or set of operations that is performed on Personal Data within an entity that maintains such information, including receipt, use, collection, recording, maintaining, organization, storage, adaptation, modification, retrieval, consultation, retention, alteration, dissemination, transmission, access, transfer, combination, erasure, destruction, deidentification, or pseudonymization. Processing does not include the release, transfer, provision of, access to, or divulging in any other manner of Personal Data outside the Party maintaining such information (and its Affiliates) and not to the other Party or its Affiliates.

1.47. "**Product Claims**" means assertions relating to the features and/or benefits of the Combined Systems excluding any assertions solely relating to the features and/or benefits of (i) a DexCom CGM Device and/or a DexCom CGM App, or (ii) a Tandem Insulin Delivery Device, a Tandem Display Device and/or a Tandem Diabetes Management App.

1.48. "**Promotion Materials**" mean all advertising, promotional and communication materials, in whatever form or medium, for marketing, advertising, promotion, labeling and/or education of all or part of the Combined Systems in the Agreed Markets approved by the Parties in accordance with Section 6.2.1. For clarity, "Promotion Materials" only includes such materials for each Party's discrete System to the extent such System is being promoted in the context of the Combined Systems.

1.49. "**Regulatory Approval**" means, with respect to a country, any and all classifications, clearances, approvals, licenses, registrations or authorizations of any Regulatory Authority (including any required approvals for reimbursement) necessary to commercially distribute, sell or market a product in such country, including, as may be applicable, PMA, a premarket notification (510(k)) or a de novo application in the United States or analogous clearance or approval in other jurisdictions, including a CE marking approval in the EU.

1.50. "**Regulatory Authority**" means the FDA, the EMA or any supranational, national or local agency, authority, department, inspectorate, ministry official, parliament or public or statutory person of any government of any country, including a notified body, having jurisdiction over any of the activities contemplated by this Agreement or the Parties, or any successor bodies thereto.

1.51. "**Regulatory Documentation**" means all (i) applications, registrations, licenses, authorizations and approvals (including Regulatory Approvals); and (ii) correspondence, reports and other submissions submitted to or received from Regulatory Authorities and all supporting documents with respect thereto, including all adverse event files and complaint files.

1.52. "**Representatives**" means a Party's and its Affiliates' employees, officers, directors, consultants and legal, technical and business advisors.

1.53. "**Sales Team**" means, with respect to each Party, all of such Party's employees or agents directly engaged in the promotion and sale of the Combined Systems, including any field-based commercial representatives.

1.54. "**Software and Copyrights**" means software, code, works of authorship and copyrightable subject matter.

1.55. "**System**" means (i) with respect to DexCom, the DexCom System as used in the Combined System, and (ii) with respect to Tandem, the Tandem System as used in the Combined System.

1.56. "**Tandem Diabetes Management App**" means any diabetes management software (including any software application), of Tandem or its Affiliates for use in connection with the Tandem Insulin Delivery Device, and associated data management software, which may include such software loaded onto a Tandem Insulin Delivery Device, mobile device, cloud infrastructure, and/or Electronic Health Record (EHR) systems, depending on the configuration of such Combined System, as described in more detail in the Development Plan.

1.57. "**Tandem Display Device**" means a device used in connection with, or as a component of the, Tandem Insulin Delivery Device that communicates with and controls (fully or partially) the Tandem Insulin Delivery Device, and which also Processes data related to the Tandem System.

1.58. "**Tandem Insulin Data**" means any insulin data generated by a Tandem System (solely to the extent such Tandem System is used as part of a Combined System in accordance

with this Agreement or the Development Agreement) and made available to DexCom through the Tandem Partner CID, as set forth in more detail in **Exhibit D**. For clarity, Tandem Insulin Data does not include any data not specified in the Tandem Partner CID.

1.59. "**Tandem Insulin Delivery Device**" means Tandem's pump products known as t:slim and t:sport, with or without a dedicated controller, including any Minor Release thereof.

1.60. "**Tandem Partner CID**" means the communication interface description ("**CID**") that defines the messaging protocol used to allow the Tandem System to communicate [***] Data to a DexCom CGM App.

1.61. "**Tandem System**" means a subcutaneous infusion system comprised of a Tandem Insulin Delivery Device, a Tandem Display Device and one or more Tandem Diabetes Management Apps, as described in more detail in the Development Plan.

1.62. "**Tandem Trademarks**" means the Trademarks set forth on **Exhibit E** and such other Trademarks as Tandem may designate in writing to DexCom from time to time.

1.63. "**Third Party**" means any entity or person other than DexCom or Tandem or their respective Affiliates.

1.64. "**Trademarks**" means all trade names, trademarks, service marks, logos and trade dress, including applications therefor, and all rights therein and thereto, together with all goodwill associated therewith.

1.65. "**Transaction Agreements**" means, collectively, this Agreement, the Development Agreement and the Quality Agreement.

1.66. **Additional Definitions:** Any capitalized terms not defined in this Agreement have the meaning as defined in the Development Agreement executed by the Parties on November 20, 2020. The following table identifies the location of definitions set forth in various Sections of this Agreement (or, where applicable, the Development Agreement):

| Defined Term | Section Reference |
|---|---|
| "[***]" | [***] |
| "**Agreement**" | Preamble to this Agreement |
| "[***]" | [***] |
| "**Combined System Infringement Action**" | Section 14.4 |
| "**Commercial Working Team**" | Section 2.3.1 |
| "[***]" | [***] |
| "**Confidential Information**" | Section 13.1 |
| "**Commercialization Plan**" | Section 2.1.1 |
| "**Current Development Agreements**" | Recitals to this Agreement |
| "**Data Breach**" | Section 8.9.2 |
| "**Development Agreement**" | Recitals to this Agreement |

| | |
|---|---|
| "**DexCom**" | Preamble to this Agreement |
| "**DexCom CGM Data IP**" | Section 8.3.1 |
| "**DexCom Improvements**" | Section 8.2 |
| "[***]" | [***] |
| "**DexCom Indemnitees**" | Section 14.2 |
| "**DexCom Trademark Guidelines**" | Section 3.2.1 |
| "**Disclosing Party**" | Section 13.1 |
| "**Effective Date**" | Preamble to this Agreement |
| "[***]" | [Section 15.4] |
| "**G4 Development Agreement**" | Recitals to this Agreement |
| "**G5 Development Agreement**" | Recitals to this Agreement |
| "**Indemnitee**" | Section 14.6 |
| "**Indemnitor**" | Section 14.6 |
| "**Initial Term**" | Section 15.1 |
| "**Legacy Development Agreements**" | Recitals to this Agreement |
| "**Licensed Data**" | Section 8.8 |
| "**Licensee**" | Section 8.8 |
| "**Licensor**" | Section 8.8 |
| "**Losses**" | Section 14.1 |
| "**Managed Care Reimbursement**" | Section 5.2.5 |
| "**Marketing Team**" | Section 6.1.2 |
| "**Notifying Party**" | Section 15.2.1 |
| "**Original G6 Development Agreement**" | Recitals to this Agreement |
| "**Original G6 Development Agreement Activities**" | Section 2.1.1 |
| "**On-Market t-slim:G6 Implementation**" | Recitals to this Agreement |
| "**Party**" and "**Parties**" | Preamble to this Agreement |
| "**Quality Agreement**" | Section 9 |
| "**Receiving Party**" | Section 13.1 |
| "**Relevant DexCom Regulatory Meetings**" | Section 4.2.4 |
| "**Relevant Tandem Regulatory Meetings**" | Section 4.1.2 |
| "**Scheduled Release**" | Section 11.2.1(ii) |
| "**Subcommittee**" | Section 2.3.2(viii) |
| "**System Labeling Guidelines**" | Section 5.2.4 |
| "**Tandem**" | Preamble to this Agreement |
| "**Tandem Improvements**" | Section 8.1 |
| "[***]" | [***] |

| | |
|---|---|
| "**Tandem Indemnitees**" | Section 14.1 |
| "**Tandem Insulin Data IP**" | Section 8.3.2 |
| "**Term**" | Section 15.1 |

| | |
|---|---|
| "**Transparency Laws**" | Section 7.4 |
| "**Unauthorized Use or Unauthorized Access**" | Section 8.9.1 |
| "**Unscheduled Release**" | Section 11.2.1(ii) |

## 2. COMMERCIALIZATION, COMMERCIAL WORKING TEAM, PARTY RESPONSIBILITIES

2.1. Commercialization Generally.

2.1.1 Commercialization Plan. As soon as reasonably practicable following the Effective Date, the Parties will jointly agree on a detailed plan defining each Party's responsibilities for commercializing the Combined Systems in the Agreed Markets (the "**Commercialization Plan**"). The Commercialization Plan will include for each Agreed Market each Party's respective responsibilities for, *inter alia*: (1) branding and promotion of the Combined Systems, (2) provision of Promotion Materials, as necessary, to enable the other Party's Sales Team to sell, market and train on the safe and effective utilization of the Combined Systems, and (3) provision of ongoing patient support for its System as used in the Combined Systems. Notwithstanding anything to the contrary in this Agreement, (a), with respect to the On-Market t-slim:G6 Implementation, the Commercialization Plan will (i) account for any existing commercialization activities that are or were agreed upon by the Parties under the Original G6 Development Agreement (the "**Original G6 Development Agreement Activities**"), and (ii) provide a reasonable time period agreed upon by the Parties for the Parties to implement any changes necessary to such existing commercialization activities and processes related thereto to bring them into conformance with the terms of this Agreement and the terms of the Commercialization Plan applicable to the Combined System Implementations and (b) any conduct of the Original G6 Development Agreement Activities with respect to the On-Market t-slim:G6 Implementation prior to such time period agreed upon by the Parties shall not be deemed a breach of this Agreement.

2.1.2 Efforts. The Parties will use Commercially Reasonable Efforts to commercialize the Combined Systems in the Agreed Markets, provided that neither Party shall be obligated to launch its System or any component thereof, or to support the Combined Systems, in countries or jurisdictions other than the Agreed Markets. Each Party will use Commercially Reasonable Efforts to (i) perform its obligations under the Commercialization Plan, (ii) obtain and maintain all Regulatory Approvals with respect to its System necessary to commercialize the Combined Systems in each Agreed Market, and (iii) maintain commercial scale manufacturing with respect to its System sufficient to support its obligations under the Commercialization Plan.

2.1.3 Costs. Unless otherwise mutually agreed to by the Parties in the Commercialization Plan, [***].

2.1.4 Commercialization of the On-Market t-slim:G6 Implementation. Section 4 (Commercialization) of the Original G6 Development Agreement is hereby deleted in its

entirety, and the Parties agree that this Agreement shall govern the Parties respective rights, obligations and liabilities with respect to the commercialization of the On-Market t-slim:G6 Implementation.

2.2 Alliance Managers. Each Party shall appoint an Alliance Manager as set forth in the Development Agreement. Responsibilities of the Alliance Managers beyond those set forth herein are set forth in the Development Agreement and may be included in other Transaction Agreements.

2.3 Commercial Working Team.

2.3.1. The Parties shall establish a management team for the implementation of the Commercialization Plan that shall be comprised of three (3) members for each Party ("**Commercial Working Team**") (who shall be Representatives of the appointing Party and at least one of which shall be a member of the Joint Steering Committee). Each Party may replace its Commercial Working Team members at any time by notice to the other Party.

2.3.2. In accordance with the provisions and objectives of this Agreement and the Commercialization Plan, the Commercial Working Team shall:

i. review and approve the Commercialization Plan;

ii. oversee, coordinate and manage the Parties' activities under, and implementation of, the Commercialization Plan;

iii. ensure communication between the Parties concerning the implementation, status and results of the Commercialization Plan;

iv. exercise decision-making authority over all Commercialization Plan activities in accordance with the Section 2.3 and make all such decisions and take all such other actions as are delegated to it in this Agreement, including, but not limited to, allocation of Commercialization Costs;

v. review, discuss and make proposals to the Joint Steering Committee regarding changes to Agreed Markets under a Commercialization Plan;

vi. oversee the format for providing forecasts under Section 5.2.2, and receive such forecasts;

vii. coordinate continuous improvement and technology upgrades for the Combined Systems with the Development Working Team (as defined in the Development Agreement);

viii. establish such additional joint subcommittees as it deems necessary to achieve the objectives and intent of this Agreement (each a "**Subcommittee**"); and

ix. oversee and perform such other functions as are appropriate to further the purposes of this Agreement as mutually determined by the Parties.

2.3.3. The Commercial Working Team shall meet as needed but not less often than [***], except as may otherwise be agreed in writing by the Parties. Commercial Working Team meetings shall be held at times and places or in such form, such as by telephone or video conference, as the Commercial Working Team determines, except that in-person meetings of the Commercial Working Team will alternate between the Parties' offices, unless otherwise agreed in writing by the Parties. Subject to Section 2.3.4, any Commercial Working Team member may designate by notice to the other members (which may be provided by e-mail) a qualified Representative of such Party to attend and perform the functions of that Commercial Working Team member at any Commercial Working Team meeting that such member cannot attend.

2.3.4. The Commercial Working Team shall appoint one (1) of the Commercial Working Team members to act as the initial Commercial Working Team chairperson during such period as the Commercial Working Team shall designate. At the end of each such designated period during the Term, the Parties shall alternate in appointing the chairperson for the next such defined period. Where the Commercial Working Team chairperson cannot attend a Commercial Working Team meeting, the other member having been previously designated by the same Party shall serve as the temporary Commercial Working Team chairperson for such meeting, unless neither of such Party's designated Commercial Working Team members can attend, in which case a qualified substitute designated by the Commercial Working Team chairperson for such purpose shall serve as the temporary Commercial Working Team chairperson for such meeting.

2.3.5. The Commercial Working Team chairperson shall be responsible for:

i. calling and presiding over each Commercial Working Team meeting during his or her tenure as chairperson;

ii. preparing and circulating the agenda for each such meeting; and

iii. preparing draft minutes of each such meeting and providing a copy of the draft minutes to each Commercial Working Team member within [***] after each such meeting for approval, which shall be deemed to have been given unless the Commercial Working Team member objects within [***] after receipt of the draft minutes.

2.3.6. Each Party shall collectively have one (1) vote in any matter requiring the Commercial Working Team's (or any Subcommittee's) action or approval. All decisions of the Commercial Working Team and each Subcommittee shall be unanimous, and no vote may be taken unless at least one Representative of each Party (or properly designated substitute) is present. The Commercial Working Team and each Subcommittee shall make all decisions and take other actions in good faith and with due care, after consideration of the information that is reasonably available to it, with the intention that the resulting decision or action shall maintain or increase the likelihood that the Parties will achieve the purposes and goals of the Commercialization Plan.

2.3.7. If a Subcommittee cannot reach a unanimous decision on a matter at a regularly scheduled Subcommittee meeting, the Subcommittee shall refer such matter to the Commercial Working Team for resolution. If the Commercial Working Team cannot reach a unanimous decision on any matter at a regularly scheduled Commercial Working Team meeting or within [***] thereafter, then either Party may, by notice to the other Party, have such matter referred to the Joint Steering Committee for resolution by good faith discussions for a period of at least [***]. In the event that the Joint Steering Committee is unable to reach agreement with respect to such matter within such [***], then the following shall apply:

i. DexCom shall have the final decision-making authority with respect to (A) countries in which to commercialize the DexCom System as part of the Combined Systems, provided that, DexCom shall not exercise its final decision-making authority to cease commercialization of the DexCom System as part of the On-Market t-slim:G6 Implementation in any country in which it is already being commercialized prior to the Effective Date unless doing so is consistent with DexCom using Commercially Reasonable Efforts to commercialize such Combined System in such country (which, for clarity, includes implementation of life cycle management consistent with the terms of Section 11), (B) any Regulatory Documentation and Regulatory Approvals for the DexCom System, (C) DexCom's day-to-day implementation of its responsibilities under the Commercialization Plan; and (D) those portions of the Promotional Materials specifically relating to the DexCom System; and

ii. Tandem shall have the final decision-making authority with respect to (A) countries in which to commercialize the Tandem System as part of the Combined Systems, provided that, Tandem shall not exercise its final decision-making authority to cease commercialization of the Tandem System as part of the On-Market t-slim:G6 Implementation in any country in which it is already being commercialized prior to the Effective Date unless doing so is consistent with Tandem using Commercially Reasonable Efforts to commercialize such Combined System in such country (which, for clarity, includes implementation of life cycle management consistent with the terms of Section 11), (B) any Regulatory Documentation and Regulatory Approvals for the Tandem Insulin Delivery Device; (C) Tandem's day-to-day implementation of its responsibilities under the Commercialization Plan; and (D) those portions of the Promotional Materials specifically relating to the Tandem System;

provided further, that neither Party may exercise its final decision-making authority in a manner that (A) goes beyond the CWT or JSC's authority, as limited by Section 2.5, (B) would unilaterally impose any additional or different material obligation on the other Party (including for the other Party to incur or share any additional cost), (C) would cause a Party to assume additional regulatory responsibilities, including reporting requirements or (D) would require changes to quality management practices.

2.3.8. The Commercial Working Team shall keep each Party fully informed of the status of the Parties' activities under the Commercialization Plan. For avoidance of doubt, the Parties are under no obligation to disclose information relating to any other commercial efforts not related to the Commercial Plan.

2.3.9. Each Party shall [***] of its respective Commercial Working Team members and their designated substitutes related to their participation on the Commercial Working Team and attendance at Commercial Working Team meetings.

2.4. Responsibilities. Subject to the terms and conditions of this Agreement, the Commercialization Plan and Development Agreement, or unless otherwise determined by the Commercial Working Team, each Party shall (i) [***] for the design, development, verification and validation, Regulatory Approvals, customer training, marketing, distribution, Managed Care Reimbursement, and on-going post First Commercial Launch support of its System or any component thereof, and (ii) use good faith efforts to support the other Party's Customer acquisition, on-boarding, and ordering of such other Party's System.

2.5. Governance Limitations. Each of the Joint Steering Committee and the Commercial Working Team has only the powers specifically delegated to it by this Agreement (or with respect to the Joint Steering Committee, the Development Agreement) and has no authority to act on behalf of any Party in connection with any Third Party. Without limiting the foregoing, and notwithstanding anything in this Agreement to the contrary, neither the Joint Steering Committee nor the Commercial Working Team has any authority to, and shall not purport to or attempt to:

i. amend this Agreement or any other Transaction Agreement;

ii. approve or take any action that would breach or conflict with any provision of this Agreement or of any other Transaction Agreement;

iii. negotiate agreements on behalf of any Party;

iv. make representations or warranties on behalf of any Party;

v. determine compliance or non-compliance with any provision of this Agreement or of any other Transaction Agreement; provided, that the Joint Steering Committee shall have the right to discuss any such non-compliance;

vi. waive any rights of any Party;

vii. extend credit on behalf of any Party; or

viii. take or grant licenses of, transfer ownership or otherwise encumber Intellectual Property on behalf of any Party.

## 3. INTELLECTUAL PROPERTY OWNERSHIP AND LICENSES

3.1. Intellectual Property Ownership. The Parties intend that all development activities related to the Combined System, including any Clinical Study or any continued technology upgrades to the Combined System will be conducted under the applicable Current Development Agreement and subject to the terms and conditions set forth therein. For clarity, the ownership and rights of each Party with respect to Intellectual Property arising from the

development of the Combined System or any component thereof, including development work resulting from any Clinical Study or any continued technology upgrades to the Combined System, will be governed by the applicable Current Development Agreement.

3.2. DexCom Granted Licenses.

3.2.1. DexCom Trademarks. Subject to terms, conditions, restrictions and approval rights set forth in this Agreement (as and to the extent applicable), DexCom hereby grants to Tandem a [***] license to use the DexCom Trademarks solely to perform Tandem's obligations under the Commercialization Plan and to otherwise exercise its rights hereunder. Any such use of the DexCom Trademarks by Tandem will be in material accordance with DexCom's trademark usage guidelines, which may be updated from time to time by DexCom, in DexCom's reasonable discretion, upon at least [***] prior written notice to Tandem (provided that Tandem shall not be required to conform to such updated guidelines during the [***] period immediately following the provision of such guidelines to Tandem) (for clarity, Tandem shall be required to conform to either the guidelines as they existed immediately prior to or following such update), a current copy of which Tandem acknowledges and agrees has been delivered to, and received by, Tandem, except as the Parties may otherwise agree in writing ("**DexCom Trademark Guidelines**"). Notwithstanding the foregoing, unless otherwise agreed in writing by DexCom, Tandem's use of the DexCom Trademarks shall be limited [***]. All goodwill arising from Tandem's use of the DexCom Trademarks pursuant to the license grant in this Section 3.2.1 shall inure to DexCom.

3.2.2. DexCom Copyrights. Subject to the terms, conditions, restrictions and approval rights set forth in this Agreement (as and to the extent applicable), DexCom hereby grants to Tandem under DexCom's copyright interests in the Promotion Materials a [***] license for the Term to use, reproduce, display and distribute the Promotion Materials (including translations thereof) solely to perform its obligations under the Commercialization Plan and to otherwise exercise its rights hereunder.

3.3. Tandem Granted Licenses.

3.3.1. Tandem Trademarks. Subject to terms, conditions, restrictions and approval rights set forth in this Agreement (as and to the extent applicable), Tandem hereby grants to DexCom a [***] license to use the Tandem Trademarks solely to perform DexCom's obligations under the Commercialization Plan and to otherwise exercise its rights hereunder. Any such use of the Tandem Trademarks by DexCom will be in material accordance with Tandem's trademark usage guidelines, which may be updated from time to time by Tandem, in Tandem's reasonable discretion, upon at least [***] prior written notice to DexCom (provided that DexCom shall not be required to conform to such updated guidelines during the [***] period immediately following the provision of such guidelines to DexCom) (for clarity, DexCom shall be required to conform to either the guidelines as they existed immediately prior to or following such update), a current copy of which DexCom acknowledges and agrees has been delivered to, and received by, DexCom, except as the Parties may otherwise agree in writing. Notwithstanding the foregoing, unless otherwise agreed in writing by Tandem, DexCom's use of the Tandem Trademarks shall be

limited [***]. All goodwill arising from DexCom's use of the Tandem Trademarks pursuant to the license grant in this Section 3.3.1 shall inure to Tandem.

3.3.2. Tandem Copyrights. Subject to the terms, conditions, restrictions and approval rights set forth in this Agreement (as and to the extent applicable), Tandem hereby grants to DexCom under Tandem's copyright interests in the Promotion Materials a [***] license for the Term to use, reproduce, display and distribute the Promotion Materials (including translations thereof) solely to perform its obligations under the Commercialization Plan and to otherwise exercise its rights hereunder.

4. Sublicenses. Any sublicense of the rights licensed under Sections 3.2 and 3.3 shall be subject to the following requirements: (i) each Third Party sublicensee must agree in writing to be bound by terms and restrictions, including as to the protection of Confidential Information, at least as protective of DexCom and Tandem (as applicable) and its Intellectual Property rights as those contained in this Agreement, and (ii) any such license rights may only be sublicensed for the purposes of and subject to any restrictions contained in this Agreement.

## 4. REGULATORY MATTERS

4.1. Tandem's Testing and Regulatory Responsibilities.

4.1.1. Tandem will be responsible for performing and leading all regulatory testing and related tasks, including all Clinical Studies and all regulatory filings, for Combined Systems, including, as applicable the Tandem Diabetes Management Apps, but excluding DexCom CGM Apps, including all necessary related translations and all Clinical Studies required for all Regulatory Approvals.

4.1.2. To the extent permitted by Applicable Laws and by the applicable Regulatory Authority, Tandem will, in the exercise of its commercially reasonable, good faith judgement and in a timely manner (and in any event with at least [***] [***] except where not reasonably feasible), [***] [***] with relevant Regulatory Authorities as necessary to support Regulatory Approval of the Combined Systems that are specific to [***] ("**Relevant Tandem Regulatory Meetings**"). At the request of Tandem, DexCom shall [***]. Where reasonably feasible with the Regulatory Authority, Tandem shall [***] reasonably in advance of such Relevant Tandem Regulatory Meeting. Tandem shall endeavor to [***]. Furthermore, in any meeting or teleconference with Regulatory Authorities (or portion thereof) that [***], Tandem shall (i) [***], and (ii) promptly (and in any event within [***]) following the Relevant Tandem Regulatory Meeting, (a) [***] and (b) [***], to the extent pertaining to [***]. As soon as practicable following [***], the Parties shall [***].

4.2.2 DexCom's Testing and Regulatory Responsibilities.

4.2.1 DexCom will be responsible for performing and leading all regulatory testing and related tasks for the DexCom CGM Devices, and the DexCom CGM App, including all necessary related translations, and for the avoidance of doubt, the DexCom System.

4.2.2 DexCom will designate personnel to provide reasonable support for Tandem in testing of the Combined Systems as related to performance of the DexCom CGM Devices and the DexCom CGM App.

4.2.3 Without limiting Section 4.1.2, upon Tandem's request, DexCom will participate in joint meetings with Tandem with relevant Regulatory Authorities as reasonably necessary to support Regulatory Approval of Combined Systems, including, as applicable the Tandem Diabetes Management Apps, but excluding DexCom CGM Apps.

4.2.4 To the extent permitted by Applicable Laws and by the applicable Regulatory Authority, DexCom will, in the exercise of its commercially reasonable, good faith judgement and in a timely manner (and in any event with at least [***] prior notice to Tandem except where not reasonably feasible), [***] any and all meetings and teleconferences with DexCom with relevant Regulatory Authorities as necessary to support Regulatory Approval of the Combined Systems that are specific to [***] ("**Relevant DexCom Regulatory Meetings**"). At the request of DexCom, Tandem shall [***]. Where reasonably feasible with the Regulatory Authority, DexCom shall [***] reasonably in advance of such Relevant DexCom Regulatory Meeting. DexCom shall endeavor to [***]. Furthermore, in any meeting or teleconference with Regulatory Authorities (or portion thereof) that [***], DexCom shall (i) [***], and (ii) promptly (and in any event within [***]) following the Relevant DexCom Regulatory Meeting, (a) [***] and (b) [***], to the extent pertaining to [***]. As soon as practicable following [***], the Parties shall [***].

4.3 Right to Reference. Each Party hereby has the right to cross reference, refer to, rely on, file, incorporate by reference, or otherwise use any regulatory submission or drug master file Controlled by the other Party or its Affiliates (and any data contained therein) for the Combined Systems or any component thereof, made in any country in the Agreed Markets (including all Regulatory Approvals); provided, that (i) Tandem's right to cross-reference, refer to, rely on, file, incorporate by reference or otherwise use shall be limited to doing so in order to support regulatory submissions that Tandem makes under this Agreement or any other Transaction Agreement for the Combined Systems in the Agreed Markets and to enable Tandem to fulfill its obligations, or exercise its rights, under this Agreement or any other Transaction Agreement to develop and/or to commercialize the Combined Systems in the Agreed Markets, including doing so in order to conduct, support or sponsor Clinical Studies utilizing such DexCom CGM-Enabled Tandem Display Device, and (ii) DexCom's right to cross-reference, refer to, rely on, file, incorporate by reference or otherwise use shall be limited to doing so in order to support regulatory submissions that DexCom makes under this Agreement or any other Transaction Agreement for the DexCom System for use with the Combined Systems in the Agreed Markets. Each Party hereby agrees to promptly provide or have provided to the applicable Regulatory Authorities and/or the other Party or its designee a letter of consent to permit such referencing. In any case in which the Regulatory Authority for the applicable jurisdiction requires a Party to have copies of such filings in order to exercise its rights or perform its obligations hereunder, the other Party shall provide such copies to such requesting Party (provided that the requesting Party shall be responsible for any translation costs in connection therewith).

4.4 Regulatory Obligations and Expenses. In connection with obtaining or maintaining Regulatory Approvals, interacting with Regulatory Authorities, filing or maintaining Regulatory Documentation, or maintaining regulatory records (in each case in relation to its System or the Combined Systems), unless required to comply with Applicable Laws, in no instance shall either Party take any action or omit to take any action that, directly or indirectly, would be reasonably likely to result in the other Party incurring (i) additional responsibilities to Regulatory Authorities or otherwise under Applicable Laws that are not listed or described in the Development Plan or Commercialization Plan, or (ii) additional internal or out-of-pocket expenses (including expenses related to additional reporting obligations) that are not listed or described in the Development Plan or Commercialization Plan, in each case without prior written consent of such other Party; provided, that the foregoing shall not limit either Party's right to make any Minor Release or Major Release of its System or component thereof.

## 5. MANUFACTURING AND DISTRIBUTION

5.2.1 Manufacturing. Each Party shall be solely responsible, at its own cost, for manufacturing its System, or components thereof, in connection with commercialization of the Combined Systems. Each Party shall manufacture its System for use in the Combined Systems in accordance with any specifications for the Combined Systems agreed upon in writing, all Applicable Laws (including cGMP) and the Quality Agreement.

5.2.2 Distribution.

5.2.1 General. Subject to the terms and conditions herein and the Commercialization Plan, each Party shall be responsible for the pricing, sale and distribution of its System or components thereof to Customers in the Agreed Markets in connection with commercialization of the Combined Systems. In particular, Customers will order the DexCom System or any component thereof directly from DexCom, through DexCom's established distribution channels, and Customers will order the Tandem System or any component thereof directly from Tandem, through Tandem's established distribution channels. To the extent contemplated by the Commercial Plan, DexCom and Tandem agree to collaborate reasonably on ways to optimize distribution [***]. For clarity, unless otherwise agreed to in a Commercialization Plan, neither Party will be obligated to identify and establish new distribution channels for its System in any Agreed Market.

5.2.2 Combined Systems Forecasts. At least [***] prior to the First Commercial Launch of the Combined System Implementations, Tandem shall deliver to DexCom a non-binding [***] forecast of shipments of such implementation of the Combined System Implementations for the [***] period following such projected First Commercial Launch, which forecast shall be updated [***] on a rolling basis for the following [***] period until such First Commercial Launch and provided to DexCom within [***] of the end of [***]. After such First Commercial Launch, Tandem shall provide DexCom on a rolling basis, within [***] of the end of [***], with non-binding [***] forecasts of shipments of the Combined System Implementations for the following [***] period. For clarity, Tandem shall continue to provide [***] forecasts of shipments for the On-Market t-slim:G6 Implementation, within [***] of the end of each [***] and using the same [***] outlook, as is being used as of the Effective Date. All forecasts provided

under this Section 5.2.2 shall be separately provided for the DexCom G6® CGM Device and the DexCom G7® CGM Device, and shall be non-binding on Tandem, and shall be in a format, subject to approval by the Commercial Working Team, that is sufficiently detailed to allow DexCom to adjust the manufacturing requirements of its System as appropriate (e.g., manufacturing ramp up or ramp down). Any change to the timing of such forecasts shall be (i) subject to approval by the Commercial Working Team and (ii) permitted only following the date that is [***] following the First Commercial Launch of a Combined System Implementation.

5.2.3 Ordering Process. As part of the Commercialization Plan, Tandem and DexCom agree to establish a process whereby each Party will deliver its System or components thereof to Customers [***]. For clarity, with respect to the On-Market t-slim:G6 Implementation, the Commercialization Plan will reflect the existing process for delivering the DexCom G6® CGM Device and related customer services practices that are in effect prior to the Effective Date. Each Party shall promptly notify the other Party of any anticipated supply shortage or supply delay with respect to its System or components thereof that is reasonably likely to impact its ability to timely deliver its System or components to Customers. Upon receipt of any such notification, the Parties will discuss in good faith how to mitigate and remediate such supply shortage or supply delay.

5.2.4 Labeling and Packaging. Subject to all Applicable Laws and conditions of Regulatory Approval, each Party will be solely responsible for packing its System for distribution to Customers in accordance with its normal shipping practices. Except as may be set forth in the Commercialization Plan, each Party shall be solely responsible for determining the labeling and packaging of its System, provided that to the extent any labeling (including any user guides) relates to the other Party's System (or any components thereof), such labeling shall (a) be in accordance with labeling language provided by the other Party ("**System Labeling Guidelines**") or (b) if not in accordance with the other Party's System Labeling Guidelines, be subject to the review and written approval of the other Party, which approval will not be unreasonably withheld, conditioned or delayed.

5.2.5 [***]. Each Party will be solely responsible for [***] provided that, upon request each Party shall reasonably support the other Party with respect to the other Party's [***] efforts. Each Party agrees that it [***.]

5.3 Reimbursements. Neither Party shall [***]. In addition, the responsible employees and authorized consultants or agents of either Party [***].

## 6. MARKETING

6.1. Marketing Plan. The Parties agree to collaborate reasonably and in good faith to support the commercial launch and marketing of the Combined Systems in the Agreed Markets. In connection therewith, the Parties will include details in the Commercialization Plan setting forth each Party's responsibilities in connection with launching and promoting the Combined Systems in the Agreed Markets, including details for the Parties to collaborate on [***]. The Commercialization Plan will also set forth the Parties' joint promotion efforts to be undertaken

with respect to the Combined Systems in the Agreed Markets, which joint efforts may include but are not limited to:

i. [***];

ii. [***];

iii. [***];

iv. [***];

v. [***];

vi. [***];

vii. public communications and press releases regarding the Combined Systems (e.g. "approved uses"), communications for investor relations, conferences, etc.;

viii. joint presentations at trade shows; and

ix. other aspects as jointly determined to be of benefit by the Parties.

6.1.2. Marketing Team. Each Party will designate a marketing team consisting of at least two (2) Representatives ("**Marketing Team**") as a subcommittee of the Commercial Working Team to coordinate activities under the Commercialization Plan, which Marketing Team shall meet at least [***] for the first [***] after First Commercial Launch of any Combined System Implementation, and at least annually thereafter.

6.2. Promotion Materials.

6.2.1. Approval. The Parties shall prepare the Promotion Materials in accordance with the Commercialization Plan with oversight by the Commercial Working Team. All Promotion Materials of a Party (solely to the extent such materials of a Party relate to the other Party's discrete System) will be subject to review and approval of the Commercial Working Team or its delegates and pursuant to each Party's internal policies and procedures. Each Party shall and shall cause its Representatives to (i) use, reproduce, display and distribute only Promotion Materials reviewed and approved as set forth in this Agreement (as may be translated for an Agreed Market, provided that neither Party may translate the other Party's Trademarks); and (ii) not modify, alter, amend, adjust or mask any portion of such Promotion Materials in any way (except to the extent required to comply with Applicable Laws, including requirements of any Regulatory Authority). Each Party will promptly notify the other Party and take all reasonably necessary corrective action in the event such Party learns that any such modification, alteration, amendment, adjustment or masking, or any such use or distribution of unapproved marketing materials has taken place by it or its Representatives. Promotion Materials will not contain Product Claims unless such claims (a) have been approved by the Commercial Working Team, (b) [***], and (c) [***].

6.2.2. Other Materials. Except as provided in Section 6.2.1 with respect to Promotion Materials, prior to a Party's usage of the other Party's Trademarks in connection with the marketing of its System, the Party that has created such materials shall submit them to the other Party for review and written approval, which may be given or withheld in the other Party's sole discretion. Each Party shall conduct its review of any materials submitted to it pursuant to this Section 6.2.2 within [***] of receipt. If such approval is given, the Party that has created such materials may use them solely in the manner that has been approved, until such time as it receives a written notice from the other Party stating that such use must stop or be modified.

6.3. Branding. Tandem agrees to [***], in each case (i) through (iii), in accordance with the DexCom Trademark Guidelines and subject to Section 6.2. DexCom agrees to [***], in each case (x)-(z), in accordance with the Tandem Trademark Guidelines and subject to Section 6.2.

6.4. Training. The Parties shall, in accordance with the Commercialization Plan, collaborate reasonably and in good faith to continually update and provide Promotion Materials for training the Parties' respective Sales Teams with respect to promoting the Combined System Implementations in the Agreed Markets in compliance with Applicable Laws. In connection therewith, each Party agrees to reasonably make its relevant Sales Team available for training from time to time.

6.5. Third Party Products.

i. Tandem shall not accept any consideration from any Third Party to [***], provided that such restriction shall not prevent Tandem from facilitating such replacement if made (a) in connection with a general advertisement not specifically targeting such replacement or (b) upon the request of a patient or such patient's health care professional.

ii. DexCom shall not accept any consideration from any Third Party to [***], provided that such restriction shall not prevent DexCom from facilitating such replacement if made (a) in connection with a general advertisement not specifically targeting such replacement or (b) upon the request of a patient or such patient's health care professional.

iii. Notwithstanding the foregoing, both Parties may engage in development and commercialization activities, including research and development activities, marketing and educational activities, with Third Parties for which they may receive a monetary or other consideration, as long as such activities are general in nature and not specifically targeting at the replacement of either Party's device with that of a Third Party.

## 7. COMPLIANCE WITH LAWS

7.1. General. Each of DexCom and Tandem shall perform, and shall procure that their respective Affiliates and its and their Representatives perform, their obligations and other activities under this Agreement in accordance with Applicable Laws and the provisions of this Agreement.

7.2. Compliance with Party-Specific Regulations. Each Party agrees to cooperate with the other Party as may reasonably be required to ensure that such other Party is able to fully meet its obligations with respect to the Party-Specific Regulations applicable to it. Neither Party shall be obligated to pursue any course of conduct that would result in such Party being in breach of any Party-Specific Regulation applicable to it, and shall give the other Party prompt written notice of any such actual or potential conflict. All Party-Specific Regulations are binding only in accordance with their terms and only upon the Party to which they relate.

7.3. Compliance with Internal Compliance Policies. All Internal Compliance Policies shall apply only to the Party to which they relate. Each Party agrees to cooperate reasonably with the other Party to ensure that such other Party is able to comply with the substance of its respective Internal Compliance Policies and, to the extent practicable, to operate in a manner consist with its usual Compliance-related processes.

7.4. Transparency Reporting. Each Party will comply with Applicable Laws relating to the tracking and reporting of payments and transfers of value provided to health care professionals, health care organizations, and other relevant individuals and entities, including the Physician Payments Sunshine Act (Section 6002 of the Patient Protection and Affordable Care Act) (collectively, "**Transparency Laws**"). Each Party agrees to cooperate with the other in good faith to provide to the other Party with all information necessary for such Party to comply with any Transparency Laws.

7.5. Privacy Laws. Each Party agrees to collect, Process and transfer cross borders Personal Data in its System in compliance with Privacy Laws. Without limiting the generality of the foregoing, each Party agrees to: (i) obtain and store all authorizations and/or lawful bases necessary to Process and share Personal Data (identified and de-identified) in connection with the Combined System, (ii) timely enter into legally required agreements with Third Parties regarding the processing of Personal Data (e.g., "Business Associate" agreements as defined by HIPAA and processor agreements as defined by GDPR); (iii) implement and maintain appropriate organizational and technical security measures to protect Personal Data; (iv) only transfer Personal Data from any jurisdiction to any other jurisdiction (the European Economic Area constituting a single jurisdiction for this purpose) pursuant to an appropriate data transfer agreement or other mechanism appropriate to comply with Applicable Laws; (v) provide end-users with a mechanism to withdraw their consent for or otherwise object to/opt-out of processing for Personal Data that it controls or possesses as required by Applicable Laws.

## 8. COLLECTION, PROCESSING, STORAGE AND SHARING OF DATA.

8.1. Tandem [***]. Subject to the restrictions set forth in this Section 8.1 and Section 8.3, Tandem will have the right to [***] for any and all lawful purposes, including in and for [***] and/or for the purposes of [***]. Tandem may not [***] (1) in connection with [***], provided, however, that the foregoing shall not [***]; (2) to [***]; (3) to [***]; or (4) to [***]. To the extent [***]; (b) [***]; and (c) to the extent Tandem [***]; and (d) Tandem shall [***]. Notwithstanding the foregoing and subject to the provisions of Section 8.8, [***] except [***].

8.2. DexCom [***]. Subject to the restrictions set forth in this Section 8.2 and Section 8.3, DexCom will have the [***] for any and all lawful purposes, [***]. DexCom may not [***] (1) in connection with [***]; (2) to [***]; (3) to [***]; and (4) to [***]. To the extent [***], (a) [***]; and (b) [***], and (c) to the extent DexCom [***]; and (d) DexCom shall [***]. Notwithstanding the foregoing and subject to the provisions of Section 8.8, [***] (i) [***]; (iii) to [***]; (iv) to [***]; (v) to [***]; or (vi) as [***].

8.3. Data [***]. DexCom (or its Affiliates, as applicable) [***] and Tandem (or its Affiliates, as applicable) [***].

8.3.1. Tandem hereby acknowledges that, [***], [***]. [***]. Tandem acknowledges and agrees that [***].

8.3.2. DexCom hereby acknowledges that, [***]. [***]. DexCom acknowledges and agrees that [***].

8.3.3. With respect to Personal Data (as defined in the GDPR) collected from a Party's Customers located in the European Economic Area, [***]. Under no circumstances will the Parties [***].

8.4. Delivery of Data. The Parties shall use Commercially Reasonable Efforts to cooperate and collaborate [***], as applicable.

8.5. Data Reconciliation. The Parties shall use Commercially Reasonable Efforts to cooperate and collaborate to [***].

8.6. Customer Consents. The Parties shall use Commercially Reasonable Efforts to cooperate and collaborate to [***], as applicable, from its [***] and for complying with subsequent [***].

8.7. Data [***].

8.7.1. Each Party may share or transfer, or allow the sharing or transfer of, [***] data (i.e., the [***] or the [***], as applicable), solely in the following circumstances: (i) [***], (ii) [***], in each case (a) solely [***], and (b) [***], and (iii) [***]. In addition, for purposes of clarity, current patient-directed sharing of data from the Tandem System or the DexCom System with [***], and research institutions may continue, provided that [***]. The data sharing restrictions in this Section 8.7.1 shall apply with respect to all of the Combined Systems, provided that, [***], and provided that (in each of the foregoing cases) [***], Tandem shall [***].

8.7.2. Except as set forth in Sections 8.1, 8.2 and 8.7.1, neither Party may share or transfer [***] (i.e., the [***] or the [***] (i.e., [***] prior written consent, not to be unreasonably withheld, it being understood that to the extent a Party wishes to [***](other than as set forth in Section 8.7.1), such Party shall (i) [***] and (ii) [***].

8.7.3. Each Party shall use good faith efforts to [***] with respect to the sharing or transferring of data (i.e., the [***] or the [***], as applicable) from [***].

8.8. No Re-identification. Each Licensee shall not re-identify any person reflected in [***], including without limitation: (a) re-identifying, or attempting to re-identify, or allowing to be re-identified any patient or individual who is the subject of Protected Health Information (as defined by HIPAA) within such [***]; (b) re-identifying, or attempting to re-identify, or allowing to be re-identified any relative, family or household member of any patient or individual reflected in such [***]; or (c) linking any of the facial or direct identifiers set forth in 45 C.F.R. 164.514 to any other information. In addition, each [***] that directly or indirectly involves developing a plan to or actually attempting to reidentify an individual. Each [***]. For the purposes of this Section 8.8, the remainder of Section 8, and Section 12.2, "**Licensee**" means (i) with respect to [***], and (ii) with respect to [***]; "**Licensor**" means (i) with respect to [***], and (ii) with respect to [***]; "**Licensed Data**" means (i) where [***], and (ii) where [***].

8.9. Security Requirements.

8.9.1 Each Licensee shall use Commercially Reasonable Efforts to employ procedures and processes as appropriate to [***] and to [***]. Licensee shall promptly notify Licensor of any actual Unauthorized Use or Unauthorized Access identified by the Licensee. As used herein, "**Unauthorized Use or Unauthorized Access**" means any use or access that results from [***] which shall mean [***] or [***].

8.9.2 Each Licensee shall implement and maintain administrative, physical, and technical safeguards to ensure protection of the security, confidentiality, and integrity of any data (including Personal Data) collected through, or generated by, its System or any component thereof (or the other Party's System or any component thereof). Licensee's security measures shall be designed to [***] from and against [***] (a "**Data Breach**");

8.9.3 Each Licensee shall maintain written risk management and security policies that cover data center operations and desktop computer use related to the [***];

8.9.4 Each Licensee shall [***] on any [***] that are in its direct control or that it manages on behalf of its employees, consultants or agents; Each Party's product software to be utilized on patient mobile devices will require [***] on [***] by the Licensee software on the mobile device.

8.9.5 Each Licensee shall conduct or have conducted on its behalf by a Third Party, [***], an evaluation of its processes and systems to [***] with respect to the confidentiality, integrity, and security of the Licensed Data. Upon request, Licensee will provide to Licensor a copy of the most recent evaluation and [***];

8.9.6 Each Licensee shall transmit Licensed Data on patient mobile devices via [***]. Licensee will use protections such as [***] when transmitting Licensed Data via the internet or encryption or other secure means; Patient directed data transmission (including download) is excluded as patient will direct the means of such export.

8.9.7 The Parties agree to execute and undertake such compliance mechanisms as may be required by Applicable Laws in order for a party to transfer or receive Personal Data from countries outside the United States, including, but not limited to, the European Economic Area, the United Kingdom and Switzerland;

8.9.8 In addition to the expressly permitted data sharing provisions in this Agreement, each Party shall make [***] available only to [***] who have a need to access the Licensed Data and Personal Data in order to perform the Party's obligations or exercise its rights under the Agreement; and

8.9.9 Each Licensee shall maintain security incident management policies and procedures and shall promptly notify Licensor [***] of any [***] in accordance with Section 8.11 below.

8.10 Audit. During the Term and for [***] thereafter, Licensee agrees to permit an independent Third Party auditor designated by Licensor (provided, that such Third Party auditor is reasonably acceptable to Licensee and has entered into a confidentiality agreement directly with Licensee containing obligations of confidentiality and non-use at least as restrictive as those contained herein), upon reasonable advance notice, during regular business hours and [***], to inspect and examine Licensee's [***] as reasonably necessary for Licensor to verify Licensee's compliance with Sections 7.5, 8, and 12.2; provided, that, such Third Party auditor shall not [***] and shall only be permitted to [***] of the [***] and a [***] of any [***].

8.11 Data Breaches. In the event of a Data Breach of Personal Data, the affected Party will [***] of any Data Breach or use or disclosure of Personal Data. The affected Party shall promptly notify the other Party ([***]) upon discovery of any suspected Data Breach. The affected Party will promptly work to [***] as required by Applicable Laws, and respond to [***] inquiries. The affected Party shall be solely responsible for (i) notifying appropriate Governmental Authorities, affected individuals and any other entity required by Applicable Laws of any Data Breach experienced by it, and (ii) [***]. If a Data Breach affects both Parties, the Parties agree to [***]. In the event of a dispute or claim brought by an individual or any Government Authority concerning Licensed Data against either or both Parties, the Parties will inform each other about any such disputes or claims, and will [***].

8.12 General Obligations.

8.12.1 The Parties will not process or otherwise use or disclose any Personal Data for any purpose other than performing their respective obligations and exercising of their respective rights under this Agreement.

8.12.2 The Parties agree (i) that any sharing of Personal Data between the Parties is not a "sale" of Personal Data pursuant to Privacy Laws, and (ii) to take such steps as may be necessary in order to avoid any sharing of Personal Data between the Parties from being characterized as a "sale" of Personal Data pursuant to Privacy Laws.

8.13. Suspension. Each Licensor reserves the right to suspend delivery of or access to the applicable Licensed Data or any portion thereof upon its reasonable belief that tortious, criminal or otherwise improper or prohibited activity may be associated with Licensee's utilization of such Licensed Data or in the event that Licensee is in default of any obligation under Sections 7.5, 8, and 12.2. Licensor shall provide written notice to Licensee explaining the reason for any such suspension and Licensee shall immediately suspend such access. Licensor may condition any restoration of access upon satisfaction of such conditions directly associated with the suspension of service as Licensor reasonably determines are appropriate.

8.14. Termination. In the event of any termination of this Agreement, the rights of a Party with respect to DexCom CGM Data and Tandem Insulin Data set forth in Sections 8.1, 8.2 and 8.3 (as applicable) will continue in effect [***], but will be [***]. Notwithstanding the foregoing, in the event of termination of this Agreement under Section 15.2 (Termination for Breach), (i) the rights of the terminating Party with respect to DexCom CGM Data or Tandem Insulin Data set forth in Sections 8.1, 8.2 and 8.3 (as applicable) will continue in effect [***], subject to this Section 8.14; and (ii) except with respect to [***], the rights of the other non-terminating Party with respect to DexCom CGM Data or Tandem Insulin Data set forth in Section 8.2 or 8.3 (as applicable) will automatically terminate, and such other non-terminating Party shall cease all use of the DexCom CGM Data or Tandem Insulin Data (as applicable).

**9. QUALITY AGREEMENT.** Within [***] after the Effective Date, the Parties shall enter into an updated Quality Agreement with respect to the Combined Systems (as amended from time to time in accordance with its terms and conditions, the **"Quality Agreement").** To the extent there is any conflict between the terms and conditions of the Quality Agreement and this Agreement with respect to quality matters, the Quality Agreement shall control and this Agreement shall control with respect to all other matters.

**10. CUSTOMER SERVICE.**

10.1 Responsibility. Each Party shall be solely responsible, [***], for providing support to Customers of its System or any component thereof in accordance with the terms of the Quality Agreement. As part of this Agreement, the Parties may also establish customer service satisfaction metrics (including, but not limited to, complaint rates and customer satisfaction scores), as agreed to by the Commercial Working Team, for maintaining a minimum level of customer service satisfaction and requirements for each Party to implement adjustments to its customer service practices should such metrics fall below the agreed upon threshold.

10.2 Coordination. The Parties shall jointly review and update the system used to evaluate, triage, and transfer customer support calls (or other methods of inquiry) relating to the Combined System to the appropriate Party, as outlined in the Quality Agreement. At least [***] prior to the projected First Commercial Launch of the first Combined System Implementation, the heads of each Party's customer team will meet to agree on such updates. The Parties will cooperate to successfully complete all testing of such system prior to such First Commercial Launch of the first Combined System Implementation.

10.3 Training and Supply. Tandem shall lead Customer support training for all of the Combined Systems beginning with First Commercial Launch of any Combined System Implementation, provided that DexCom shall provide to Tandem (i) existing training materials, and (ii) [***] at no cost to Tandem. [***]. DexCom agrees to provide Tandem with a reasonable quantity of samples of its System (or components thereof) for Customer support training.

## 11. LIFECYCLE MANAGEMENT

11.1 Improvements and Technology Upgrades. During the Term, the Parties will cooperate on the (i) on-going development, maintenance, and support of the Combined Systems, and (ii) continuous improvement and technology upgrades for the Combined Systems or any component thereof, under and in accordance with the Current Development Agreements.

11.2 Version Support.

11.2.1 Each Party agrees [***]. In addition:

i. [***], each Party shall provide the other Party with at least [***] advance written notice with respect to [***]. In the event that, despite using Commercially Reasonable Efforts, [***], then the releasing Party will ensure [***] including [***].

ii. DexCom may [***]. DexCom shall provide Tandem with at least [***] written notice prior to [***]. DexCom shall provide [***].

iii. For clarity, in no event shall either Party be obligated to [***].

11.3. DexCom Discontinuation. Notwithstanding Section 11.2, DexCom may, in its sole discretion, (i) discontinue its support of the then-current DexCom CGM Device (a) in [***] any time commencing [***] subsequent to [***], or (b) in [***] any time commencing [***] subsequent to [***] and (ii) discontinue its support of features of its then current DexCom CGM Device [***] at any time commencing [***] after [***].

11.4. Notwithstanding anything to the contrary herein, the Parties acknowledge and agree that the Parties will work together in good faith to modify the approach set forth in Sections 11.2 and 11.3 to the extent necessary to efficiently roll-out any release that is required under Applicable Laws or by a Regulatory Authority.

## 12. REPRESENTATIONS AND WARRANTIES

12.1. Each Party hereby represents, warrants and covenants, as applicable, to the other Party that:

i. it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation;

ii. it is duly authorized to execute and deliver this Agreement, the person or persons executing this Agreement on its behalf have been duly authorized to do so by

all requisite corporate action, and this Agreement is legally binding upon it and enforceable in accordance with its terms;

iii. it has full corporate right, power and authority to perform its respective obligations under this Agreement, including the right to grant the rights and licenses granted to the other Party hereunder;

iv. it will obtain and maintain all licenses, permits and other authorizations necessary to perform its obligations hereunder, and will fully cooperate in obtaining and maintaining any approvals from Regulatory Authorities necessary to implement this Agreement;

v. it will perform its obligations hereunder in compliance with all Applicable Laws, and it has in place a compliance program and internal policies and procedures for its employees and agents to comply with Applicable Laws (including Anti-Corruption Law and Privacy Law) as contemplated by Section 7, including training on such policies and procedures and reporting obligations for non-compliance;

vi. it will not violate rights of any third party in performing obligations under this Agreement;

vii. it has obtained or will obtain all necessary institutional and regulatory approvals necessary to perform its obligations under this Agreement, including, without limitation, any institutional review board approval;

viii. it has not been:

A. Debarred by the United States Food and Drug Administration under any provision of the Generic Drug Enforcement Act; or

B. Excluded by the Office of the Inspector General of the United States Department of Health and Human Services, or by any other authority, from participating in any health care program (such as Medicare or Medicaid) funded by any Governmental Authority.

Each Party agrees that no person who has been debarred or excluded as described above will furnish any of the services or deliverables or perform any obligations on behalf of such Party under this Agreement. Neither Party shall subcontract any performance of this Agreement to any Party that is on the specialty designated nationals and blocked persons list maintained by the United States Department of the Treasury Office of Foreign Assets Control (available via http://www.ustreas.gov/offices/enforcement/ofac/ as of the Effective Date) or to any Party who is located in or has its principal place of business in a country subject to economic sanctions maintained by the United States Department of the Treasury Office of Foreign Assets Control. Each Party will promptly notify the other Party in writing (with a copy to legal counsel) of any formal actions taken or pending, of which the Party has knowledge, that could reasonably be

construed to threaten or to confirm a debarment or exclusion of any person on the lists specified in sub-clause (A) or (B) above.

12.2. Representations and Warranties regarding Licensed Data. Each Licensor represents and warrants that: (a) it has or will obtain all rights, power and authority that are necessary for its collection, use, processing, and disclosure of its Licensed Data as contemplated under Section 8; and (b) Licensee's use of the applicable Licensed Data pursuant to this Agreement will not violate any Intellectual Property Rights, rights of publicity or privacy, other proprietary rights, or any applicable local, state or federal laws, regulations, orders or rules.

12.3. Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 12 OR ELSEWHERE IN THIS AGREEMENT, NEITHER TANDEM NOR DEXCOM MAKES ANY REPRESENTATIONS OR WARRANTIES UNDER THIS AGREEMENT, AND EXPRESSLY DISCLAIMS ANY WARRANTIES WHETHER EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, OR NON-INFRINGEMENT.

12.4. Non-Disparagement.

12.4.1. Neither Party shall make any statement or take any action to disparage the other Party's System (or any component thereof or services related thereto) or engage in any unfair, misleading or deceptive practices regarding the same.

12.4.2. Neither Party shall make any statement (i) comparing the other Party's System (or any component thereof or services related thereto) with respect to performance, quality or clinical benefits, with the products of any Third Party, or (ii) that could reasonably be expected to adversely affect the goodwill of the other Party or its products, except in the case of (i) and (ii) to the extent such public statements are based on (x) published (in any industry recognized scientific publication) peer-reviewed studies; provided, however, that any peer-reviewed studies shall be [***] or (y) are specifically included in a product registration with a Regulatory Authority or in response to a product safety or quality issue or (z) relate to the other Party's material breach of its obligations under either this Agreement or any other Transaction Agreement.

12.4.3. The Parties shall educate and train their employees regarding acceptable public communications regarding the other Party's System consistent with this Section 12.4.

## 13. CONFIDENTIALITY

13.1 Confidential Information. Except as expressly provided in this Agreement or any other Transaction Agreement, during the Term and for [***], except with respect to Confidential Information constituting trade secrets (to the extent identified by the Disclosing Party in writing or to the extent reasonably identifiable as a trade secret based on the nature and content of the disclosure), which such obligations shall not expire, the Party receiving Confidential Information from the Disclosing Party (the "**Receiving Party**") will not publish or otherwise disclose and

will not use such Confidential Information for any purpose other than carrying out Receiving Party's obligations and exercising its rights under this Agreement and any other Transaction Agreement. For purposes of this Agreement, "**Confidential Information**" means any information furnished by or on behalf of a Party (the "**Disclosing Party**") in connection with this Agreement or any other Transaction Agreement (including in connection with the negotiation thereof) which is confidential or proprietary to the Disclosing Party, including research and development plans and results; processes; evaluation procedures (including clinical and field testing); manufacturing methods; applications to government authorities; pricing or cost information; construction plans; sales, marketing, and advertising studies and plans; customer lists; computer information and software; special techniques unique to a Party's business; information subject to a right of privacy in favor of a Third Party; information the Disclosing Party maintains under a system of protection against unauthorized access; and, subject to the rights and obligations with respect to disclosure and use thereof contained in the Transaction Agreements, DexCom CGM Data and Tandem Insulin Data. Notwithstanding the foregoing, the Disclosing Party's Confidential Information will not include information that the Receiving Party can demonstrate with competent evidence:

13.1.1 was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure;

13.1.2 was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

13.1.3 became generally available to the public or otherwise part of the public domain after its disclosure hereunder and other than through any act or omission of the Receiving Party in breach of this Agreement; or

13.1.4 was subsequently lawfully disclosed to the Receiving Party by a person without breaching a duty of confidentiality or developed by or for the Receiving Party without use of, reliance on, or reference to any Confidential Information of the Disclosing Party.

13.2 Permitted Disclosures. Notwithstanding Section 13.1, a Receiving Party may use or disclose the Disclosing Party's Confidential Information solely to the extent such use or disclosure is reasonably necessary in complying with an order of a court of law, prosecuting or defending litigation, complying with applicable governmental regulations, submitting information to tax or other Governmental Authorities, or conducting Clinical Studies; provided that, subject to Section 13.5, if a Receiving Party is required to make any such disclosure of Confidential Information, it will give the other Party reasonable advanced notice of the disclosure, and use its reasonable efforts to secure confidential treatment of the information prior to its disclosure (whether through protective orders or otherwise).

13.3 Unauthorized Disclosure of Confidential Information. If a Party becomes aware of an unauthorized disclosure of the other Party's Confidential Information, then such Party shall notify the other Party promptly in writing.

13.4 Return of Confidential Information. Following any expiration or termination of this Agreement and all other Transaction Agreements, within [***] after receipt of the Disclosing Party's written request, the Receiving Party will return to the Disclosing Party (where practicable), or, at the Receiving Party's option, destroy and provide written certification of the destruction of, all tangible materials that contain the Disclosing Party's Confidential Information, other than such Confidential Information to which the Receiving Party retains a right to use under this Agreement or any other Transaction Agreement. Notwithstanding the foregoing, (i) the Receiving Party may retain one copy of the Disclosing Party's Confidential Information in the legal files of the Receiving Party for the sole purpose of determining the scope of obligations incurred under this Agreement or as otherwise required by Applicable Laws; (ii) the Receiving Party may retain any electronic copies of the Disclosing Party's Confidential Information held securely in the Receiving Party's electronic backup storage in accordance with its established document retention policies and (iii) the Receiving Party may retain the Disclosing Party's Confidential Information to the extent included in the Receiving Party's board of director or board committee materials or minutes or actions, quality systems, or regulatory history; subject in each case to the Receiving Party's continuing confidentiality and non-use obligations under this Agreement with respect to such Confidential Information.

13.5 Confidentiality Terms; Confidentiality of Agreement; Press Releases.

13.5.1 Except as explicitly permitted under this Section 13.5 or any other Transaction Agreement, neither Party will disclose to any Third Party the terms of this Agreement without the prior written consent of the other Party hereto, except each Party may disclose the terms of this Agreement and any other Transaction Agreement: (i) on a confidential basis to its Representatives, members of the Party's board of directors in their capacity as such, to advisors (including financial advisors, attorneys and accountants), existing or potential investors (provided that such investors are not [***]) and others on a need to know basis, in each case under appropriate confidentiality provisions substantially equivalent to those in this Agreement, providing that such Party shall be responsible for any disclosure of information by any of the persons referred to in the preceding sentence in contravention of the terms of this Agreement; or (ii) to the extent necessary to comply with Applicable Laws; provided that the Disclosing Party shall promptly notify the other Party (other than in the case where such disclosure is necessary, in the reasonable opinion of the Disclosing Party's legal counsel, to comply with Applicable Laws) and allow the other Party a reasonable opportunity to oppose with the Governmental Authority initiating the process and, to the extent allowable by Applicable Laws, to seek limitations on the portion of the Agreement that is required to be disclosed.

13.5.2 The Parties shall not issue a press release disclosing the existence of this Agreement or any other Transaction Agreement, any specific term hereof, or any specific transaction contemplated herein unless required by Applicable Laws or as agreed in writing by the Parties. Where such a press release or other public disclosure is so required, no Party shall issue a press release without first giving the other Party reasonable opportunity to review and approve the proposed public disclosure or press release, such approval not to be unreasonably withheld, delayed or conditioned. For clarity, no such review and approval shall be required for any public disclosure or press release that restates information that has been previously approved for public

disclosure or that is otherwise in the public domain without a breach of this Agreement or any Transaction Agreement, provided that such information remains accurate in all material respects.

13.6 Records. At its own expense, each Party will create and maintain and provide access to upon reasonable request all records that relate to this Agreement and to a Party's performance under this Agreement (i) to the extent required by this Agreement and Applicable Laws, (ii) sufficient to demonstrate that any and all amounts invoiced to a Party under this Agreement are accurate and proper in both kind and amount; (iii) sufficient to demonstrate the accuracy of reports submitted to either Party under this Agreement; and (iv) sufficient to enable a Party to comply with Applicable Laws and other legal obligations, to the extent that such Party has or reasonably should have knowledge of those Applicable Laws and other legal obligations. Each of the Parties will maintain all such records for the longer of (a) any period prescribed by Applicable Laws or stated expressly in this Agreement, (b) [***] after the term of this Agreement.

13.7 Personal Data; DexCom CGM Data and Tandem Insulin Data. To the extent any Personal Data, DexCom CGM Data and/or Tandem Insulin Data is collected, received or shared by a Party or its Affiliates with or from the other Party or its Affiliates in connection with activities contemplated by this Agreement or the Development Agreement, the use of such data shall be governed solely by Section 8 of this Agreement.

## 14. INDEMNIFICATION AND DEFENSE OF INFRINGEMENT

14.1. DexCom will defend and indemnify Tandem, its Affiliates, and each of their respective directors, officers, employees, agents, successors and assigns (collectively, "**Tandem Indemnitees**"), against all Third Party claims, suits and proceedings, and will hold the Tandem Indemnitees harmless against all judgments, settlements, costs, liabilities and expenses (including reasonable attorneys' fees and litigation costs) (collectively, "**Losses**") payable to Third Parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) DexCom's breach of its [***] under this Agreement, (ii) the [***], (iii) the [***], or (iv) physical injury (including death) and/or property damage [***].

14.2. Tandem will defend and indemnify DexCom, its Affiliates, and each of its directors, officers, employees, agents, successors and assigns (collectively, "**DexCom Indemnitees**"), against all Third Party claims, suits and proceedings, and will hold the DexCom Indemnitees harmless against all Losses payable to Third Parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) Tandem's breach of its [***] under this Agreement, (ii) [***], (iii) the [***], or (iv) physical injury (including death) and/or property damage [***].

14.3. If the manufacture or use of the Combined Systems results in a claim, suit or proceeding in which DexCom and Tandem are both entitled to indemnification by the other Party pursuant to Sections 14.1 and 14.2, then the Parties will discuss in good faith their cooperation in connection with such matter, and shall [discuss in good faith an equitable allocation of each Party's indemnification obligations under this Section 14.]

14.4. If the manufacture or use of the Combined Systems results in a Third Party claim, suit, allegation, action or proceeding against Tandem or DexCom alleging infringement or misappropriation of the Intellectual Property of such Third Party and neither DexCom nor Tandem is entitled to indemnification pursuant to Sections 14.1 and 14.2 (a "**Combined System Infringement Action**"), such Party will promptly notify the other Party in writing. The Parties will [***] in connection with the Combined System Infringement Action and shall ***] of any Combined System Infringement Action. The Parties will [***] concerning any Combined System Infringement Action and, in the [***] that the [***], the Parties will [***].

14.5. At either Party's request, the Parties shall promptly enter into a common-interest agreement to protect any available attorney-client privileges and the like, on reasonable and customary terms.

14.6. A Party seeking indemnification hereunder (the "**Indemnitee**") will promptly notify the indemnifying Party (the "**Indemnitor**") of any claim, suit, proceeding, loss, or expense likely to lead to a claim for indemnification, along with all material related information in the Indemnitee's possession. The Indemnitor will have the right to manage the defense and settlement of any claim, except that [***]. The Indemnitee may not enter into any settlement of any such claim without the prior written consent of Indemnitor. The Indemnitee will [***]. The Indemnitee may [***]. In addition, the Indemnitee may [***].

14.7. Notwithstanding the foregoing in this Section 14, an Indemnitor under this Section 14 has no obligation for any Losses to the extent resulting from (i) [***], or (ii) [***].

14.8. In the event of any actual or alleged infringement of a valid claim of a patent or the actual or alleged infringement or misappropriation of any Third Party Intellectual Property by the Tandem System (or components thereof, including any DexCom CGM-Enabled Tandem Display Device, but excluding any Communication Protocol provided by DexCom), (a) Tandem shall have the right to modify the Tandem System [***] to render such Tandem System non-infringing or to be no longer misappropriating such Third Party Intellectual Property] and (b) if Tandem cannot reasonably modify the Tandem System to be non-infringing or to no longer be misappropriating such Third Party Intellectual Property, Tandem shall have the right to terminate this Agreement upon [***] written notice to DexCom.

14.9. In the event of any actual or alleged infringement of a valid claim of a patent or the actual or alleged infringement or misappropriation of any Third Party Intellectual Property by the DexCom System (or components thereof), (a) DexCom shall have the right to modify the DexCom System [***] to render such DexCom System non-infringing or to be no longer misappropriating such Third Party Intellectual Property] and (b) if [DexCom cannot reasonably modify the DexCom System to be non-infringing or to no longer be misappropriating such Third Party Intellectual Property, DexCom shall have the right to terminate this Agreement upon [***] written notice to Tandem.

14.10. In the event that either Party is entitled to indemnification of any Third Party claim, suit or proceeding under both (a) this Agreement and (b) either of the Current Development Agreements, then such Party shall only be entitled to seek indemnification for such

claim, suit or proceeding (and only entitled to recover for a particular Loss) [***] under either this Agreement or the applicable Current Development Agreement and in no event shall such Party be permitted to seek indemnification for such claim, suit or proceeding (or recover for any particular Loss) under both this Agreement and the applicable Current Development Agreement.

## 15. TERM AND TERMINATION

15.1. Term. The initial term of this Agreement will commence on the Effective Date and will continue for a period of five (5) years from the date of First Commercial Launch of any Combined System Implementation (the "**Initial Term**"), unless terminated earlier pursuant to the other provisions of this Section 15. Following the Initial Term, this Agreement shall automatically renew for successive two (2) year periods (the Initial Term and any renewal terms, collectively, the "**Term**"), unless either Party delivers to the other Party a termination notice six (6) months before the expiration of the Initial Term or the then-current renewal term.

15.2. Termination for Material Breach.

15.2.1. Either Party (the "**Notifying Party**") shall be entitled to terminate this Agreement upon written notice to the other Party if such other Party materially breaches this Agreement and fails to cure such breach within [***] following written notice from the Notifying Party specifying such breach in reasonable detail.

15.2.2. Notwithstanding the foregoing, if the allegedly breaching Party in good faith disputes such material breach or the failure to cure such material breach, then such Party shall provide the Notifying Party written notice of that dispute putting forward in reasonable detail the rationale for disputing the alleged breach or failure to cure to the Notifying Party. In such event, the Parties shall promptly undertake good faith efforts to resolve such dispute, in which case, such termination shall not be effective until [***] after the resolution as to whether such material breach has occurred (and, if it is determined that there was a material breach that remains uncured at the expiration of such [***] period); provided, that, during the pendency of any such dispute resolution the Parties shall continue performing their respective obligations, and exercising their respective rights, under this Agreement. The Parties hereby agree to take such steps as may be reasonably necessary to complete such dispute resolution as expeditiously as possible given the circumstances.

15.3. Termination for Change of Control. Each Party shall provide to the other Party written notice within the later of [***] after or as soon as permitted under Applicable Laws after undergoing a Change of Control. If such Change of Control is [***], then such other Party shall have the right (but not the obligation) to terminate this Agreement upon [***] prior written notice, provided that such notice is given within [***] following such other Party's receipt of the notice of such Change of Control. [***].

15.4. [***]. If a Party [***] asserting that [***] then the [***] may, [***]. Notwithstanding the foregoing, the [***] shall not have the right to [***] to the extent [***].

15.5. Effect of Termination.

15.5.1. General. In the case of expiration or termination of this Agreement, all rights and obligations of the Parties under this Agreement shall cease immediately, unless otherwise stated in this Agreement.

15.5.2. Accrued Rights and Obligations. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accrued prior to such expiration or termination, nor shall expiration or any termination of this Agreement preclude either Party from pursuing all rights and remedies it may have under this Agreement, at law or in equity, with respect to breach of this Agreement nor prejudice any Party's right to obtain performance of any obligation.

15.5.3. Post-Termination Support. Upon any expiration or termination of this Agreement, the Parties will (a) ensure continued provision of support services to the then-current Customers for the applicable System, as set forth in the then-current warranty terms covering such System (or such longer period as may be required under Applicable Laws) and (b) agree upon a commercially reasonable plan to effect the orderly wind-down of the activities contemplated under this Agreement with respect to the Combined Systems; provided that in no event shall such wind-down activities under subsection (b) continue for more than [***] after termination (or such longer period as may be required under Applicable Laws). The license grants set forth in this Agreement shall continue for the length of the Post Termination Support, provided that upon any expiration or termination of this Agreement, all such license grants will immediately and automatically be limited to the extent necessary to support the units of the Combined Systems for such then-current Customers.

15.5.4. Survival. In addition, Sections 1, 3.1, 8.1 (subject to Section 8.14), 8.2 (subject to Section 8.14), 8.3, 8.5, 8.6 8.7 (subject to Section 8.14), 8.8, 8.9, 8.10, 8.11, 8.12, 8.13, 8.14, 12.3, 13, 14, 15.5, 16 and 17 will survive expiration or termination of this Agreement, provided that, in the event any Section identified above expressly sets forth a limited period of time with respect to the duration or survival of such right or obligation beyond the expiration or termination of this Agreement, then such right or obligation shall survive only for such expressly identified period of time.

**16. LIMITATION OF LIABILITY.** IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OTHER PERSON OR ENTITY FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, LOST PROFITS, OR ANY OTHER SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE. THESE LIMITATIONS SHALL APPLY WHETHER OR NOT THE BREACHING PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN. IF EITHER PARTY TERMINATES THIS AGREEMENT IN ACCORDANCE WITH ANY OF ITS PROVISIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER, BECAUSE OF SUCH TERMINATION, FOR COMPENSATION, REIMBURSEMENT OR DAMAGES ON ACCOUNT OF THE LOSS OF PROSPECTIVE

PROFITS OR ANTICIPATED SALES OR ON ACCOUNT OF EXPENDITURES, INVENTORY, INVESTMENTS, LEASES OR COMMITMENTS IN CONNECTION WITH THE BUSINESS OR GOODWILL OF TANDEM OR DEXCOM.

THE FOREGOING EXCLUSION OF CERTAIN DAMAGES IN THIS SECTION DOES NOT APPLY TO DAMAGES FOR ANY OF THE FOLLOWING:

(I) BREACH OF AN OBLIGATION OF CONFIDENTIALITY UNDER SECTION 13 OR MISAPPROPRIATION OF INTELLECTUAL PROPERTY OR TRADE SECRETS; OR

(II) INDEMNIFICATION OBLIGATIONS UNDER SECTION 14, INCLUDING INDEMNIFICATION OBLIGATIONS UNDER SECTION 14 RELATED TO INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS.

**17. MISCELLANEOUS**

17.1. No Exclusivity. This Agreement shall be non-exclusive for both Tandem and DexCom, and, subject to compliance with the terms and conditions of this Agreement, shall in no way prohibit either Party from working with any Third Party, including other insulin pump or CGM and/or data management companies, or acquiring, licensing, designing, developing, marketing, selling and/or distributing products that compete, directly or indirectly, with the products contemplated by this Agreement. Each Party further acknowledges that the personnel assigned to the activities contemplated by this Agreement may also participate in other activities that may utilize technologies similar to or involve products competitive with those contemplated by this Agreement.

17.2. Subcontractors. Subject to the terms and conditions of this Agreement, either Party may subcontract the performance of its obligations under this Agreement to a Third Party [***], provided that (i) such subcontractor is bound by terms and conditions consistent, in all relevant respects, with this Agreement, including restrictions with respect to the protection and use of Confidential Information which are no less stringent than those set forth in this Agreement; (ii) such Party hereby expressly waives any requirement that the other Party exhaust any right or remedy (or otherwise proceed) against any such subcontractor for any obligation or performance hereunder prior to proceeding directly against such Party; and (iii) each Party shall be fully responsible for the performance of its subcontractors.

17.3. Force Majeure. Nonperformance of any Party will be excused to the extent that performance is prevented or delayed by strike, fire, earthquake, flood, governmental acts or orders or restrictions (other than due to a failure to comply with Applicable Laws), epidemic, pandemic, or any other reason where failure to perform is beyond the reasonable control of the nonperforming Party.

17.4. No Implied Waivers; Rights Cumulative. No failure on the part of DexCom or Tandem to exercise and no delay in exercising any right under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, nor will any partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right.

17.5. Independent Contractors. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute DexCom or Tandem as partners in the legal sense. No Party hereto will have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.

17.6. Notices. All notices, requests and other communications hereunder will be in writing and will be personally delivered or sent by registered or certified mail, return receipt requested, postage prepaid, or via email (with delivery or receipt confirmation), in each case to the respective address specified below, or such other address as may be specified in writing to the other Parties hereto:

Tandem: Tandem Diabetes Care, Inc.
11075 Roselle St.
San Diego, CA 92121
Attn: CEO
[***]

With Copy to: Tandem Diabetes Care, Inc.
11075 Roselle St.
San Diego, CA 92121
Attn: General Counsel
[***]

DexCom: DexCom, Inc.

6340 Sequence Drive
San Diego, California 92121
Attn: Legal Department
[***]

17.7. Assignment. Except as otherwise expressly provided under this Agreement, neither Party may assign or otherwise transfer this Agreement or any right or obligation hereunder without the express prior written consent of the other Party; provided that: either Party shall be permitted to effect such an assignment or other transfer of this Agreement in its entirety, without the written consent of the other Party (i) to any of its then-existing Affiliates, or (ii) in connection with a merger or the transfer or sale of all or substantially all of its business or assets related to this Agreement, or (iii) subject to Section 15.3, in connection with a Change of Control.

17.8. Modifications. No amendment or modification of any provision of this Agreement will be effective unless in writing signed by each Party hereto. No provision of this Agreement will be varied, contradicted or explained by any oral agreement, course of dealing or

performance or any other matter not set forth in an agreement in writing and signed by all Parties. In the event of a conflict between the provisions of the exhibits or the attachments to this Agreement and the provisions of this Agreement itself, the conflicting provision(s) of the Agreement shall control over the language in the exhibit or attachments, unless otherwise agreed by the Parties.

17.9. Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

17.10. Governing Law.

17.10.1 This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with, the laws of the State of California without regard for conflicts of laws principles. Disputes as to matters within the authority of the Commercial Working Team will be resolved as set forth in Section 2.3.7; provided that any dispute as to the application of such Section 2.3.7 shall be subject to this Section 17.10.

17.10.2 Notwithstanding any other provision of this Agreement, either Party may seek interim equitable relief in any court of competent jurisdiction in connection with any alleged breach or violation of Section 7.1, Section 13 or Intellectual Property rights.

17.11 Choice of Forum. The Parties hereby submit and consent to the exclusive jurisdiction of any state or federal court located in [***], and irrevocably agree that all actions or proceedings relating to this Agreement shall be litigated in such courts, and each of the Parties waives any objection which it may have based on improper venue or forum non conveniens to the conduct of any such action or proceeding in such court.

17.12 Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same instrument.

17.13 Contract Interpretation**.** The meaning of a provision of this Agreement will be considered in context with other provisions of the Agreement. The following principles apply to the construction of this Agreement unless the construction is plainly contrary to the intent of the Parties:

17.13.1 “Including” means “including but not limited to.”

17.13.2 “Or” means “and/or.”

17.13.3 “Will” and “shall” have the same meaning.

17.13.4 Language that has a generally prevailing meaning is given that meaning unless the Agreement expressly assigns a different one.

17.13.5 Technical terms used in the technical field of the subject of the Agreement are given their technical meaning.

17.13.6 Singular words may be treated as plural, and plural words may be treated as singular.

17.13.7 The masculine gender may be treated as feminine, and the feminine gender may be treated as masculine.

17.13.8 In computing any period of time under this Agreement, the day of the act, event, or default from which the designated period of time begins to run is not included. If the Agreement specifies that a period is to run for a certain number of business days, only business days are included in the count, and the period may not end on day that is not a business day.

17.14 Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

17.15 Entire Agreement. This Agreement (including the exhibits attached hereto which are hereby incorporated into this Agreement by reference), together with the Transaction Agreements, constitutes the entire agreement with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, whether written or oral, between DexCom and Tandem with respect to such subject matter. For clarity, (i) the Original G6 Development Agreement (as amended herein) shall remain in full force and effect except to the extent expressly stated otherwise herein and (ii) the License Agreement between TypeZero Technologies LLC and Tandem dated July 14, 2016, as amended, shall remain in full force and effect and shall not be amended or modified by this Agreement.

17.16 Performance by Affiliates. Either Party may discharge any obligation and exercise any right hereunder through any of its Affiliates. Each Party hereby guarantees the performance by its Affiliates of such obligations under this Agreement, and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance. Any breach by a Party's Affiliate of any of such Party's obligations under this Agreement shall be deemed a breach by such Party, and the other Party may proceed directly against such first Party without any obligation to first proceed against such Affiliate.

17.17 Standstill.

17.17.1 Except as permitted by the last sentence of this Section 17.17, during the Term of this Agreement and for a period of twelve (12) months thereafter, without the prior written consent of the Board of Directors of Tandem, DexCom and its officers, directors and Affiliates, will not directly or indirectly in any manner: (i) acquire, announce an intention to acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule 13d-3

under the Securities Exchange Act of 1934 (the "Exchange Act")) or interest in any securities or direct or indirect rights, warrants or options to acquire, or securities convertible into or exchangeable for, any securities of Tandem (ii) make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the SEC promulgated pursuant to Section 14 of the Exchange Act) any securities of Tandem with respect to any business combination, restructuring, recapitalization or similar transaction; (iii) form, join or in any way participate in a "group" within the meaning of Section 13(d)(3) of the Exchange Act with respect to any voting securities of Tandem; (iv) acquire, announce an intention to acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, exchange or otherwise, (a) any of the assets, tangible or intangible, of Tandem or (b) direct or indirect rights, warrants or options to acquire any assets of Tandem, other than in the ordinary course of business; (v) enter into any arrangement or understanding with, or otherwise assist or encourage, others to do any of the actions restricted or prohibited under clauses (i), (ii), (iii) or (iv) of this Section 17.17; (vi) otherwise act in concert with others, to seek to offer to Tandem or any of its stockholders any business combination, restructuring, recapitalization or similar transaction to or with Tandem, or (vii) take any action to control the management, Board of Directors or policies of Tandem. Notwithstanding the above, cumulative acquisitions by DexCom, including any Affiliate of DexCom, of less than one percent (1%) of Tandem's outstanding common shares shall not be deemed a breach of this provision.

17.17.2 The standstill provisions of Section 17.17.1 shall not apply in the event that, without any violation of the standstill provision, (i) a Third Party unrelated to DexCom shall have entered into a definitive agreement with Tandem to acquire more than 50% of the outstanding common stock of Tandem, or (ii) a Third Party unrelated to DexCom commences a tender offer for more than 50% of the outstanding common stock of Tandem that the board of directors of Tandem recommends. The standstill provisions of Section 17.17.1 shall automatically become applicable again if the Third Party announces its intent not to proceed with the acquisition or commenced tender offer.

17.17.3 DexCom recognizes that, if it fails to perform or breaches any of its obligations under this Section 17.17, any remedy at law may prove to be inadequate relief to Tandem. DexCom therefore agrees that Tandem is entitled to seek temporary and permanent injunctive relief or specific performance in any such case.

17.18 Original G6 Development Agreement. Section 10.7 of the Original G6 Development Agreement, is hereby amended to be Section 10.7(a) of the Original G6 Development Agreement, and Section 17.17.2 of this Agreement is hereby incorporated into the Original G6 Development Agreement as a new Section 10.7(b), provided that all reference to Section 17.17.1 of this Agreement shall be revised to be references to Section 10.7(a) of the Original G6 Development Agreement.

**[Signature Page Follows]**

**IN WITNESS WHEREOF**, the Parties hereto have caused this Agreement to be signed by duly authorized officers or representatives as of the Effective Date.

| **DEXCOM, INC.** | **TANDEM DIABETES CARE, INC.** |
| --- | --- |
| By:__ | By:__ |
| Print Name:__ | Print Name:__ |
| Title:__ | Title:__ |
| Date:__ | Date:__ |

**Exhibit A: Agreed Markets**

[***]

**Exhibit B**: **DexCom CGM Data**

[***]

**Exhibit C: DexCom Trademarks**

[***]

**Exhibit D: Tandem Insulin Data**

[***]

**Exhibit E: Tandem Trademarks**

**TANDEM DIABETES CARE TRADEMARK KEY**

**[***]**

# SUBSIDIARIES OF THE REGISTRANT

| Name of Entity | State/Country of Organization |
| --- | --- |
| Tandem Diabetes Canada | Canada |
| Sugarmate Inc. | United States |

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-222143) of Tandem Diabetes Care, Inc.,

(2) Registration Statement (Form S-8 No. 333-226944) pertaining to the 2013 Stock Incentive Plan of Tandem Diabetes Care Inc.,

(3) Registration Statement (Form S-8 No. 333-226915) pertaining to the 2013 Stock Incentive Plan, and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care Inc.,

(4) Registration Statement (Form S-8 No. 333-192406) pertaining to the 2006 Stock Incentive Plan, 2013 Stock Incentive Plan, and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care Inc.,

(5) Registration Statement (Form S-8 No. 333-202254) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc.,

(6) Registration Statement (Form S-8 No. 333-209685) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc.,

(7) Registration Statement (Form S-8 No. 333-223377) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc., and

(8) Registration Statement (Form S-8 No. 333-216529) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc;

of our reports dated February 24, 2021, with respect to the consolidated financial statements of Tandem Diabetes Care, Inc. and the effectiveness of internal control over financial reporting of Tandem Diabetes Care, Inc., included in this Annual Report (Form 10-K) of Tandem Diabetes Care, Inc. for the year ended December 31, 2020.

/s/Ernst & Young LLP

San Diego, California

February 24, 2021

**Exhibit 31.1**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, John F. Sheridan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tandem Diabetes Care, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Tandem Diabetes Care, Inc.

By: _____

John F. Sheridan
President, Chief Executive Officer

Dated: February 24, 2021

**CERTIFICATION OF CHIEF FINANCIAL OFFICER**
**PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Leigh A. Vosseller, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tandem Diabetes Care, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the

    c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

    a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

    b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Tandem Diabetes Care, Inc.

By: _____

Leigh A. Vosseller

Executive Vice President, Chief Financial Officer and Treasurer

Dated: February 24, 2021

**Exhibit 32.1**

**CERTIFICATION**
**PURSUANT TO U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Tandem Diabetes Care, Inc. (the "Company") for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John F. Sheridan, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Dated: February 24, 2021

John F. Sheridan
President, Chief Executive Officer

The *foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Exchange Act, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.*

**Exhibit 32.2**

**CERTIFICATION**
**PURSUANT TO U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of Tandem Diabetes Care, Inc. (the "Company") for the period ended December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leigh A. Vosseller, Executive Vice President, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Dated: February 24, 2021

Leigh A. Vosseller
Executive Vice President, Chief Financial Officer and Treasurer

*The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Exchange Act, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.*