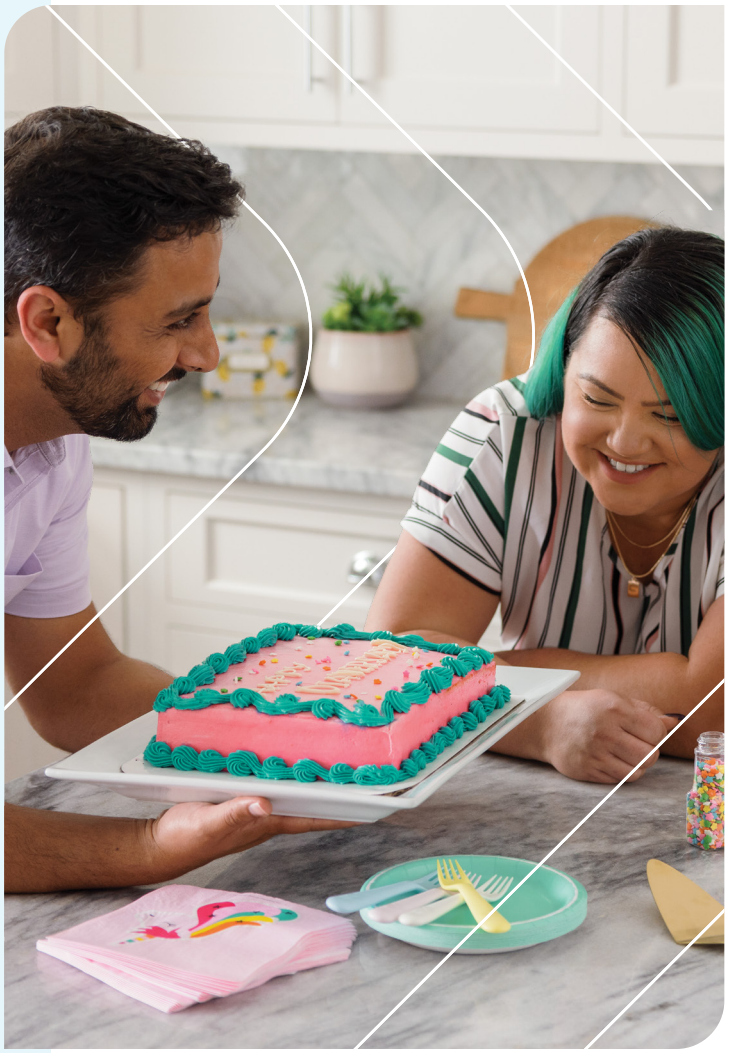
TANDEM
Diabetes Care

2021 Annual Report

positively different

Live the moments that count

Tandem Diabetes Care can keep you in the moment by helping to create a better diabetes management experience.



- Adjusts basal insulin delivery to help prevent highs and lows
- Delivers automatic correction boluses (up to one per hour)
- Dedicated Exercise Activity and Sleep Activity for more targeted control

t:slim X2
Insulin Pump
WITH Control-IQ TECHNOLOGY

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, 2021
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	☒	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, 2021, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $5.4 billion based on the closing price for the common stock of $97.40 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 17, 2022, there were 63,872,310 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for the 2022 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, 2021, 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, including the impacts of the COVID-19 global pandemic, 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 focused on the design, development and commercialization of technology solutions for people living with diabetes. Diabetes management can vary greatly from person-to-person, creating multiple market segments based on clinical needs and personal preferences. Our goal is to lead in insulin therapy management across multiple of these market segments by providing a portfolio of delivery devices, software, and data insight solutions to people living with diabetes, as well as their caregivers and healthcare providers.

Since our initial commercial launch, we have rapidly innovated and brought 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 Insulin Delivery System (t:slim X2) hardware platform represents 100% of our new pump shipments. In the four-year period ended December 31, 2021, we shipped nearly 330,000 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. Nearly 240,000 of these pumps were shipped to customers in the United States and nearly 90,000 were shipped to international markets.

Our manufacturing, sales and support activities principally focus on our flagship pump platform, the t:slim X2 and our complementary product offerings. Our simple-to-use t:slim X2 is based on our proprietary technology platform and is the smallest durable insulin pump available in the United States. We have commercially offered two different automated insulin dosing (AID) algorithms on t:slim X2, including our Control-IQ technology, which is an advanced hybrid-closed loop feature, designed to help increase a user's time in their targeted glycemic range. It was the first system cleared by the U.S. Food and Drug Administration (FDA) to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar based on continuous glucose monitoring (CGM) readings. Approximately 200,000 t:slim X2 users have our Control-IQ technology, which launched in the United States in the first quarter of 2020, and is now available in more than 20 countries. Our Control-IQ technology uses information from Dexcom Inc.'s (Dexcom) G6 sensor, which is the third generation of Dexcom CGM that we have integrated with our pump technology.

The t:slim X2 is unique in that it is the only pump on which remote software updates have been made commercially available in the United States. Now available in the countries we serve worldwide, our Tandem Device Updater (TDU), is a revolutionary tool that has allowed more than 130,000 people to update their t:slim X2 software from a personal computer. This offering is a competitive advantage as it allows us to bring new features, such as our AID technology and CGM integration, to our customers faster than the industry has been able to historically.

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. Additionally, we sell accessories such as belt clips and cases for use with pumps which are designed to enhance usability. In the United States, we also offer t:connect, our data management web 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.

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 2,000 regular full-time employees as of December 31, 2021.

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 as an acute event during childhood or adolescence. Individuals with type 1 diabetes require intensive 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 intensive insulin therapy.

The International Diabetes Federation estimates that, in 2021, approximately 297 million adults age 20-79 years worldwide had diagnosed type 1 or 2 diabetes. In addition, approximately 1.2 million children and adolescents had type 1 diabetes, and nearly 150,000 people under age 20 are estimated to be diagnosed annually. In the United States, the Centers for Disease Control and Prevention estimates that in 2021 approximately 37.3 million people were living with diabetes of which approximately 28.5 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 intensive insulin therapy. Throughout this Annual Report, we refer to these individuals as people with insulin-dependent diabetes.

Estimated Diagnosed Diabetes Prevalence[(1)]

	Worldwide	United States
Type 1	30.9 million	1.8 million
Type 2 (all therapies)	267.3 million	26.9 million
Type 2 (insulin only)	*10 million*	*2 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, 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 hyperglycemic and/or hypoglycemic 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.

More than 1 million people worldwide are estimated to use an insulin pump to manage their diabetes. We estimate that 750,000 people in the United States use an insulin pump. In addition, we estimate that approximately 450,000 people use an insulin pump in the more than 20 countries outside the United States in which our insulin pump is available. There are a variety of insulin pump manufacturers worldwide, while in the United States, 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 - May 2021
t:slim X2 with Basal-IQ technology	August 2018 - present	September 2019* - present
t:slim X2 with Control-IQ technology	January 2020 - present	July 2020* - present

*Scaled launch based on the timing of 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.

Our t:slim X2 Insulin Pump Form Factor

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 durable 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 - 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). Approximately 200,000 t:slim X2 users worldwide have our Control-IQ technology. Control-IQ was the first AID algorithm cleared by the FDA to deliver automatic correction boluses in addition to adjusting basal 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 activities that adjust the algorithm parameters 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 includes a Bluetooth radio for communicating with multiple external devices simultaneously and allows for uploading pump and CGM therapy data to the Tandem cloud via the t:connect mobile app. The t:slim X2 also includes a micro-USB port that supports charging the lithium-polymer battery, software updates and therapy data uploads.
- Mobile Control - In the first quarter of 2022, we received FDA clearance for our mobile bolus feature that allows t:slim X2 users to control a bolus of insulin through our t:connect mobile app using their personal smartphone. It is the first-ever FDA-cleared smartphone application capable of initiating insulin delivery on both iOS and Android operating systems. Our mobile app provides users with convenient and discreet data display and alerts, and functions as a pipeline for getting pump data to the cloud.

Tandem Device Updater

A 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. We have used this technology to offer in-warranty t:slim customers in the United States four different software updates for no-cost, most recently including our 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.

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 in the 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 the 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 2021, approximately 180,000 customers had downloaded our mobile app. We believe t:connect (web data management and mobile app) can serve as key components of additional health applications and services 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

Diabetes management can vary greatly from person-to-person, creating multiple market segments based on clinical needs and personal preferences. Our goal is to lead in insulin therapy management by providing a portfolio of delivery devices, software, and data insight solutions to people living with diabetes, as well as their caregivers and healthcare providers. We believe that our positively different approach uniquely positions us to significantly expand and further penetrate the varying segments of the intensive insulin using 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 developing insulin delivery systems as part of a therapy management portfolio that is designed to improve patient experience and outcomes. Our product development efforts fall into three pillars of innovation: delivery devices, device software including algorithms, and data and insights.

Delivery Devices

We are developing a family of delivery device solutions to meet the varying needs of people living with type 1 and type 2 diabetes by providing choice within our own portfolio. Preferences 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.

Mobi

Formerly referred to under its development name, t:sport, the Tandem Mobi is approximately half the size of our t:slim X2 pump, and is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. Its features include a 200-unit cartridge, an on-pump bolus button, inductive charging, an AID algorithm, and is waterproof. We anticipate that Mobi will be our first insulin pump to support full pump-control from our mobile application.

t:slim X3

Advancing our flagship t:slim platform, the t:slim X3 is being designed to provide a modernized user interface and even greater usability for our planned feature updates. It is also being designed to include enhanced technology, such as greater processing power and capacity to support our advanced algorithms, as well as increased battery life, improved durability, and wireless software update capabilities.

Mobi: Tubeless

This offering is being developed to provide an alternative tubeless infusion site option for Mobi pump users. A goal of this design is to allow for people living with diabetes to customize the way they wear their pump with each cartridge change to best suit their personal preferences and lifestyle.

Patch

Our patch pump design is in its early stages and is being developed for people living with diabetes who want a disposable tubeless solution.

Device Software

Our device software is used to control our pumps either directly through the pump's interface or through our mobile application. It also includes our AID technology, and the software used to support remote pump updatability.

Control-IQ Technology Advancements

We are driving innovation in our algorithms, emphasizing automation, personalization and simplification, all intended to continue to improve therapeutic outcomes and provide a positive patient experience characterized by simplicity and ease of use. Additionally, we have initiated clinical studies to expand the indications of our Control-IQ technology to include people with type 1 diabetes ages 2 to 5 years old, as well as people living with type 2 diabetes. We are also researching the use of different insulins with our Control-IQ technology.

Mobile Control

We are working to expand our mobile control capability. In the future, our t:connect mobile app is planned to include additional pump control features, such as full operation of our Mobi pump.

Integration

Building a robust ecosystem and portfolio around our flagship insulin pumps requires product development efforts to integrate, add and enhance complementary system components.

Dexcom CGM: 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.

Abbott CGM: 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.

Data and Insights

Our goal is to innovate across our digital health platforms by using the vast amount of data that we collect, in combination with technology such as artificial intelligence or machine learning, to provide information and insights to people living with diabetes, their caregivers and healthcare providers and insurance payors. Key areas of development include making these insights easy to understand, provided in a flexible format with mobile or web apps, and available real time. In addition, we are working to integrate health-related information from third-party sources and use our data to support current and future products under development.

Tandem Source

Expanding the capabilities of our t:connect data management application available for customers in the United States, Tandem Source is our second-generation web-based data management application that is being designed to become our single, global platform. This application enhances clinical data visualization, provides added interface customization for users to personalize how they engage with their data and for healthcare providers to better manage their care. In the second quarter of 2021, we began limited testing of an initial version of Tandem Source in the United Kingdom. We continue to develop and test new features for Tandem Source in anticipation of a future commercial release of the product.

Settings Automation

Our automation research and development activities center around opportunities for enhanced user and healthcare provider experience, and improved clinical outcomes. In support of this effort, we are working to automate our pump settings adjustments to further enhance ease of use and expand adoption of our insulin pump products.

Sales, Marketing and Customer Care

In 2021, our U.S. sales organization was comprised of approximately 95 territories, which we began expanding to approximately 110 territories at the end of the year. The vast majority of these territories are supported by a sales representative and a clinical diabetes specialist who, as a team, call on endocrinologists, nurse practitioners, primary care physicians, certified diabetes educators and potential customers. Where appropriate, some territories are supported by multiple clinical diabetes specialists. Our 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. Typically, customers are eligible for insurance reimbursement to purchase a new insulin pump once every four years; however, some plans may be limited to once every five years or have additional restrictions or requirements. Insurance reimbursement processes outside the United States vary by geography.

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. We commenced marketing and sales efforts of the t:slim X2 with G5 integration in the fourth quarter of 2018, for the t:slim X2 with Basal-IQ technology in the fourth quarter of 2019, and for the t:slim X2 with Control-IQ technology in the first quarter of 2021.

In more than 20 countries outside the United States, we have contracted with distributors who have substantial responsibility for sales, marketing and customer support efforts. We began our scaled launch outside the United States in the third quarter of 2018 after obtaining the right to affix the CE Mark to the t:slim X2 with G5 integration, followed by the scaled launches of our Basal-IQ technology and Control-IQ technology in the third quarter of 2019 and 2020, respectively.

Revenue Concentrations and Significant Customers. A small number of independent distributors in the United States have historically accounted for a significant portion of our revenues. During the year ended December 31, 2021, we made sales to approximately 44 independent distributors in the United States, and 16 independent distributors internationally. During the year ended December 31, 2021, sales to our two largest distributors accounted for a combined 21.5% of consolidated sales. During the year ended December 31, 2020, sales to our two largest distributors accounted for a combined 28.8% of consolidated sales. 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.

Training and Customer Care. In the United States and Canada, our customer care infrastructure consists of specialists focused on product training, pump and supply order processing and 24/7/365 technical services. We also provide training and technical services to our distribution partners who fulfill their customer care responsibilities outside the United States. Our goal is to offer the highest level of customer support and services as these offerings are often viewed by people with diabetes and their healthcare providers as being equally as important as the products we offer.

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 insulin cartridges have increased modestly. In the United States, 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 insulin 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. If we are not contracted with a prospective customer'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. For the year ended December 31, 2021, approximately 34% of our sales in the United States were generated through our direct third-party payor contracts, compared to approximately 30% for the same period of 2020. As of December 31, 2021, our distribution channel was comprised of approximately 44 independent distributors.

In most cases, but not all, our network of distributors allows us access to prospective customers who are covered by commercial payors with whom we are not contracted, at in-network rates that are generally more affordable for our customers. The most significant exception was in the period from July 2016 to June 2020. During that time, only a small subset of UnitedHealthcare's members were able to obtain reimbursement for our products through our direct or distribution channels, primarily select pediatric and government plan members. In July 2020, we were named as a network provider by UnitedHealthcare.

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

Manufacturing and Quality Assurance

Our pump products are currently assembled, tested and packaged at our facilities in San Diego, California. Prior to 2020, we manufactured and tested our disposable cartridge products at our Barnes Canyon facility in San Diego, California. Since that time, we have transferred a substantial portion of our cartridge manufacturing and testing to an experienced third-party contract manufacturer to provide us additional flexibility in scaling our business while creating additional leverage. We also utilize external third parties for sterilization of our finished cartridges. All finished cartridges are packaged for sale at our facilities in San Diego.

Outside suppliers are the source for components and some sub-assemblies in the production of our insulin pumps and cartridges. In addition, we purchase all of our currently marketed infusion sets from a third party supplier, Unomedical A/S, a subsidiary of ConvaTec Group. Unomedical is responsible for all manufacturing, testing, sterilization and packaging of the infusion sets under our brands. 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 follow and comply with a comprehensive set of quality certifications and standards. For example, in the product development process, we follow standards such as IEC 62304:2006, the international consensus for medical device software lifecycle processes, ISO 14971:2019 for the application of risk management to medical devices, and IEC 60601 which is a series of technical standards regarding the basic safety and essential performance of medical electrical equipment. In addition, we have built and maintain our quality management system to comply with the FDA's Code of Federal Regulations Title 21 CFR Parts 820, 806, 803 and 11, ISO 13485 and 14971, as well as any other country-specific requirement where Tandem products are distributed.

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 with specialist experience across diverse engineering disciplines 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 had 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, 2021, our patent portfolio consisted of approximately 117 issued U.S. patents and 83 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2022 and 2040. Our foreign patent portfolio consisted of approximately 41 issued patents and 15 pending patent applications in other countries throughout the world. Of these, our issued foreign patents expire between approximately 2025 and 2036. In addition, we also have 94 trademark registrations, including 18 U.S. trademark registrations and 76 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.

In July 2020, we entered into a non-exclusive patent cross-license agreement for certain technologies in the field of diabetes with Medtronic plc (Medtronic). 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 markets worldwide with a number of companies that manufacture insulin delivery devices, such as Medtronic MiniMed, a division of Medtronic, and Insulet Corporation (Insulet). In addition, Eli Lilly & Co. (Eli Lilly) announced a collaboration to commercialize a version of Ypsomed AG's existing insulin pump as part of a to-be-developed system and Becton Dickinson and Company announced its intention to spin off its diabetes care business as a separate publicly-traded company. 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 markets outside the U.S. 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. We anticipate that most of our future AID offerings will require supporting clinical data, either from clinical trials or potentially from evidence that we are able to collect through real-world use of our products. 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.

We are currently sponsoring or supporting several clinical trials that are intended to support future enhancements to our AID products.

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 Act, 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 Health Administration programs.

Federal Anti-Kickback Statute. 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 were meaningfully expanded beginning in 2021 and we implemented 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 the United Kingdom's (UK) exit from the European Economic Area, commonly referred to as Brexit, 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

We have implemented, and continually improved, an Information Security Program that was developed to secure our non-public information, systems, networks, databases, and workstations. This program is built on fundamental data security principles, which create the baseline suite of security controls that we have adopted to govern our current and future data security compliance mandates and practices. 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

We have a focused effort on understanding the environmental impact of our business, both the direct impact as an employer and manufacturer, as well as the impact resulting from consumer use of the products we offer. We have metrics and initiatives across the business in support of these efforts, and our company goals for 2022 include driving economic efficiencies and process improvement, with environmental impact in mind.

As an employer and manufacturer, we are mindful of the impact our facilities and employee transportation have on the environment. In September 2021, we signed a new lease agreement for approximately 180,000 square feet of additional general administrative, laboratory, and research and development office space. This building is certified under the U.S. Green Building Council's Leadership in Energy and Environmental Design (LEED), and energy use and environmental impact were key factors in the selection of our new facility. We intend to use this facility, which features a solar generating power system, for our operations that are currently located at four separate buildings, which is anticipated to result in more efficient energy use and reduced consumption of resources. In addition, we have reduced our general administrative space requirements, as in 2021 we adopted a remote-hybrid work policy for a majority of employees following the recent periods in which they worked remotely due to the COVID-19 pandemic. This helps to reduce carbon emissions associated with employees commuting to our facility on a daily basis.

We have metrics in place to monitor our environmental impact on a monthly basis, including electricity consumption, electricity cost, and weight of waste (non-hazardous, hazardous, biohazard, universal and recycling). In addition, we have initiatives in place in support of monitoring and reducing our environmental impact. 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.

The environmental impact of consumer use of our product offerings is also a focus for our company. This starts with innovation in our product design. The t:slim X2 has two key environmental design features that are a competitive advantage:

1. 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 13 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 26.4 million batteries.

2. Since August 2017, more than 130,000 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. The t:slim X2 is unique in that it is the only pump on which remote software updates have been made commercially available in the United States.

In addition, we utilize a refurbishment program that allows for the use of key components thereby reducing electronic waste. We are also mindful of the environmental impact of our supply chain efforts. For example, we utilize sea freight for a majority of our international shipments, which has lower emissions than road or air. We also use electronic forklifts and repeat pallet use in our warehouse operations. Our third party logistics provider, Omni, signed the Climate Pledge in Q3 2021 committing to net zero carbon by 2040. In addition, our supplier agreements warrant that all products sold to us are manufactured in full compliance with all applicable national, provincial, state and local environmental, health and safety statutes, acts, ordinances, rules, codes, standards, laws and regulations and elimination of human trafficking, child labor, or modern slavery. We also receive annual conflict mineral disclosure from our suppliers.

We continue to use innovative techniques to reduce environmental impact and deliver products that can change people's lives. For example, our product pipeline includes Mobi Tubeless, which is being developed to provide a tubeless infusion site option for our Mobi pump that allows the pump portion to be reused rather than disposed of every three days. Our research and development efforts also include infusion set innovations that focus on extending the length of infusion set wear, thereby reducing the number of sets used per customer, and reducing waste.

Community Outreach and Impact

We strive to be a good corporate citizen in the communities in which our employees live and work. 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 JDRF, Beyond type 1, Connected in Motion, Riding on Insulin, College Diabetes Network, Diabetes Exercise and Camping Association, and Touched by Type 1, among others, as well as regional diabetes events such as Children with Diabetes, Taking Control of Your Diabetes, American Diabetes Association, and camps where our employees participate and volunteer.

Our employee community outreach efforts include donations and volunteer work, serving on boards and advisory committees and other corporate and individual actions. Examples of our corporate giving efforts include:

- Bright Funds Employee Giving & Volunteering platform launch, which provides employees choice to where they direct giving and volunteering time for causes of significance to them.
- JDRF annual employee fundraising campaign in support of diabetes research.
- Athena sponsorships in support of women in STEM leadership in San Diego, including the Lifting While Climbing Summit and "Clinical Trial Diversity: Closing the Gap to Achieve Health Equity" event.
- Virtual Spanish Summit hosted by our community partners, JDRF and Beyond Type One designed to reach the Spanish-speaking type 1 diabetes population in the United States.
- Diabetes Camp Partnerships with Camp Conrad Chinnock and Camp Kudzu that specifically support underserved communities.
- Spare a Rose campaign in support of Life For a Child which provides under-resourced countries with insulin, supplies and diabetes education.

Human Capital

We are committed to creating and maintaining a safe, diverse, and inclusive community for all employees while we serve our customers and fulfill our mission to improve the lives of people with diabetes. As of December 31, 2021, we had approximately 2,000 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 training and quality related activities, 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. Our core values statement was created by our employees in a bottom-up, cross-functional process that we revisit and refresh on a periodic basis. Our *Words We Live By* describe our core values and reflect who we are and the way our employees interact with one another, our customers, partners and stockholders. *Innovate Every Day* 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. *Team 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. *People First* 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.

In 2021, we conducted our first employee engagement survey through Gallup, a leading global consulting firm on employee engagement. More than 90% of our employees participated, and the results demonstrated that our overall engagement levels exceed Gallup's averages worldwide, in the United States, and in life sciences. The results also reflected that we are a mission-driven company with employees' response on our strength of purpose far exceeding Gallup's measurement for world class. 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, Equity and Inclusion

Our diversity, equity and inclusion (DE&I) goals focus on cultivating and encouraging an inclusive and equitable culture where diversity of thought is represented and can thrive throughout our organization. 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 continuing to raise the bar in the field of diabetes technology.

2021 was our first full year of having a DE&I Council. This Council is sponsored by executive management and we provide regular updates to our Board of Directors on its initiatives and progress. It 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. Our DE&I efforts are focused on diabetes representation and access, representation in leadership, representation in technology roles and pro-inclusion. In addition, we are 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.

Many of our community outreach and impact efforts are focused on support for diversity-related causes. We have also been expanding our support for diabetes-related clinical investigators, camps, and other organizations that are actively focusing their research on underserved groups. We embrace the importance of diverse cultural perspectives in the customer stories we promote, which is reflected in our website articles, social media posts, and roster of compensated ambassadors, and influences our sponsorship and grant commitments.

Organizational Development

Attracting, developing and retaining employees is critical to our longer-term success. In mid-2021, we began evolving our organizational structure by creating new senior leadership positions to strengthen our management team as we prepare for continued growth, near-term product expansions and the execution of our longer-term product pipeline strategy. In addition, 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. In 2021, more than 150 employees participated in our leadership development programs. In addition, more than 800 employees participated in our first virtual Peak Performance Summit in 2021, with both internal and external experts as part of Employee Development Week.

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, health savings accounts, flexible spending accounts, life and disability coverage, voluntary accident, critical illness, legal and identity theft coverage, employee discount program, and an employee loaner pump program. In addition, we engage nationally recognized outside compensation and benefits consulting firms 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.

In 2021, we implemented safety management software to better manage safety inspections, assessments, and safety data sheets. 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 through the implementation of new protocols, trainings and communications.

COVID-19 Global Pandemic Impact and Considerations

Our business has been impacted in a variety of ways since the onset of the COVID-19 global pandemic in early 2020, and will likely continue to be impacted for the remainder of 2022. Specific factors that have influenced our financial results and the way in which we operate include fluctuations in shelter-in-place restrictions, supply chain constraints, labor shortages, the timing and extent of vaccine availability and surges in infection and hospitalization rates as new COVID variants have emerged. Throughout this time, we have responded to each of these unique challenges, while prioritizing the health and safety of our employees and customers and working diligently to maintain a continuous supply of products, training and customer support.

Most notably, our sales results reflected a high degree of variability across the quarters during this time, unlike historical seasonal trends. We experienced a modest impact early in 2020, which became more pronounced and continued in varying degrees as the pandemic progressed. Initially, the impact on our business was relatively consistent worldwide but we have since seen variations in individual markets based on local conditions and anticipate ongoing fluctuations may continue.

Our inventory levels have also fluctuated as we respond to supply chain constraints, due to availability of components from the various suppliers we use to build our products. While we have adequate raw material inventory for a substantial portion of our pump and cartridge components, we are below our targeted stocking levels for others. In early 2020, we initiated regular discussions with our key suppliers regarding their abilities to fulfill existing orders and assess their ongoing capacity. Over the course of the pandemic, we have increased the frequency of those communications. We continue to monitor factors that could negatively impact our supply chain, such as global shortages of semiconductors, copper and paper, as well as custom components for our insulin pumps and cartridges where we rely on a limited number of qualified suppliers. We anticipate experiencing continued challenges managing supply chain constraints, including the potential for limitations on availability of components as well as increased purchase costs.

Generally, our entire operation has been impacted as we navigate the generalized labor shortages impacting global markets. The labor challenges affect our ability to recruit and hire key talent at the same pace as in years past, but we remain active in our recruiting efforts and competitive in our offerings. In particular, these labor challenges combined with regulatory delays have impacted our product development and launch timelines. The FDA has generally stated that its review process may take longer than normal due to prioritization of COVID-related products and services. We have experienced lengthy delays in the review of pending submissions with the FDA, making regulatory timelines increasingly difficult to predict.

We have adapted well in our commercial operations and customer-facing functions. Our sales organization balances remote and in-person interactions based on the needs and requirements of the customers with whom they interact. For example, prior to the onset of the pandemic, nearly all trainings for customers purchasing our pump platform were in-person. We quickly pivoted to nearly all trainings being provided on remote platforms. Since that time, we have achieved a balance that includes options for the individual based on their unique needs. We continue to see variability across the markets in which we operate and anticipate these fluctuations between in-person and remote interactions will continue.

Our facilities have been closed for non-essential purposes throughout most of the pandemic, while our manufacturing operations were deemed essential due to the critical nature of our product and the communities that we serve. To help ensure the safety and health of those employees working in our facilities, we have implemented preventative measures by requiring employees to wear masks and perform temperature checks before each shift. We are currently developing a return-to-work strategy for the rest of the organization that will incorporate a hybrid approach to meet the needs of our employees, as well as optimize usage of our facilities.

Overall, we anticipate that our sales and operating results will continue to be impacted and subject to unpredictable variability. The full extent of the impact of the 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.

Management

John F. Sheridan (age 66) 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 52) has served as our Executive Vice President and Chief Operating Officer since February 2022 and is responsible for the Company's manufacturing, supply chain, quality, regulatory and clinical functions. He previously served as our Chief Business Operations and Compliance Officer since November 2020, as our Executive Vice President, Chief Legal and Compliance Officer since April 2019, and as General Counsel 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. 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.

Rick A. Carpenter (age 58) has served as our Chief Technical Officer since November 2021. Prior to joining our company, Mr. Carpenter served from February 2020 as the Senior Vice President of Engineering at Inseego Corporation, where he led the worldwide engineering team and was responsible for device hardware and software, cloud software, quality assurance, regulatory and product certification and technical account management. From April 2017 to January 2020, he was the General Manager of the IoMT Business and the Senior Director of Engineering at Capsule Technologies, a company that integrates medical devices and wearables into a secure medical grade system that collects data and provides it to healthcare professionals for patient monitoring. Prior to that, from May 2009 until March 2017, Mr. Carpenter served as the Senior Vice President of Engineering at Smith Micro Software. Earlier in his career, he held various engineering development and leadership roles at Nextwave Wireless, Sierra Wireless, General Dynamics, Motorola and Denso. Mr. Carpenter received a BS in Computer Science from The University of Texas Permian Basin, and completed coursework for a MS in Computer Science from The University of Texas at Arlington.

Elizabeth A. Gasser (age 46) 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.

Brian B. Hansen (age 54) 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.

Shannon M. Hansen (age 56) has served as Senior Vice President, General Counsel, Chief Compliance Officer and Secretary since January 2022 and is responsible for the Company's legal, compliance and privacy functions. Before joining our Company, Ms. Hansen served as General Counsel, Corporate Secretary and Chief Privacy Officer at Alto Pharmacy from April 2020 to September 2021, where she oversaw the development of the legal, privacy and compliance functions. Before her role at Alto Pharmacy, she held various leadership roles at Abbott, including Division Vice President & Associate General Counsel, Patents from June 2017 to February 2020, Division Vice President and Associate General Counsel for the Diabetes, Vascular and Structural Heart divisions from June 2015 to June 2017, Head of Legal for the Diabetes Division from January 2013 to June 2015, and Division Counsel, Patents from May 2009 to December 2012. Earlier in her career, she served as a partner at Kirkland & Ellis LLP, a global law firm, and worked in the Solicitor's Office at the United States Patent and Trademark Office. Ms. Hansen holds a BS in Chemical Engineering from Carnegie Mellon University, and a JD from Stanford Law School.

James Leal (age 58) has served as our Senior Vice President, Operations since August, 2017. Dr. Leal joined Tandem in October 2010 as Vice President, Operations. Previously, Dr. Leal was the Vice President of Manufacturing and Field Support for Volcano Corporation and held Director Roles with CardioNet, Inc. and Digirad Corporation. He held Senior Engineering roles with FlipChip Technologies and Hughes Aircraft Company. He has won several awards including a Hughes Aircraft Doctoral and Masters Fellowship and was a recognized nominee for Most Promising Hispanic Engineer of the Year Award. Dr. Leal is a University of Arizona graduate with a B.S. in Metallurgical Engineering, and both a M.S. and a PhD in Materials Science and Engineering.

Susan M. Morrison (age 42) 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, program 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 49) 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 fail to meet our sales forecasts if we are 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 and development-stage testing 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.
- Global economic and market uncertainty may adversely impact our business, financial condition and operating results.

- 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.
- If we are found to have violated laws concerning the privacy and security of patient health information or other personal information, civil or criminal penalties could increase our liabilities and harm our business.
- 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 the integration of 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.
- Patent litigation is not uncommon in the medical device industry, and we may be 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, and regulatory approvals could be denied or delayed.
- New products or modifications to our existing products may require new regulatory approvals, or require us to cease marketing or recall modified products.
- If we or our third-party suppliers, contract manufacturers or service providers fail to comply with manufacturing regulations, it could impair our ability to market our products.
- A recall of our products, or the discovery of safety issues with our products, could have a negative impact on us.
- Our failure to comply with foreign, 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.
- We may be at increased risk of securities class action litigation.

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.
- Conversion of the Notes may dilute the ownership interest of existing stockholders.
- The Capped Call Transactions may affect the value of the Notes and our common stock.
- We are subject to counterparty risk with respect to the Capped Call Transactions.

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, 2021, we had an accumulated deficit of $634.6 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 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, 2021 and 2020, our gross profit was $376.2 million and $260.5 million, respectively. Although we have achieved a positive overall gross margin and generated net income for the first time for the year ended December 31, 2021, we may still operate at a net loss from time to time due to fluctuations in our business.

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, training 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;
- 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, Abbott, 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, and that it may continue to have, an adverse impact on sales of our products. Furthermore, any disruption in our supply chain could negatively impact our ability to manufacture or otherwise supply sufficient product quantities to meet current customer demand, or any unexpected increase in demand, which 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 resulted in a rapid and sustained rise in unemployment rates and decreases in global economic activity. While we observed some increase in economic activity in the United States beginning in the second quarter of 2021, the overall scope of the COVID-19 global pandemic and its impacts continue to fluctuate, and in some instances worsen, in various regions worldwide. Although the overall negative impact from the COVID-19 global pandemic on our business 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 notwithstanding relaxed travel and social distancing restrictions. Further, certain development activities, such as human factors studies associated with our product development efforts, activities to support the manufacturing scale-up for new products and the recruitment of participants in ongoing clinical studies, were modified or delayed due to impacts of the COVID-19 global pandemic, which has and continues to impact 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 appropriate 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, we continue to limit employee travel and visitors to our facilities, and many of our employees who are able to perform their job function outside of our facilities remain in 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 for our field-based sales and clinical employees have resumed on a limited basis and are gradually increasing, though the scope and scale vary by geography 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. We temporarily 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 could impact future periods. In addition, for the duration of the COVID-19 global pandemic, some of 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. As the COVID-19 global pandemic improves, we anticipate that more of our employees will return to working in our facilities under modified conditions. We are implementing protocols and safety measures and for the time being are continuing to limit the number of employees allowed in our facilities while planning for increased occupancy at a later date.

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 has and could continue to have a material adverse impact on the operations of one or more of our suppliers. These adverse impacts on our suppliers 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 since the beginning of the pandemic our primary infusion set manufacturer experienced certain production and 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. Additionally, we have been and may continue to be negatively impacted by global shortages of semiconductors and copper, which could limit our insulin pump manufacturing capacity. If we continue to experience these or similar manufacturing challenges, or if these challenges worsen in the future, it could increase our manufacturing costs, disrupt our manufacturing operations, negatively impact our 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 and any resulting changes to general economic conditions in the countries in which we operate and sell our products. Further spread or escalation of the COVID-19 global pandemic, a resurgence of the pandemic in the United States, or even the threat or perception that this could occur, or any protracted duration of decreased economic activity or increase in inflation, could have a material adverse impact on our business, operations and financial results and could negatively impact or disrupt our plans to have employees return to our facilities.

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 infusion sets, insulin cartridges and other supplies. In addition, our pumps are designed and tested to remain effective for at least four years and a 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 as anticipated or projected 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 the cancellation or postponement of company-sponsored educational events, as well as third-party conferences, trade shows and similar events. The impact continues even as some third-party conferences, trade shows and events are being held remotely from time to time, which restricts our engagement with customers and healthcare providers. 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. In addition, Eli Lilly has announced a collaboration to commercialize an existing third-party insulin pump as part of a to-be-developed system and Becton Dickinson and Company announced its intention to spin off its diabetes care business as a separate publicly-traded company. 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 is selling a connected insulin pen delivery device. Additionally, Medtronic recently announced the launch in select European countries of an infusion set that can be worn for up to seven days.

In addition, the competitive environment in which we operate has resulted and may continue to result in competitive pressures on our manufacturers, suppliers, distributors, collaboration partners and other business constituents. For example, we have entered into development agreements with Dexcom, which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. Abbott also offers glucose sensors which compete with Dexcom CGMs. In June 2020, we entered into an agreement with Abbott to develop and commercialize integrated diabetes solutions using Abbott's glucose sensor. 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 negatively 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 continue to delay their purchasing decisions, or physicians may continue to 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. Government involvement in funding healthcare may limit access to or reimbursement for the Company's products. In addition, existing contracts with third-party payors generally include numerous quality and compliance related requirements, including audit rights, and can be modified or terminated by the third-party payor without cause and with little or no notice to us. Our compliance with the administrative procedures or requirements may result in increased costs for us and delays in processing approvals by those third-party payors for customers to obtain coverage for our products, and any payor audits of our compliance obligations may result in requests for refunds or other costs. 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 the first quarter of 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 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 and new clinical training staff. 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. These risks may be greater now than in the past due to current general labor shortages in the United States, and in particular in our office locations in San Diego, California and Boise, Idaho.

We expect the oversight of our sales, marketing, clinical and customer service personnel will continue to place significant burdens on our management team, which may be compounded as we manage remote employees during the COVID-19 global pandemic and as we work towards returning personnel to our facilities. 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, 2021, our two largest independent distributors in the United States collectively comprised approximately 21% of our worldwide sales, and our three largest independent international distributors collectively comprised approximately 55% 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 participants in our current and anticipated clinical trials and human factors studies, and the failure to successfully complete those trials and studies 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 participants in our clinical trials or users in our human factors testing and other third parties to manage such trials and testing 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 or other studies. 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 or other studies, 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. Further, our view is that diabetes management can vary greatly from person to person, creating multiple market segments based on clinical needs and personal preferences. 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 has made, and may continue to 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 and other studies 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 is 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 and we are implementing safety measures and protocols as employees transition back into our facilities. We also temporarily increased our staffing in certain operations in order to mitigate potential risks associated with increases in unplanned employee absences or illness. In addition, due to shortages of specific components, we have had to qualify alternative components or source components from alternative distributors. 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. We are also subject to other general market and economic conditions that may increase our expenses, including unpredictable variability in commodity prices, wage increases and inflation. 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 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 due to shipping delays at ports of entry or exit, the impact of the COVID-19 global pandemic, or other issues, 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, 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, at various times our cartridge inventory was below our targeted stocking levels and our inventory of certain pump and cartridge components are currently below our targeted stocking levels. We continue to monitor factors that could negatively impact our supply chain, such as shortages of semiconductors and copper that are needed to manufacture our insulin pumps and accessories and custom components for our insulin pumps and cartridges where we rely on a limited number of qualified suppliers. If we continue to experience these or similar manufacturing challenges, or if these challenges worsen 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 insulin 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, inability to obtain raw materials or other components, or problems with their own suppliers. For instance, we are currently subject to allocation limits for certain semiconductor components. 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, Mexico and Costa Rica. Depending on a limited number of suppliers exposes us to risks, including limited control over costs, including 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 at acceptable prices, or at all. 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. We are actively pursuing alternative suppliers of several existing components and qualifying new alternatives to existing select components, but there is no assurance that we will be able to identify alternative sources that meet our requirements and at comparable prices, or at all. 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. By the same token, if we underestimate future demand we may be unable to meet future production requirements or our inventory of critical materials may be below our targeted stocking levels. We expect it will be particularly difficult to accurately forecast demand during the global pandemic and even for some time while travel and social-distancing restrictions are lifted.

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, some manufacturing processes, and the majority of our 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 two years 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 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 as we continue to scale our business operations and add manufacturing requirements for products currently under development. In addition, beginning in 2020 we outsourced a portion of our cartridge manufacturing demand to an experienced third-party contract manufacturer and we expect to increase our reliance on this third party cartridge manufacturer over the next 24 months while reducing our own internal t:slim cartridge manufacturing capacity in our existing facility. 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 third-party 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 facilities, increasing reliance on third-party contract manufacturers 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 third-party contract manufacturing.

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 on a timely basis.

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. We have also recently experienced delays in the regulatory review and approval process, including due to the impacts of the current global pandemic. 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 latest products in a controlled setting are only available over the past few years. 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. We remain subject to regulatory and product liability risks, and 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 have caused or carry a risk of causing 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's 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, and our third-party contract manufacturers are located, 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, our Tandem Source data management platform, 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 the 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 third-party service providers are subject to similar risks. Whether or not our security measures and those of our third-party 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 commenced use 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 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. It is possible that our legal expenses and defense costs, alone or together with any monetary damages, may exceed the limits of any applicable insurance coverage that we carry.

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 foreign, 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. In addition, entities operating in the healthcare industry have increasingly become targets for hackers. 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 privacy and security laws (such as the CCPA) 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 over the past year we have also experienced general labor shortages in various areas of our business. We cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. In addition, we may need to increase employee wages and benefits in order to attract and retain our personnel, which would increase our expenses. 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, and any general labor shortages could also negatively impact our ability to expand and scale functions that are needed to support the ongoing development of our products and the future growth of our business. Each member of senior management, as well as the vast majority of our 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 and other EU member state directives;
- 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, maintaining or operating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs, impairment charges or write-offs 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 have experienced and may continue to experience one or more of these risks in connection with our acquisition of Sugarmate, which was completed in 2020. For example, as a result of an update to Dexcom's data systems in October 2021, Sugarmate users in all geographies were unable to receive Dexcom CGM data in the Sugarmate app. Connections for users in the United States were restored in December 2021 but we have not yet restored connections in other geographies. While we continue to work towards restoring service for most users outside the US, we may not be able to restore services to all countries on the same timeline, or restore services to all users. These service disruptions, or other problems utilizing the mobile app or other assets acquired from Sugarmate, could adversely affect our ability to realize the expected benefits from the Sugarmate acquisition. Further, it is possible that we could experience a loss of Sugarmate customers or reputational harm arising from this service outage or similar events, which could adversely affect our business, results of operations, and financial condition.

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, 2021, we had $623.8 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, increasing the size of our facility footprint due to increases in 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 and distribution capabilities, including leasing additional property, hiring additional personnel, and purchasing additional equipment;
- the expenses associated with developing and commercializing our proposed products or technologies;
- 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 current or future 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 commercialize and sell our current and future products and our ability to increase sales and gross profit from our products, including insulin pumps and the related insulin cartridges and infusion sets;
- 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, or adverse regulatory or legal actions, 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 comprehensively 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, 2021, our patent portfolio consisted of approximately 117 issued U.S. patents and 83 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2022 and 2040. Our foreign patent portfolio consisted of approximately 41 issued patents and 15 pending patent applications in other countries throughout the world. Of these, our issued foreign patents expire between approximately 2025 and 2036. In addition, we also have 94 trademark registrations, including 18 U.S. trademark registrations and 76 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, it could result in us forfeiting certain patent rights in that jurisdiction. Further, we cannot assure you that any of our patent applications will be granted 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 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 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 one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other intellectual property 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 protection 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 narrowly interpreted 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.

Patent litigation in the medical device industry is not uncommon, 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 considerable 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 their intellectual property relating 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 allegedly infringes third-party 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 allegedly infringe third-party 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, inspection, and sale of medical devices. We are subject to product liability lawsuits alleging that component failures, manufacturing flaws, manufacturing defects, negligence in manufacturing, design defects, negligence in design, or inadequate disclosure of product-related risks, warnings, 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 in the United States 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 and international regulatory authorities 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 Food, Drug and Cosmetic Act 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 or other regulatory authority requires a more rigorous examination for our 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 or other regulatory authority 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 pre-clinical studies or 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 or other regulatory authority 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 and 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.

Since our inception we have been audited or inspected by various regulatory authorities on numerous occasions. We also regularly respond to routine inquiries from regulatory authorities. In some instances these audits, inspections and inquiries result in findings that require us to take corrective actions, which could include changes to our internal policies, procedures or operations, revisions to our product labeling, issuances of customer notifications or the initiation of product recalls, any of which could result in product liability claims and lawsuits. Since mid-2021 we have completed several audits and inspections, some of which include findings that require us to take one or more corrective actions. Our failure to appropriately respond to these findings and take corrective actions, or our failure to comply with applicable regulations for any other reason, 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 in 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.

New products or modifications to our existing 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 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. We also are subject to similar requirements by regulatory authorities in other geographies. The FDA and other regulatory bodies routinely audit our compliance with the QSR and equivalent international requirements through periodic announced and unannounced inspections of manufacturing and other facilities which may occur at any time. We cannot assure you that our facilities or our contract manufacturer or third-party suppliers' facilities would pass any 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 third-party suppliers, contract 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 serious injury or death in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to serious injury or death. 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, the Australian Therapeutic Goods Administration (TGA) temporarily suspended our pump product sales in Australia commencing November 24, 2020, however sales of pump-related supplies were allowed to continue. Effective April 1, 2021, following discussions with the TGA, the temporary suspension was lifted for our t:slim X2 with Basal-IQ technology, subject to certain post-market surveillance obligations and other conditions. We have discontinued sales of earlier generation products in Australia and to date we have not offered our Control-IQ technology in Australia but may elect to do so in the future. There can be no assurance that the TGA will not reimpose the suspension of our pump product sales or impose other regulatory restrictions in the future. In addition, other regulatory bodies may take similar actions against us, and any regulatory challenges we encounter could have a negative impact on our product sales and harm our reputation. Any corrective actions we take in response to this action or future matters with the TGA or other regulatory bodies, whether voluntary or involuntary, will require the dedication of our time and capital, may 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;

- 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; and

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

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 have been 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. 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 such modifications on the health care industry and our business operations is not yet known. Further, the federal government has 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 and whether they might be 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 fines 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 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. In addition, the ACA continues to be the subject of various legal challenges. 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;
- the announcement of a product recall, suspension or other safety notice associated with our products or the products of our competitors, or other similar regulatory enforcement actions;
- the inclusion or removal of our stock from one or more market indexes;
- 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, 2021, we had accumulated federal and state net operating loss (NOL) carryforwards of approximately $301.2 million, and $291.0 million, respectively, which included the reduction recorded in 2019 discussed below. Of the total federal NOL carryforwards, approximately $112.1 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 $189.1 million will begin to expire in 2026, and state tax loss carryforwards continue to expire in 2022, 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.

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, the principal, premium, if any, and interest, if any, may become 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 due to the Notes Offering:

- our level of vulnerability to adverse economic conditions and competitive pressures may be heightened;

- we are 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.

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, 2021, we occupied facilities with an aggregate total of approximately 367,000 square feet, increasing to 511,000 square feet in the first quarter of 2022, as follows:

United States

- 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: 73,929 square feet of general office space located on Vista Sorrento Parkway in San Diego, California, which is scheduled to expire in January 2028. We have two options to extend the term of the Vista Sorrento Parkway lease, with each option providing for an additional period of five years.

- 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.

- 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.

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

- High Bluff Lease: 31,372 square feet of general office space located on High Bluff Drive, in San Diego, California. The High Bluff lease is a direct lease agreement for the same property subject to the High Bluff sublease. The lease term begins in April 2022 following the termination of the High Bluff sublease in March 2022, and is scheduled to expire in March 2024.

- Tech Center Lease: 181,949 square feet of general administrative, laboratory and research and development office space located on High Bluff Drive in San Diego, California. Phase I of the lease, consisting of 143,850 square feet, is expected to commence in the first quarter of 2022. Phase II of the lease, consisting of 38,099 square feet, is expected to commence in 2025. The lease term covering both Phase I and Phase II is currently expected to expire in April 2035. We have two options to extend the term of the lease, with each option providing for an additional period of five years.

- 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.

International

- 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 of no less than one month to the landlord.

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 April 2020, we were named as a defendant in four federal class action lawsuits relating to a data breach we experienced in January 2020, each of which was subsequently dismissed.

In addition, in May 2020 we were named as a defendant in three California state court class action lawsuits arising from the same data breach. 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), California Consumer Privacy Act (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; (ii) the demurrer of the CCPA claim was sustained; and (iii) the demurrer of the UCL and contract claims were sustained with leave to amend the pending complaint. A second demurrer was heard by the Court on March 29, 2021 with the following outcome: (i) the demurrer of the CMIA claim was denied; and (ii) the demurrer of the UCL and contract claims were narrowed in scope to dismiss three plaintiffs for failing to allege cognizable damages or injuries-in-fact, resulting in two remaining plaintiffs. Although we intend to vigorously defend against these claims, there is no guarantee that we will prevail. We are presently unable to determine the ultimate outcome of these lawsuits or determine the amount (or range) of possible losses associated with the lawsuits.

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 the County of San Diego. 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 case was brought as a class action and was later amended to also include a representative action under the California Private Attorney General Act, or PAGA. The 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. The parties recently agreed to resolve all claims in the lawsuit. The settlement of claims covered by the PAGA matter were approved by the Superior Court of the State of California in the County of San Diego on September 21, 2021 and settlement amounts were disbursed in 2021. Also in October 2021, a settlement of the class action related claims was preliminarily approved by an independent arbitrator mutually acceptable to both parties. The class action settlement is intended to resolve the claims of the individual plaintiff, as well as the remaining members of the class, unless an individual class member submits a timely request for exclusion. The material terms of the settlement are set forth in a binding Memorandum of Agreement dated as of July 1, 2021, which is subject to the completion of a number of conditions, as well as final approval by the independent arbitrator. There is no guarantee that the conditions will be met or that final approval will be obtained. If the final class settlement is not approved, or if other conditions to approval of the settlement are not met, the case will continue and the Company will continue to vigorously defend against the claims.

From time to time, we are involved in various other legal proceedings, regulatory matters, and other disputes or claims arising from or related to the normal course of our business activities, including actions with respect to intellectual property, data privacy, employment, regulatory, product liability and contractual matters. Although the results of legal proceedings, disputes and other 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.

PART II

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, 2021		
First Quarter	$ 105.00	$ 77.77
Second Quarter	$ 100.80	$ 76.19
Third Quarter	$ 130.73	$ 92.17
Fourth Quarter	$ 155.86	$ 116.21
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

Holders of Record

As of February 17, 2022, there were approximately 42 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, 2021 and 2020.

Item 6. [Reserved]

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 focused on the design, development and commercialization of technology solutions for people living with diabetes. Diabetes management can vary greatly from person-to-person, creating multiple market segments based on clinical needs and personal preferences. Our goal is to lead in insulin therapy management across multiple of these market segments by providing a portfolio of delivery devices, software, and data insight solutions to people living with diabetes, as well as their caregivers and healthcare providers.

Since our initial commercial launch, we have rapidly innovated and brought 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 Insulin Delivery System (t:slim X2) hardware platform represents 100% of our new pump shipments. In the four-year period ended December 31, 2021, we shipped nearly 330,000 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. Nearly 240,000 of these pumps were shipped to customers in the United States and nearly 90,000 were shipped to international markets.

Our manufacturing, sales and support activities principally focus on our flagship pump platform, the t:slim X2 and our complementary product offerings. Our simple-to-use t:slim X2 is based on our proprietary technology platform and is the smallest durable insulin pump available in the United States. We have commercially offered two different automated insulin dosing (AID) algorithms on t:slim X2, including our Control-IQ technology, which is an advanced hybrid-closed loop feature, designed to help increase a user's time in their targeted glycemic range. It was the first system cleared by the U.S. Food and Drug Administration (FDA) to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar based on continuous glucose monitoring (CGM) readings. Approximately 200,000 t:slim X2 users have our Control-IQ technology, which launched in the United States in the first quarter of 2020, and is now available in more than 20 countries. Our Control-IQ technology uses information from Dexcom Inc.'s (Dexcom) G6 sensor, which is the third generation of Dexcom CGM that we have integrated with our pump technology.

The t:slim X2 is unique in that it is the only pump on which remote software updates have been made commercially available in the United States. Now available in the countries we serve worldwide, our Tandem Device Updater (TDU), is a revolutionary tool that has allowed more than 130,000 people to update their t:slim X2 software from a personal computer. This offering is a competitive advantage as it allows us to bring new features, such as our AID technology and CGM integration, to our customers faster than the industry has been able to historically.

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. Additionally, we sell accessories such as belt clips and cases for use with pumps which are designed to enhance usability. In the United States, we also offer t:connect, our data management web 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.

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 2,000 regular full-time employees as of December 31, 2021.

For the years ended December 31, 2021, 2020 and 2019, our consolidated sales were $702.8 million, $498.8 million, and $362.3 million, respectively. For the year ended December 31, 2021, our net income was $15.6 million. For the years ended 2020 and 2019, our net loss was $34.4 million, and $24.8 million, respectively. Worldwide pump sales accounted for 59%, 63%, and 68% of our total sales, respectively, for the years ended December 31, 2021, 2020 and 2019, while pump-related supplies and accessories accounted for the remainder in each year.

Recent Developments

On February 16, 2022, we announced FDA clearance for the t:connect mobile app, which is the first-ever smartphone application capable of initiating insulin delivery on both iOS and Android operating systems. The updated t:connect mobile app is designed to offer t:slim X2 insulin pump users the ability to program and cancel bolus insulin requests through the convenience of their compatible smartphone. The new feature will be offered in the United States for no additional cost to new t:slim X2 insulin pump customers, and to in-warranty customers through remote software updates for both the t:slim X2 insulin pump and t:connect mobile app.

COVID-19 Global Pandemic Impact and Considerations

Our business has been impacted in a variety of ways since the onset of the COVID-19 global pandemic in early 2020, and will likely continue to be impacted for the remainder of 2022. Specific factors that have influenced our financial results and the way in which we operate include fluctuations in shelter-in-place restrictions, supply chain constraints, labor shortages, the timing and extent of vaccine availability and surges in infection and hospitalization rates as new COVID variants have emerged. Throughout this time, we have responded to each of these unique challenges, while prioritizing the health and safety of our employees and customers and working diligently to maintain a continuous supply of products, training and customer support.

Most notably, our sales results reflected a high degree of variability across the quarters during this time, unlike historical seasonal trends. We experienced a modest impact early in 2020, which became more pronounced and continued in varying degrees as the pandemic progressed. Initially, the impact on our business was relatively consistent worldwide but we have since seen variations in individual markets based on local conditions and anticipate ongoing fluctuations may continue.

Our inventory levels have also fluctuated as we respond to supply chain constraints, due to availability of components from the various suppliers we use to build our products. While we have adequate raw material inventory for a substantial portion of our pump and cartridge components, we are below our targeted stocking levels for others. In early 2020, we initiated regular discussions with our key suppliers regarding their abilities to fulfill existing orders and assess their ongoing capacity. Over the course of the pandemic, we have increased the frequency of those communications. We continue to monitor factors that could negatively impact our supply chain, such as global shortages of semiconductors, copper and paper, as well as custom components for our insulin pumps and cartridges where we rely on a limited number of qualified suppliers. We anticipate experiencing continued challenges managing supply chain constraints, including the potential for limitations on availability of components as well as increased purchase costs.

Generally, our entire operation has been impacted as we navigate the generalized labor shortages impacting global markets. The labor challenges affect our ability to recruit and hire key talent at the same pace as in years past, but we remain active in our recruiting efforts and competitive in our offerings. In particular, these labor challenges combined with regulatory delays have impacted our product development and launch timelines. The FDA has generally stated that its review process may take longer than normal due to prioritization of COVID-related products and services. We have experienced lengthy delays in the review of pending submissions with the FDA, making regulatory timelines increasingly difficult to predict.

We have adapted well in our commercial operations and customer-facing functions. Our sales organization balances remote and in-person interactions based on the needs and requirements of the customers with whom they interact. For example, prior to the onset of the pandemic, nearly all trainings for customers purchasing our pump platform were in-person. We quickly pivoted to nearly all trainings being provided on remote platforms. Since that time, we have achieved a balance that includes options for the individual based on their unique needs. We continue to see variability across the markets in which we operate and anticipate these fluctuations between in-person and remote interactions will continue.

Our facilities have been closed for non-essential purposes throughout most of the pandemic, while our manufacturing operations were deemed essential due to the critical nature of our product and the communities that we serve. To help ensure the safety and health of those employees working in our facilities, we have implemented preventative measures by requiring employees to wear masks and perform temperature checks before each shift. We are currently developing a return-to-work strategy for the rest of the organization that will incorporate a hybrid approach to meet the needs of our employees, as well as optimize usage of our facilities.

Overall, we anticipate that our sales and operating results will continue to be impacted and subject to unpredictable variability. The full extent of the impact of the 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.

Products Under Development

Our products under development support our strategy of developing insulin delivery systems as part of a therapy management portfolio that is designed to improve patient experience and outcomes. Our product development efforts fall into three pillars of innovation: delivery devices, device software including algorithms, and data and insights.

Delivery Devices

We are developing a family of delivery device solutions to meet the varying needs of people living with type 1 and type 2 diabetes by providing choice within our own portfolio. Preferences 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.

Mobi

Formerly referred to under its development name, t:sport, the Tandem Mobi is approximately half the size of our t:slim X2 pump, and is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump. Its features include a 200-unit cartridge, an on-pump bolus button, inductive charging, an AID algorithm, and is waterproof. We anticipate that Mobi will be our first insulin pump to support full pump-control from our mobile application.

t:slim X3

Advancing our flagship t:slim platform, the t:slim X3 is being designed to provide a modernized user interface and even greater usability for our planned feature updates. It is also being designed to include enhanced technology, such as greater processing power and capacity to support our advanced algorithms, as well as increased battery life, improved durability, and wireless software update capabilities.

Mobi: Tubeless

This offering is being developed to provide an alternative tubeless infusion site option for Mobi pump users. A goal of this design is to allow for people living with diabetes to customize the way they wear their pump with each cartridge change to best suit their personal preferences and lifestyle

Patch

Our patch pump design is in its early stages and is being developed for people living with diabetes who want a disposable tubeless solution.

Device Software

Our device software is used to control our pumps either directly through the pump's interface or through our mobile application. It also includes our AID technology and the software used to support remote pump updatability.

Control-IQ Advancements

We are driving innovation in our algorithms, emphasizing automation, personalization and simplification, all intended to continue to improve therapeutic outcomes and provide a positive patient experience characterized by simplicity and ease of use. Additionally, we have initiated clinical studies to expand the indications of our Control-IQ technology to include people with type 1 diabetes ages 2 to 5 years old, as well as people living with type 2 diabetes. We are also researching the use of different insulins with our Control-IQ technology.

Mobile Control

We are working to expand our mobile control capability. In the future, our t:connect mobile app is planned to include additional pump control features, such as full operation of our Mobi pump.

Integration

Building a robust ecosystem and portfolio around our flagship insulin pumps requires product development efforts to integrate, add and enhance complementary system components.

Dexcom CGM: 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.

Abbott CGM: 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.

Data and Insights

Our goal is to innovate across our digital health platforms by using the vast amount of data that we collect, in combination with technology such as artificial intelligence or machine learning, to provide information and insights to people living with diabetes, their caregivers and healthcare providers and insurance payors. Key areas of development include making these insights easy to understand, provided in a flexible format with mobile or web apps, and available real time. In addition, we are working to integrate health-related information from third-party sources and use our data to support current and future products under development.

Tandem Source

Expanding the capabilities of our t:connect data management application available for customers in the United States, Tandem Source is our second-generation web-based data management application that is being designed to become our single, global platform. This application enhances clinical data visualization, provides added interface customization for users to personalize how they engage with their data and for healthcare providers to better manage their care. In the second quarter of 2021, we began limited testing of an initial version of Tandem Source in the United Kingdom. We continue to develop and test new features for Tandem Source in anticipation of a future commercial release of the product.

Settings Automation

Our automation research and development activities center around opportunities for enhanced user and healthcare provider experience, and improved clinical outcomes. In support of this effort, we are working to automate our pump settings adjustments to further enhance ease of use and expand adoption of our insulin pump products.

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.

Insulin pumps in the markets we serve worldwide are generally subject to a four-year reimbursement cycle, imposed by the third-party insurance carrier, government plan or healthcare system that serves as the primary payor. At the end of each four-year cycle, customers may be eligible for the purchase of a new insulin pump, subject to the rules and requirements of the primary payor. The majority of our pump sales through the current period have been generated by new customers, but the opportunity for existing customers to purchase a renewal insulin pump increases each period as individual customer warranties expire. With programs dedicated to customer retention efforts, we expect such renewal purchases to represent a more significant portion of our shipments in the long-term.

Since inception through December 31, 2021, we have shipped approximately 395,000 pumps worldwide, of which nearly 330,000 insulin pumps were shipped in the last four years, which is representative of our estimated global in-warranty installed customer base, assuming the typical four-year reimbursement cycle. Nearly 240,000 of these pumps were shipped to customers in the United States, and nearly 90,000 were shipped to international markets. In the year ended December 31, 2021, we shipped 128,312 insulin pumps worldwide, compared to 90,771 insulin pumps shipped in 2020.

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
2021	16,644	20,665	20,296	25,712	83,317

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
2021	8,708	13,152	11,262	11,873	44,995

Trends Impacting Financial Results

Overall, we have experienced considerable sales growth each year since the commercial launch of our first product in the third quarter of 2012, only recognizing an operating profit on a full year basis for the first time in 2021. 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, or create uncertainty or delay with respect to regulatory approvals;
- timing of holidays and summer vacations, which may vary by geography and may be further influenced by the lifting or relaxation of COVID-19 related restrictions and broader availability of vaccines;

- 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 potential claims, investigations, information requests, or legal, regulatory or administrative proceedings with respect to potential or asserted violations of law, including: sales and marketing practices, anti-corruption and FCPA, antitrust, securities, employment, product liability, environmental, data privacy breaches and patent infringement, which may subject us to fines, penalties, expenses, or 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 in additional geographies, 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;
- ability to enter into, maintain agreements, and accomplish continued success in current and future product integrations with CGM partners;
- 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 administrative 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 the fourth quarters of 2019 and 2020, and were profitable for the year ended December 31, 2021. Though we have yet to achieve profitability consistently from period to period, we believe we can ultimately achieve sustained profitability by driving incremental sales growth in the United States 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 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 insulin cartridges and infusion sets, as well as our complementary t:connect, TDU 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.

In the United States, we primarily sell our products through national and regional distributors on a non-exclusive basis. These distributors are generally providers of medical equipment and supplies to individuals with diabetes. Our primary end customers are people with insulin-dependent diabetes. Similar to other durable medical equipment, the 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 we can continue to increase sales by promoting 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. Our products are now sold in more than 20 countries, including in Canada, France and Germany. 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 a distributor partner 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. Outside the United States, we do not expect this same impact from seasonality associated with reimbursement, although the quarterly sales trends may be impacted by a number of other factors, including summer vacations, the timing of product launches into new geographies and variability in the ordering patterns of our distributor partners.

Since early 2020, the COVID-19 global pandemic had a major impact on businesses around the world, as well as our own quarterly trends. Initially, the impact on our business was relatively consistent worldwide but we have since seen varying degrees of impact in individual markets based on local conditions. For example, during 2021, we saw a gradual increase in the amount of in-person sales and training activities in the United States as vaccination availability expanded and social-distancing requirements were relaxed. During the second half of 2021, we saw reduced availability of customers and healthcare providers relating to people taking time off to vacation, which adversely impacted our sales of new pumps to customers during the period. We anticipate that our sales may not follow historical trends and may be subject to unpredictable variability in the coming months based on varying levels of impact of the global pandemic across the markets in which we operate. 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 example, 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, and similar occurrences may occur in future periods. 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 insulin cartridges at our manufacturing facility in San Diego, California. In early 2020, our third-party cartridge manufacturer completed validation and commenced commercial-scale manufacturing to supplement our existing cartridge manufacturing capacity. By the end of 2021, the majority of our t:slim cartridge manufacturing capacity transitioned to our partner in order to create capacity for t:sport cartridge manufacturing in the future. 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.

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 could 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, 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 implemented temporary operational changes that introduced 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. We are also experiencing higher costs as we manage global supply challenges and anticipate that this will continue for the remainder of 2022. 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, we have and will continue to evaluate investing in additional manufacturing equipment to substantially increase 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, cost 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 for our sales, marketing and administrative functions, which also includes our clinical, customer support, technical services, insurance verification and regulatory affairs personnel. We had approximately 95 sales territories in the United States in 2021 and we commenced an expansion in the fourth quarter of 2021 to approximately 110 sales territories. 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 typically 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. While we experienced reduced spending in areas such as travel and trade shows in 2020 and 2021 due to the COVID-19 global pandemic, we may experience additional costs as our employees return to work at our offices and as we adapt to alternative hybrid work models, or as needed to respond to general labor shortages and heightened competition for employees with specialized skills. Overall, we expect our SG&A expenses, including the cost of our customer support infrastructure, to continue to increase as our customer base grows in the United States and international markets. In addition, 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. 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 hardware, software and digital health 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, develop new products and technologies and support more clinical trials. 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 interest expense which includes the amortization of debt issuance costs related to our 1.50% Convertible Senior Notes due 2025, issued in May 2020 (our Notes), changes in the fair value of certain warrants issued in connection with our public offering of common stock in October 2017, and interest earned on our cash equivalents and short-term investments. We expect interest expense in future quarters to be comparable with the amount expensed in 2021, through the date of conversion or redemption of the Notes. We expect the revaluation of the outstanding Series A warrants will not have a significant impact on our other income and expense through their expiration in the fourth quarter of 2022.

Income Tax Expense (Benefit)

Because the Company maintains a full valuation allowance against its net deferred tax assets, income tax expense is expected to primarily consist of current state and foreign cash tax expense as a result of taxable income anticipated or incurred 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, 2021	2020	2019
Sales:			
Domestic	$ 524,907	$ 415,680	$ 302,084
International	177,892	83,150	60,221
Total sales	702,799	498,830	362,305
Cost of sales	326,584	238,310	168,093
Gross profit	376,215	260,520	194,212
Gross margin	54 %	52 %	54 %
Operating expenses:			
Selling, general and administrative	261,508	204,903	165,735
Research and development	92,054	63,574	45,199
Total operating expenses	353,562	268,477	210,934
Operating income (loss)	22,653	(7,957)	(16,722)
Other income (expense), net:			
Interest income and other, net	674	1,567	3,193
Interest expense	(6,040)	(12,805)	—
Change in fair value of common stock warrants	(1,386)	(17,087)	(11,075)
Total other expense, net	(6,752)	(28,325)	(7,882)
Income (loss) before income taxes	15,901	(36,282)	(24,604)
Income tax expense (benefit)	335	(1,900)	149
Net income (loss)	$ 15,566	$ (34,382)	$ (24,753)

Comparison of Years Ended December 31, 2021 and 2020

Sales. For the year ended December 31, 2021, sales were $702.8 million, which included $177.9 million of international sales. For the year ended December 31, 2020, sales were $498.8 million, which included $83.2 million of international sales.

The increase in worldwide sales of $204.0 million in 2021, as compared to 2020, was driven by a 41% increase in worldwide pump shipments to 128,312 in 2021, compared to 90,771 in 2020, and a 56% increase in pump-related supply sales. Sales of pump-related supplies increased primarily due to a 52% growth in our estimated worldwide installed base of customers.

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

	Year Ended December 31, 2021	2020
Pump	$ 319,898	$ 269,856
Infusion sets	140,387	99,743
Cartridges	63,375	45,342
Other	1,247	739
Total Domestic Sales	$ 524,907	$ 415,680

Domestic pump sales were $319.9 million for the year ended December 31, 2021, compared to $269.9 million in the year ended December 31, 2020, as pump shipments increased 18% compared to the prior year due to continued strong demand for our t:slim X2 insulin pump with Control-IQ technology despite the challenging COVID-19 environment which has impacted the availability of both customers and healthcare providers. Domestic pump shipments were 83,317 in the year ended December 31, 2021 compared to 70,825 in 2020. Sales of pump-related supplies increased primarily due to a 39% increase in our estimated domestic installed base of customers. Sales to distributors accounted for 67% and 70% of our total domestic sales for the years ended December 31, 2021 and 2020, 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,	
	2021	2020
Pump	$ 96,458	$ 44,851
Infusion sets	57,063	28,016
Cartridges	23,509	9,884
Other	862	399
Total International Sales	$ 177,892	$ 83,150

International pump sales were $96.5 million for the year ended December 31, 2021, compared to $44.9 million in the year ended December 31, 2020. Pump shipments increased 126% compared to the prior year due to strong demand for our products as we continue to expand the launch of our Control-IQ technology, which began in the third quarter of 2020 outside the United States. Sales of pump-related supplies increased primarily due to an 102% 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 as they continue to gain familiarity with the markets in which they operate and the acceptance of our products in those markets. This variability was compounded by the changing levels of impact of the global pandemic across the international markets. Sales to distributors accounted for 95% and 94% of our total international sales for the years ended December 31, 2021 and 2020, respectively.

Cost of Sales and Gross Profit. Our cost of sales for the year ended December 31, 2021 was $326.6 million, resulting in gross profit of $376.2 million, compared to cost of sales of $238.3 million and gross profit of $260.5 million for the year ended December 31, 2020. The gross margin for 2021 was 54%, compared to 52% in 2020.

The increase in our gross profit for the year ended December 31, 2021, was primarily the result of the $204.0 million increase in total sales. Gross profit and gross margin both benefited from improvement in the per unit manufacturing costs for pumps and supplies from efficiencies in the manufacturing process, leverage of fixed overhead, increased volumes from our third-party cartridge manufacturer as well as labor and material cost reductions. On an aggregate basis, non-manufacturing costs, which primarily consist of warranty, royalty, freight, training and digital health product support costs, also reflected improvement on a per unit basis. To a lesser extent, overall average selling prices slightly pressured gross margin as international pump sales comprised a greater portion of total pump sales compared to the prior year, while supply average selling prices reflected modest benefit from the growth of our international installed base. Other factors that have and may continue to impact 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 59% of total worldwide sales for the year ended December 31, 2021, compared to 63% in 2020. Non-cash stock-based compensation expense allocated to cost of sales was $6.4 million for the year ended December 31, 2021, compared to $8.2 million in 2020, representing 1% and 2% of sales in those periods, respectively.

Selling, General and Administrative Expenses. SG&A expenses increased 28% to $261.5 million for the year ended December 31, 2021, from $204.9 million for the same period in 2020. Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. The increase compared to 2020 was primarily the result of a $43.9 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. We also experienced a $12.7 million increase in other non-employee discretionary spending for software maintenance, outside consulting and services and supplies.

Research and Development Expenses. R&D expenses increased 45% to $92.1 million for the year ended December 31, 2021, from $63.6 million for the same period in 2020. The increase in R&D expenses was primarily the result of an increase of $20.7 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts, as well as a $7.8 million increase in other non-employee discretionary spending, including outside consulting and services, equipment and supplies attributable to R&D.

Other Income (Expense). Total other expense, net for the year ended December 31, 2021 was $6.8 million, compared to $28.3 million in 2020. Other expense for 2021 primarily consisted of $6.0 million of interest expense which included the amortization of debt issuance costs related to our Notes issued in the second quarter of 2020, and a $1.4 million revaluation loss from the change in the fair value of certain warrants. Other expense for 2020 consisted primarily of an $17.1 million revaluation loss from the change in the fair value of certain warrants due to the appreciation in our stock price during 2020, and $12.8 million of interest expense which included the amortization of debt discount and debt issuance costs related to our Notes issued in the second quarter of 2020. The decrease in interest expense in 2021 was primarily due to the adoption of ASU No. 2020-06 in the first quarter of 2021 (see Note 7, "Debt"). Interest income and other, for the years ended December 31, 2021 and 2020, primarily consisted of interest earned on our cash equivalents and short-term investments, which decreased in 2021 primarily due to the lower interest rate environment as compared to 2020.

Income Tax Expense (Benefit). We recognized income tax expense of $0.3 million on pre-tax income of $15.9 million for the year ended December 31, 2021, compared to an income tax benefit of $1.9 million on a pre-tax loss of $36.3 million for the same period in 2020. The income tax expense for the year ended December 31, 2021 was primarily attributable to state and foreign income tax expense as a result of current taxable income in those jurisdictions. 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 Sugarmate, partially offset by state and foreign income tax expense as a result of current taxable income in those jurisdictions.

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 included 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 Sugarmate, 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.

Liquidity and Capital Resources

At December 31, 2021, we had $623.8 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 2019, 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 pay the cost of the Capped Call Transactions related to the Notes (see Note 7, “Debt”).

- From January 2019 through December 31, 2021, we issued 4,887,211 shares of common stock upon the exercise of stock options, and 804,275 shares of common stock were purchased under our 2013 Employee Stock Purchase Plan, which generated aggregate proceeds of $143.6 million.

- From January 2019 through December 31, 2021, we received proceeds of $1.8 million from the exercise of 509,785 outstanding warrants which were originally issued in connection with our registered public offering of common stock in October 2017. As of December 31, 2021, there were warrants to purchase 1,000 shares outstanding relating to the October 2017 offering.

- From January 2019 through December 31, 2021, we received proceeds of $2.1 million from the exercise of 34,728 outstanding warrants which were originally issued between August 2011 and August 2012. As of December 31, 2021, there were warrants to purchase 19,722 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 and equity investments, 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.

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, 2021, 2020 and 2019:

(in thousands)	Year Ended December 31, 2021	2020	2019
Net cash provided by (used in):			
Operating activities	$ 111,359	$ 24,669	$ 41,906
Investing activities	(186,876)	(296,056)	(56,955)
Financing activities	51,932	314,438	24,207
Effect of foreign exchange rate changes on cash	153	387	191
Net increase (decrease) in cash and cash equivalents	$ (23,432)	$ 43,438	$ 9,349

Operating activities. Net cash provided by operating activities was $111.4 million for the year ended December 31, 2021, compared to and $24.7 million and $41.9 million, respectively, for the years ended December 31, 2020 and 2019.

The improvement to net cash provided by operating activities for 2021 compared to 2020 was driven by higher sales and gross profit in 2021, which resulted in a $35.7 million improvement to net income when adjusted for non-cash expenses, particularly stock-based compensation expense and depreciation and amortization expense, as well as a $51.0 million increase from working capital changes. Working capital changes in 2021 primarily consisted of increases in accounts payable, employee-related liabilities, deferred revenue, and other current and long-term liabilities, offset by increases in accounts receivable and inventories, all of which were related to the growth in our business. Accounts receivable increased to $110.7 million at December 31, 2021 from $82.2 million at December 31, 2020, as a result of higher sales in the fourth quarter of 2021 as compared to the fourth quarter of 2020. Inventories increased to $68.6 million at December 31, 2021 from $63.7 million at December 31, 2020.

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.

Investing activities. Net cash used by investing activities was $186.9 million for the year ended December 31, 2021, which was primarily related to $733.4 million of purchases of short-term investments, $14.2 million in purchases of property and equipment, and $9.3 million cash paid for the acquisition of intangible assets and equity investments, offset by $570.0 million in proceeds from maturities and sales of short-term investments. 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 senior 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.

Financing activities. Net cash provided by financing activities was $51.9 million for the year ended December 31, 2021, which primarily consisted of proceeds from the issuance of common stock under our stock plans. 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 related to the Capped Call Transactions (see Note 7, “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.

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;
- investments for the development, improvement and acquisition of manufacturing, testing and packaging equipment to support business growth and increase 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 proceeds from the issuance of the Notes were $244.6 million, net of debt issuance costs and cash used to pay the cost of the Capped Call Transactions (see Note 7, “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.

Cash payments due by calendar year for our Convertible Senior Notes at December 31, 2021 are as follows (in thousands):

	Total	2022	2023	2024	2025
Contractual interest	$ 14,357	$ 4,313	$ 4,313	$ 4,313	$ 1,418
Principal amount of convertible senior notes	287,500	—	—	—	287,500
Total	$ 301,857	$ 4,313	$ 4,313	$ 4,313	$ 288,918

Contractual Obligations & Off-Balance Sheet Arrangements

Contractual Obligations

The Company leases general office space, laboratory, manufacturing and warehouse facilities, and equipment under noncancelable operating leases for use in our operations. For a description of our contractual obligations related to leases at December 31, 2021, see Note 6 “Leases” to the consolidated financial statements in Part II, Item 8 of this Annual Report.

The Company has agreements with suppliers and other parties to purchase inventory, other goods and services and long-lived assets. For a description of our contractual obligations related to purchase order commitments at December 31, 2021, see Note 12 “Commitments and Contingencies” to the consolidated financial statements in Part II, Item 8 of this Annual Report.

Off-Balance Sheet Arrangements

As of December 31, 2021, we are a party to certain standby letter of credit arrangements in support of our operating lease obligations. For a description of the arrangements we consider significant, see Note 12 “Commitments and Contingencies” to the consolidated financial statements in Part II, Item 8 of this Annual Report.

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 insulin 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. 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, net of estimated returns. 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 direct the use of and obtain the benefit from the product. Complementary products, such as the t:connect cloud-based data management application and the Tandem Device Updater, are considered distinct 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 over a four-year period. When there is no standalone value for the complementary product, we determine its 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 assurance type warranty on our insulin pumps to end user customers and may replace any pumps that do not function as intended in accordance with the product specifications within the warranty period. Insulin pumps returned to us may be refurbished and redeployed. We establish the warranty reserve liability when control of the pump is transferred to the customer, and we reevaluate our estimate of the warranty obligation at each reporting period. Warranty costs are estimated primarily based on the current expected product replacement cost and expected replacement rates utilizing historical experience. Experience has shown that initial data for any given pump version may be insufficient; therefore, our process relies on long-term historical averages until sufficient data are available. As actual experience becomes available, we use the data to update the historical averages. Changes to the actual replacement rates or the expected product replacement cost could cause a material increase or decrease to our estimated warranty reserve and related cost of goods sold. We may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to the length of time each pump version has been in the field and revised future expectations of performance based on new features and capabilities that may become available through Tandem Device Updater.

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. We use the asset and liability approach to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. 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. Significant judgment is required to evaluate the need for a valuation allowance. 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 determination of cumulative pre-tax book income after permanent differences, projections of pre-tax book income for the foreseeable future, 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. Changes in the recognition or measurement of valuation allowance could result in material increases or decreases in our income tax expense in the period in which we make a change, which could have a material impact on our effective tax rate and operating results.

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.

We recognize liabilities for uncertain tax positions using a two-step approach. 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.

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

Credit and Interest Rate Risks

We invest our excess cash in marketable securities consisting primarily of commercial paper, corporate debt securities, U.S. Treasury securities and U.S. Government-sponsored enterprise 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. As a result of the COVID-19 global pandemic and the perceived increased credit risks associated with certain securities, credit rating agencies have, from time to time, issued downgrades or revised outlooks to negative for certain issuers of the debt securities held in our short-term investments portfolio. Unrealized losses on available-for-sale debt securities at December 31, 2021 were not significant. Based on the credit quality of the available-for-sale debt securities that are in an unrealized loss position, and our current estimates of future cash flows to be collected from those securities, we believe the unrealized losses were not credit losses (see Note 3, "Short-Term Investments").

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, 2021, it would not have had a material effect on the fair value of our investment portfolio as of that date.

In May 2020, we issued $287.5 million principal amount of Convertible Senior Notes, which bear interest at a fixed rate of 1.50% per year. Accordingly, we are not subject to interest rate risk as a result of the Convertible Senior Notes (see Note 7, "Debt").

Foreign Currency Exchange Rate Risk

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. As we expand our operations in markets outside the United States, we may be exposed to further foreign currency exchange rate risk. We believe our exposure to foreign currency rate fluctuations 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, 2021 and 2020 and for each of the three years in the period ended December 31, 2021, 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, 2021 and 2020, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2021 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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 22, 2022 expressed an unqualified opinion thereon.

Adoption of ASU No. 2020-06

As discussed in Note 2 to the consolidated financial statements, the Company changed its method of accounting for convertible instruments in 2021 due to the adoption of ASU No. 2020-06, Debt–Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging–Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.

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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was 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 matter 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 matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

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 $30.4 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

/s/ Ernst & Young LLP

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

San Diego, California
February 22, 2022

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

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 71,181	$ 94,613
Short-term investments	552,630	390,323
Accounts receivable, net	110,725	82,195
Inventories	68,551	63,721
Prepaid and other current assets	8,433	6,383
Total current assets	811,520	637,235
Property and equipment, net	50,386	50,022
Operating lease right-of-use assets	27,503	19,773
Other long-term assets	15,728	9,385
Total assets	$ 905,137	$ 716,415
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 28,032	$ 17,805
Accrued expenses	9,419	4,783
Employee-related liabilities	51,556	34,159
Deferred revenue	10,182	6,082
Common stock warrants	147	14,261
Operating lease liabilities	9,279	9,421
Other current liabilities	23,241	17,341
Total current liabilities	131,856	103,852
Convertible senior notes, net - long-term	281,467	202,984
Operating lease liabilities - long-term	23,922	15,914
Other long-term liabilities	34,780	27,360
Total liabilities	472,025	350,110
Commitments and contingencies (Note 12)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 63,833 and 62,335 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively.	64	62
Additional paid-in capital	1,068,259	1,025,233
Accumulated other comprehensive income (loss)	(616)	220
Accumulated deficit	(634,595)	(659,210)
Total stockholders' equity	433,112	366,305
Total liabilities and stockholders' equity	$ 905,137	$ 716,415

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

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

	Year Ended December 31,		
	2021	2020	2019
Sales	$ 702,799	$ 498,830	$ 362,305
Cost of sales	326,584	238,310	168,093
Gross profit	376,215	260,520	194,212
Operating expenses:			
Selling, general and administrative	261,508	204,903	165,735
Research and development	92,054	63,574	45,199
Total operating expenses	353,562	268,477	210,934
Operating income (loss)	22,653	(7,957)	(16,722)
Other income (expense), net:			
Interest income and other, net	674	1,567	3,193
Interest expense	(6,040)	(12,805)	—
Change in fair value of common stock warrants	(1,386)	(17,087)	(11,075)
Total other expense, net	(6,752)	(28,325)	(7,882)
Income (loss) before income taxes	15,901	(36,282)	(24,604)
Income tax expense (benefit)	335	(1,900)	149
Net income (loss)	$ 15,566	$ (34,382)	$ (24,753)
Other comprehensive income (loss):			
Unrealized gain (loss) on short-term investments	$ (693)	$ (20)	$ 77
Foreign currency translation gain (loss)	(143)	118	58
Comprehensive income (loss)	$ 14,730	$ (34,284)	$ (24,618)
Net income (loss) per share - basic	$ 0.25	$ (0.56)	$ (0.42)
Net income (loss) per share - diluted	$ 0.24	$ (0.56)	$ (0.42)
Weighted average shares used to compute basic net income (loss) per share	63,000	60,990	58,507
Weighted average shares used to compute diluted net income (loss) per share	64,349	60,990	58,507

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

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

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
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
Exercise of stock options	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 senior notes issuance, net of issuance costs	—	—	85,803	—	—	85,803
Payment for capped call transactions related to convertible senior 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
Effect of change in accounting for convertible senior notes (1)	—	—	(85,803)	—	9,049	(76,754)
Exercise of stock options	1,129	2	41,821	—	—	41,823
Vesting of restricted stock units, net of shares withheld for taxes	38	—	(1,551)	—	—	(1,551)
Issuance of common stock for Employee Stock Purchase Plan	173	—	11,069	—	—	11,069
Exercise of common stock warrants	158	—	899	—	—	899
Fair value of common stock warrants at time of exercise	—	—	15,500	—	—	15,500
Stock-based compensation expense	—	—	61,091	—	—	61,091
Unrealized loss on short-term investments	—	—	—	(693)	—	(693)
Foreign currency translation adjustments	—	—	—	(143)	—	(143)
Net income	—	—	—	—	15,566	15,566
Balance at December 31, 2021	63,833	$ 64	$ 1,068,259	$ (616)	$ (634,595)	$ 433,112

(1) The Company adopted ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* effective January 1, 2021 (see Note 2, "Summary of Significant Accounting Policies").

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,		
	2021	**2020**	**2019**
Operating Activities			
Net income (loss)	$ 15,566	$ (34,382)	$ (24,753)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization expense	13,845	10,451	6,072
Amortization of debt discount and issuance costs	1,727	10,096	—
Provision for expected credit losses	2,333	3,016	2,322
Provision (recovery) for inventory obsolescence	467	(57)	2,353
Change in fair value of common stock warrants	1,386	17,087	11,075
Amortization of premium (discount) on short-term investments	365	(1,296)	(565)
Benefit for deferred income taxes	—	(2,126)	(25)
Stock-based compensation expense	60,752	58,431	58,071
Other	546	38	(295)
Changes in operating assets and liabilities:			
Accounts receivable, net	(30,980)	(38,837)	(13,698)
Inventories	(4,954)	(15,361)	(30,975)
Prepaid and other current assets	(1,570)	(2,427)	(584)
Other long-term assets	1,313	129	(580)
Accounts payable	10,275	1,118	8,910
Accrued expenses	4,640	(3,256)	4,076
Employee-related liabilities	17,399	5,339	4,285
Deferred revenue	10,611	7,029	4,589
Operating leases and other current liabilities	6,217	5,789	4,216
Other long-term liabilities	1,421	3,888	7,412
Net cash provided by operating activities	111,359	24,669	41,906
Investing Activities			
Purchases of short-term investments	(733,388)	(497,076)	(164,572)
Proceeds from maturities of short-term investments	545,735	180,922	114,908
Proceeds from sales of short-term investments	24,288	52,392	12,250
Purchases of property and equipment	(14,180)	(27,408)	(19,541)
Acquisition of intangible assets and equity investments	(9,331)	(4,886)	—
Net cash used in investing activities	(186,876)	(296,056)	(56,955)
Financing Activities			
Proceeds from issuance of convertible senior notes, net of $8,809 debt issuance costs	—	278,691	—
Payment for capped call transactions related to convertible senior notes	—	(34,069)	—
Proceeds from issuance of common stock under Company stock plans, net	51,340	66,866	23,880
Proceeds from exercise of common stock warrants	592	2,950	327
Net cash provided by financing activities	51,932	314,438	24,207
Effect of foreign exchange rate changes on cash	153	387	191
Net increase (decrease) in cash and cash equivalents	(23,432)	43,438	9,349
Cash and cash equivalents at beginning of period	94,613	51,175	41,826
Cash and cash equivalents at end of period	$ 71,181	$ 94,613	$ 51,175
Supplemental disclosures of cash flow information			
Interest paid	$ 4,313	$ 2,707	$ —
Income taxes paid	$ 260	$ 177	$ 67
Supplemental schedule of non-cash investing and financing activities			
Right-of-use assets obtained in exchange for operating lease obligations	$ 15,191	$ 11,022	$ 11,635
Property and equipment included in accounts payable	$ 1,034	$ 1,082	$ 2,134
Intangible costs in accounts payable and other long-term liabilities	$ 1,029	$ 2,244	$ —

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

1. Organization and Basis of Presentation

The Company

Tandem Diabetes Care, Inc. is a medical device company focused on the design, development and commercialization of technology solutions for people living with diabetes. Tandem Diabetes Care, Inc. 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 software 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 diabetes management application (t:connect) and the Tandem Device Updater, a Mac and PC-compatible tool which offers and supports updates of the Company's insulin pump software from a personal computer. 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 other comprehensive income (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.

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, 2021, other than the adoption of ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, effective January 1, 2021 (see Note 7, "Debt").

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 that are not related to credit factors are reported as a component of other comprehensive income (loss) within the statements of operations and accumulated other comprehensive income (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 reviews its available-for-sale debt securities for credit losses quarterly, considering a variety of factors, including the significance of the decline in value as compared to the amortized cost basis; underlying factors contributing to a decline in the prices of securities in a single asset class; the security's relative performance versus its peers, sector or asset class; the market and economy in general; views of external investment managers; news or financial information that has been released specific to the investee; and the outlook for the overall industry in which the investee operates. Losses on available-for-sale debt securities as a result of credit factors are recognized by recording an impairment loss as a component of other income or expense within the consolidated statements of operations and a corresponding allowance for credit losses. The Company has not recognized any impairment losses related to its short-term investments during the years ended December 31, 2021, 2020 and 2019.

Accounts Receivable

The Company grants credit to various customers in the ordinary course of business and is paid directly by customers who use its 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 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,	
	2021	**2020**
Customer A	*	12.7 %
Customer B	11.2 %	12.3 %

* Amount related to the respective customer represented less than 10% for the period presented.

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Customer B	11.9 %	15.9 %	14.8 %
Customer C	*	12.9 %	15.4 %

* Amount related to the respective customer represented less than 10% for the period presented.

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 carrying value and estimated fair value of certain of the Company's common stock warrants was determined using the Black-Scholes pricing model as of December 31, 2021 and 2020 (see Note 5, "Fair Value Measurements").

The Company's convertible senior notes are carried at amortized cost on the consolidated balance sheets (see Note 7, "Debt"). The Company determined the fair value of its convertible senior notes to be $430.0 million and $333.5 million at December 31, 2021 and 2020, respectively, based on Level 2 quoted market prices as of that date.

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

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 *Leases*, 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 sheets. 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.

Cost Basis Equity Investment

During the second quarter of 2021, the Company made an $8.1 million equity investment in a private company, which represented less than 5% of the outstanding equity of that company. The investment is recorded using the cost minus impairment adjusted for changes in observable prices and is included as a component of other long-term assets on the consolidated balance sheet at December 31, 2021. We monitor this investment to evaluate whether any increase or decline in its value has occurred, based on the implied value of recent company financings, public market prices of comparable companies and general market conditions.

Intangible Assets Subject to Amortization

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recognized over their estimated useful lives on a straight-line basis. The Company reviews its 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 during the years ended December 31, 2021, 2020 and 2019.

On June 24, 2020, the Company acquired Sugarmate, Inc. (Sugarmate), the developer of a mobile app designed to help people 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 asset is being amortized on a straight-line basis over an estimated useful life of five years. The Company's results of operations include the operating results of Sugarmate since the date of acquisition, the amounts of which were not material.

Revenue Recognition

Revenue is generated primarily from sales of insulin pumps, disposable insulin 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 control of the 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, net of estimated returns.

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 typically is upon shipment 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 distinct 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 over a four-year period. Where there is no standalone value for the complementary product, the Company determines its 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, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Deferred revenue	$ 9,625	$ 5,508
Other long-term liabilities	16,940	10,426
Total	$ 26,565	$ 15,934

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 $0.6 million at December 31, 2021 and 2020, 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 as intended in accordance with the product specifications within the warranty period. Insulin pumps returned to the Company may be refurbished and redeployed. Additionally, the Company offers a six-month warranty on disposable insulin cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment, and the Company reevaluates the estimate of the warranty reserve obligation at each reporting period. Warranty costs are estimated primarily based on the current expected product replacement cost and expected replacement rates utilizing historical experience. Experience has shown that initial data for any given pump version may be insufficient; therefore, our process relies on long-term historical averages until sufficient data are available. As actual experience becomes available, we use the data to update the historical averages. The Company may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to the length of time each pump version has been in the field and revised 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, 2021, 2020 and 2019 (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Balance at beginning of the year	$ 22,075	$ 16,724	$ 9,138
Provision for warranties issued during the period	27,604	21,135	18,335
Settlements made during the period	(18,768)	(13,736)	(10,167)
Decrease in warranty estimates	(510)	(2,048)	(582)
Balance at end of the year	$ 30,401	$ 22,075	$ 16,724

As of December 31, 2021 and December 31, 2020, total product warranty reserves of $30.4 million and $22.1 million, respectively, were included in the following consolidated balance sheet accounts (in thousands):

	December 31,	
	2021	2020
Other current liabilities	$ 13,076	$ 8,409
Other long-term liabilities	17,325	13,666
Total warranty reserve	$ 30,401	$ 22,075

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 income (loss).

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 (see Note 8, "Stockholders' Equity"). 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. The fair value of RSU awards issued under the 2013 Plan that vest based upon the Company's actual performance relative to predefined performance metrics is estimated based on the fair market value of the underlying stock on the date of grant and the probability that the specified performance criteria will be met, subject to the awardee's continuing service through the measurement date. At each reporting period, we reassess the probability of the achievement of such performance metrics. Any expense change resulting from an adjustment in the estimated shares to be released is recorded in the period of adjustment.

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.

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 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 using a two-step approach. 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 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 (see Note 10, "Income Taxes." for further information).

Comprehensive Income (Loss)

All components of comprehensive income (loss), including net income (loss), are reported in the consolidated financial statements in the period in which they are recognized. Comprehensive income (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 Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net income 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 stock options and unvested RSUs outstanding under the Company's stock plans, potential awards to be granted pursuant to the ESPP, and common stock warrants, each calculated using the treasury stock method; and shares issuable upon conversion of the convertible senior notes calculated using the if-converted method. For common stock warrants that are recorded as a liability in the accompanying 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 years ended December 31, 2020 and 2019, there was no difference in the weighted average number of shares used to calculate basic and diluted net loss per share due to the Company's net loss position. For the year ended December 31, 2021, the numerator and denominator of the diluted net income per share computation were calculated as follows (in thousands):

	Year Ended December 31, 2021
Net income - basic and diluted	$ 15,566
Weighted average shares outstanding - basic	63,000
Dilutive common share equivalents:	
Options to purchase common stock	1,129
Unvested restricted stock units	62
Warrants to purchase common stock	157
Awards to be granted under the ESPP	1
Weighted average shares outstanding - diluted	64,349

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,		
	2021	2020	2019
Options to purchase common stock	3,124	5,021	5,619
Unvested restricted stock units	—	78	N/A
Warrants to purchase common stock	1	379	611
Awards granted under the ESPP	—	3	5
Convertible senior notes (if-converted)	2,554	1,605	N/A
	5,679	7,086	6,235

Recent Accounting Pronouncements

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 eliminated certain models that require separate accounting for embedded conversion features, and eliminated 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 could 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 elected to early adopt the new standard on January 1, 2021 using the modified retrospective method and, accordingly, recorded a net reduction to accumulated deficit of $9.0 million, a decrease to additional paid-in capital of $85.8 million, and an increase to convertible senior notes, net - long-term of $76.8 million to reflect the impact of the accounting change (see Note 7, "Debt").

3. Short-Term Investments

The Company invests in marketable securities primarily consisting of debt instruments of the U.S. Government, U.S. Government-sponsored enterprises, and 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, 2021 and 2020 (in thousands):

At December 31, 2021	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
U.S. Treasury securities	$ 222,206	$ —	$ (482)	$ 221,724
Commercial paper	218,391	14	(24)	218,381
Corporate debt securities	58,881	—	(45)	58,836
U.S. Government-sponsored enterprises	50,773	1	(88)	50,686
Supranational bonds	3,003	—	—	3,003
Total	$ 553,254	$ 15	$ (639)	$ 552,630

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

The contractual maturities of available-for-sale debt securities as of December 31, 2021, were as follows (in thousands):

	Years to Maturity		
At December 31, 2021	Within One Year	One to Two Years	Estimated Fair Value
U.S. Treasury securities	$ 105,231	$ 116,493	$ 221,724
Commercial paper	218,381	—	218,381
Corporate debt securities	58,836	—	58,836
U.S. Government-sponsored enterprises	32,282	18,404	50,686
Supranational bonds	3,003	—	3,003
Total	$ 417,733	$ 134,897	$ 552,630

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 reviews the portfolio of available-for-sale debt securities quarterly to determine if any investment is impaired due to changes in credit risk or other potential valuation concerns. Unrealized losses on available-for-sale debt securities at December 31, 2021 were not significant and were primarily due to changes in market interest rates. 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 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 did not recognize any impairment losses related to its available-for-sale debt securities at December 31, 2021.

4. Composition of Certain Financial Statement Items

Accounts Receivable

Accounts receivable, net consisted of the following at (in thousands):

	December 31,	
	2021	2020
Accounts receivable	$ 114,974	$ 86,052
Less: allowance for credit losses	(4,249)	(3,857)
Accounts receivable, net	$ 110,725	$ 82,195

Allowance for Credit Losses

The following table provides a reconciliation of the changes in the allowance for estimated accounts receivable credit losses for the years ended December 31, 2021, 2020 and 2019 (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Balance at beginning of the year	$ 3,857	$ 3,304	$ 1,837
Provision for expected credit losses	2,333	3,016	2,322
Write-offs and adjustments, net of recoveries	(1,941)	(2,463)	(855)
Balance at end of the year	$ 4,249	$ 3,857	$ 3,304

Inventories

Inventories consisted of the following at (in thousands):

	December 31,	
	2021	2020
Raw materials	$ 26,911	$ 30,880
Work-in-process	16,612	15,664
Finished goods	25,028	17,177
Total inventories	$ 68,551	$ 63,721

Property and Equipment

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

	December 31,	
	2021	2020
Leasehold improvements	$ 25,245	$ 22,834
Office furniture and equipment	9,943	9,876
Computer equipment and software	11,544	12,219
Manufacturing and scientific equipment	52,823	44,026
Total cost	99,555	88,955
Less: accumulated depreciation and amortization	(49,169)	(38,933)
Total property and equipment, net	$ 50,386	$ 50,022

Depreciation and amortization expense related to property and equipment was $11.7 million, $9.2 million, and $5.7 million for the years ended December 31, 2021, 2020, and 2019, 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, 2021 and 2020, which were included in other long-term assets on the consolidated balance sheets, were as follows (in thousands):

	December 31,	
	2021	2020
Intangible assets, gross amount	$ 12,502	$ 12,502
Accumulated amortization	(5,866)	(3,697)
Intangible assets, net	$ 6,636	$ 8,805
Weighted average remaining amortization period (in months)	41	52

Amortization expense related to intangible assets subject to amortization amounted to $2.2 million, $1.2 million and $0.3 million for the years ended December 31, 2021, 2020, and 2019, 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 $1.9 million for 2022, $1.9 million for 2023, $1.9 million for 2024, and the remaining $0.9 million in 2025.

5. 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, 2021 and 2020, 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, 2021			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents [1]	$ 48,286	$ 48,286	$ —	$ —
U.S. Treasury securities	221,724	221,724	—	—
Commercial paper	218,381	—	218,381	—
U.S. Government-sponsored enterprises	50,686	—	50,686	—
Corporate debt securities	58,836	—	58,836	—
Supranational bonds	3,003	—	3,003	—
Total assets	$ 600,916	$ 270,010	$ 330,906	$ —
Liabilities				
Common stock warrants	$ 147	$ —	$ —	$ 147
Total liabilities	$ 147	$ —	$ —	$ 147

	Fair Value Measurements at December 31, 2020			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents [1]	$ 87,300	$ 87,300	$ —	$ —
U.S. Treasury securities	143,254	143,254	—	—
Commercial paper	108,896	—	108,896	—
U.S. Government-sponsored enterprises	52,350	—	52,350	—
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

(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, 2021 and 2020 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, provide holders the right to purchase shares of the Company's common stock at an exercise price of $3.50 per share. As of December 31, 2021 and 2020, there were Series A warrants outstanding to purchase 1,000 shares and 154,700 shares, respectively, of the Company's common stock (see Note 8, "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, as well as estimated stock price volatility, dividend yield, remaining warrant term and risk-free interest rate. 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, 2021 and 2020 are presented below:

	Series A Warrants	
	December 31, 2021	December 31, 2020
Risk-free interest rate	0.3 %	0.1 %
Expected dividend yield	0.0%	0.0%
Expected volatility	39.1 %	55.3 %
Expected term (in years)	0.8	1.8

The following table presents a summary of changes in the fair value of the Company's Level 3 financial liabilities for the years ended December 31, 2021 and 2020:

	2021	2020
Balance at beginning of year	$ 14,261	$ 23,509
Loss recognized from the change in fair value of common stock warrants	1,386	17,087
Common stock warrants exercised during the period	(15,500)	(26,335)
Balance at end of year	$ 147	$ 14,261

Of the loss recognized from the change in fair value of common stock warrants for the years ended December 31, 2021 and 2020, $0.1 million and $5.5 million, respectively, was attributable to warrants outstanding as of December 31, 2021 and 2020.

6. 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 two years to twelve years, eight months. 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 Company's consolidated balance sheets. The Company is required to recognize operating lease right-of-use assets and liabilities, and begin recording lease expense when the Company takes possession of the leased property (the Commencement Date). The Company recognizes lease expense for these 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 to determine the operating lease right-of-use assets and liabilities based on the present value of future lease payments over the lease term. The Company used the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date.

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. For renewal options that are reasonably certain at the lease Commencement Date of being exercised, the Company includes the renewal option period in the lease term. 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.

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 began in July 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 sublease agreement for approximately 30,703 square feet of general office space located on High Bluff Drive, in San Diego, California (High Bluff Sublease). 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 four separate buildings that comprise in aggregate 77,458 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.

In March 2021, the Company entered into a second amendment (Second Amendment) to its lease agreement for office space located on Vista Sorrento Parkway in San Diego, California (Vista Sorrento Lease) covering 59,013 square feet of general administrative office space (Existing Premises). The Second Amendment expanded the Existing Premises by adding 14,916 square feet of general administrative office space (Expansion Space), and extended the lease term for the Existing Premises through January 2028. The Expansion Space lease Commencement Date occurred in March 2021, and the lease term expires in January 2028. The Company has two options to extend the term of the Vista Sorrento Lease, covering both the Existing Premises and the Expansion Space, with each option providing for an additional period of five years. The Vista Sorrento Lease term was determined assuming the renewal options would not be exercised. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of $15.1 million on the consolidated balance sheet in the first quarter of 2021 related to the Second Amendment.

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

	Year Ended December 31,		
	2021	2020	2019
Operating lease cost	$ 8,627	$ 7,514	$ 4,542
Short-term lease cost	90	219	165
Total lease cost	$ 8,717	$ 7,733	$ 4,707

Maturities of operating lease liabilities at December 31, 2021 were as follows (in thousands):

Years Ending December 31,		
2022	$	9,281
2023		6,949
2024		5,744
2025		5,825
2026		5,531
Thereafter		5,144
Total undiscounted lease payments		38,474
Less: amount representing interest		(5,273)
Present value of operating lease liabilities		33,201
Less: current portion of operating lease liabilities		(9,279)
Operating lease liabilities - long-term	$	23,922

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

	December 31, 2021	December 31, 2020
Weighted-average remaining lease term (in years)	5.0	3.7
Weighted-average discount rate used to determine operating lease liabilities	5.6 %	5.9 %

Cash paid for amounts included in the measurement of lease liabilities, representing operating cash flows from operating leases, was $9.5 million and $8.2 million for the years ended December 31, 2021 and 2020, respectively.

Leases For Which Accounting Has Not Yet Commenced

As of December 31, 2021, the Commencement Date for the High Bluff and Tech Center Leases described below, had not yet occurred. Accordingly, the consolidated balance sheet at December 31, 2021 does not include operating lease right-of-use assets and operating lease liabilities, and the consolidated statement of operations for the year ended December 31, 2021 does not include any lease costs, related to the High Bluff Lease and the Tech Center Lease. In addition, the above disclosures of the Company's lease costs, maturities of operating lease liabilities, and the weighted-average remaining lease term and weighted-average discount rate, do not include any amounts related to the High Bluff and Tech Center Leases.

High Bluff Lease

In May 2021, the Company entered into a lease agreement for approximately 31,372 square feet of general office space located on High Bluff Drive, in San Diego, California (High Bluff Lease). The High Bluff Lease is a direct lease agreement for the same property subject to the High Bluff Sublease. The lease term begins in April 2022 following the termination of the High Bluff Sublease in March 2022, and is scheduled to expire in March 2024. The Company expects to recognize right-of-use leased assets and corresponding operating lease liabilities of approximately $3.0 million on the consolidated balance sheet on the Commencement Date in the second quarter of 2022.

Tech Center Lease

In September 2021, the Company entered into a lease agreement for 181,949 square feet of additional general administrative, laboratory, and research and development office space (the Premises) located on High Bluff Drive in San Diego, California (Tech Center Lease). Possession of the Premises is expected to be tendered to the Company by the landlord in two phases, with Phase I consisting of 143,850 rentable square feet, and Phase II consisting of 38,099 rentable square feet. The Company intends to use Phase I of the Tech Center Lease for operations currently located at the Roselle Street Leases.

The initial lease term Phase I Commencement Date will occur on the date the Company is tendered possession of the Phase I portion of the Premises (which is currently expected to be in March 2022), and rent payments commence six months thereafter (the Phase I Rent Commencement Date). The Phase II Commencement Date is expected to occur upon the earlier of (i) the date upon which the Company first commences business in the Phase II portion of the Premises, and (ii) May 1, 2025 (the Phase II Rent Commencement Date). The lease will expire twelve years, eight months from the first day of the first full month following the Phase I Rent Commencement Date. The Company has two options to extend the term of the lease, with each option providing for an additional period of five years, by delivering written notice to the landlord in accordance with the terms of the Tech Center Lease.

The Tech Center Lease also includes a first right of offer with respect to an additional 34,569 rentable square feet of general office space should the space become available. The lease term and associated base rent for the additional space will not be known until the Company is notified that the additional space has become available, and the Company elects to lease the space on terms mutually satisfactory to the Company and the landlord.

The initial base rent for the Tech Center Lease is approximately $906,000 per month beginning on the Phase I Rent Commencement Date, and the base rent increases by approximately $255,000 per month on the Phase II Rent Commencement Date. The monthly base rent will increase annually by 3.0% on each annual anniversary of the respective Rent Commencement Date. In addition to the monthly base rent, the Company is required to pay its proportionate share of certain ongoing operating expenses throughout the duration of the lease. No base rent, other than the proportionate share of operating expenses, will be due for the Phase I portion of the Premises for months two through nine of the initial lease term, and for the Phase II portion of the Premises for months two through five following the Phase II Rent Commencement Date.

Future minimum payments for monthly base rent due under the respective High Bluff Lease and Tech Center Lease terms, are currently estimated to be as follows (in thousands), subject to a number of factors, including the actual Commencement Date of the lease:

Years Ending December 31,	High Bluff Lease[1]	Tech Center Lease[2]	Total
2022	$ 1,029	$ —	$ 1,029
2023	1,594	6,453	8,047
2024	403	11,313	11,716
2025	—	12,694	12,694
2026	—	15,181	15,181
2027 through 2035	—	145,583	145,583
Total	$ 3,026	$ 191,224	$ 194,250

(1) The Company currently estimates that the Commencement Date will occur in the second quarter of 2022, at which time the operating lease right-of-use assets and liabilities will be recorded.

(2) The Company currently estimates that the Phase I Commencement Date will occur in the first quarter of 2022, and the Phase II Commencement Date will occur in the first quarter of 2025, at which time the respective operating lease right-of-use assets and liabilities will be recorded.

7. 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 (Notes) in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The proceeds from the issuance of the Notes were $244.6 million, net of debt issuance costs and cash used to pay the cost of 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 $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 expects to settle conversions through a combination settlement, which 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 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 or in connection with a redemption are entitled to an increase in the conversion rate. Additionally, in the event of a fundamental change, 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.

Initially, 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 carrying amount of the equity component representing the conversion option for the Notes was $88.5 million and was recorded as a debt discount, which was being amortized to interest expense at an effective interest rate of 9.9%. In addition, 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 were being amortized to interest expense under the effective interest rate method.

On January 1, 2021, the Company early adopted 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. The ASU eliminates the cash conversion feature models in ASC 470-20, *Debt with Conversion and Other Options*, which required an issuer of certain convertible debt to separately account for embedded conversion features as a component of equity. Instead, an issuer will account for these securities as a single unit of account, unless the conversion feature meets certain criteria. The Company adopted the new standard using the modified retrospective method, and recorded a net reduction to accumulated deficit of $9.0 million, a decrease to additional paid-in capital of $85.8 million, and an increase to convertible senior notes, net - long-term of $76.8 million to reflect the impact of the accounting change. The Notes are now accounted for as a single liability measured at amortized cost, as no other embedded features require bifurcation and recognition as derivatives.

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

	December 31, 2021	December 31, 2020
Liability:		
Principal amount	$ 287,500	$ 287,500
Unamortized debt issuance costs	(6,033)	(5,446)
Unamortized debt discount	—	$ (79,070)
Net carrying amount	$ 281,467	$ 202,984
Carrying amount of the equity component	$ —	$ 85,803

As of December 31, 2021, the unamortized debt issuance costs of $6.0 million associated with the Notes will be amortized to interest expense, at an effective interest rate of 2.2% over the remaining period of approximately 3.3 years.

The following table details interest expense recognized related to the Notes for the years ended December 31, 2021 and 2020 (in thousands):

	December 31, 2021	December 31, 2020
Contractual interest expense	$ 4,313	$ 2,707
Amortization of debt issuance costs	1,727	652
Amortization of debt discount	N/A	9,446
Total interest expense	$ 6,040	$ 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, 2021, the if-converted value of the Notes exceeded the principal amount by $96.9 million. 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 in May 2020 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 Call Transactions are separate transactions, and not part of the terms of the Notes, while they are integrated for federal tax purposes. As these transactions met certain criteria under the applicable accounting guidance, the Capped Call Transactions were recorded in stockholders' equity and were 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.

8. Stockholders' Equity

Shares Reserved for Future Issuance

The following shares of the Company's common stock were reserved for future issuance at December 31, 2021 (in thousands):

Shares reserved for issuance upon conversion of Convertible Senior Notes	2,554
Shares underlying outstanding warrants	215
Shares underlying outstanding stock options	4,814
Shares underlying unvested restricted stock units	612
Shares authorized for issuance pursuant to awards granted under the ESPP	1,216
Shares authorized for future equity award grants	1,382
	10,793

Common Stock Warrants

Warrants outstanding to purchase shares of the Company's common stock as of December 31, 2021 were as follows:

Issue Date	Exercise Price Per Share	Warrants Outstanding	Expiration Date of Warrants Outstanding
October 2017	$3.50	1,000	October 2022
March 2017	$23.50	193,788	March 2027
August 2011 - August 2012	$73.73	19,722	May 2022 - August 2022
		214,510	

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 155,517 and 295,526 shares of its common stock upon the exercise of warrants during the years ended December 31, 2021 and 2020, respectively.

Stock Plans

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 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 1,128,791 and 2,339,467 shares of its common stock, respectively, upon the exercise of stock options during the years ended December 31, 2021 and 2020. During the years ended December 31, 2021 and 2020, the Company issued 38,156 and 1,892 shares of its common stock, respectively, 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, 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
Granted	355,008	$ 86.68		
Exercised	(1,128,791)	$ 37.05		$ 86,149
Canceled/forfeited/expired	(215,372)	$ 76.29		$ 6,963
Outstanding at December 31, 2021	4,814,350	$ 57.08	7.07	$ 452,081
Vested and expected to vest at December 31, 2021	4,769,317	$ 56.95	7.06	$ 448,460
Exercisable at December 31, 2021	3,013,030	$ 49.28	6.50	$ 307,235

Restricted Stock Units

Restricted stock units (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. In addition, the Company granted 25,674 performance-based RSUs during the year ended December 31, 2021. The performance-based RSUs have a grant value equal to the closing price of the Company's common stock on the award date, and vest upon the Company's actual performance relative to predefined performance metrics and subject to the awardee's continuing service through the December 31, 2024 measurement date. A summary of RSU activity for the years ended December 31, 2021 and 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
Granted	564,034	$ 96.37	
Vested	(53,957)	$ 82.74	
Canceled/forfeited	(30,705)	$ 87.21	
Unvested awards outstanding at December 31, 2021	612,174	$ 95.11	$ 92,144

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.

During the years ended December 31, 2021 and 2020, 172,694 shares and 302,509 shares of our common stock, respectively, were purchased under the ESPP for proceeds of $11.1 million and $9.1 million, respectively.

Stock-Based Compensation

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,		
	2021	2020	2019
Cost of sales	$ 6,434	$ 8,210	$ 6,415
Selling, general & administrative	43,567	41,563	42,857
Research and development	10,751	8,658	8,799
Total stock-based compensation expense	$ 60,752	$ 58,431	$ 58,071

The total stock-based compensation capitalized as part of the cost of the Company's inventories was $1.0 million and $0.6 million at December 31, 2021 and 2020, respectively.

At December 31, 2021, the total unamortized stock-based compensation expense of approximately $129.2 million will be recognized over the remaining weighted average vesting term of approximately 2.6 years.

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

	Stock Options		
	Year Ended December 31,		
	2021	2020	2019
Weighted average grant date fair value (per share)	$ 56.89	$ 54.20	$ 39.06
Risk-free interest rate	1.0 %	0.6 %	2.1 %
Expected dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	75.1 %	74.6 %	71.8 %
Expected term (in years)	6.1	6.1	6.0

	ESPP		
	Year Ended December 31,		
	2021	2020	2019
Weighted average grant date fair value (per share)	$ 38.19	$ 36.83	$ 30.32
Risk-free interest rate	0.2 %	0.2 %	1.9 %
Expected dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	44.2 %	60.3 %	69.9 %
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 for 2021 was estimated based on a weighted-average of the Company's actual historical volatility of its common stock measured over the expected term. During 2020, the Company transitioned to solely using the expected volatility of its own common stock. Prior to this transition, the expected volatility was estimated based on a weighted-average 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 were publicly available. The peer group consisted of publicly traded companies in the same industry and in a similar stage of development.

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.

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, and the Company may elect to match a discretionary percentage of employee contributions. The Company did not provide a matching contribution during the three years ended December 31, 2021, but approved a discretionary match to begin in 2022.

10. Income Taxes

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

	Year Ended December 31,		
	2021	**2020**	**2019**
U.S.	$ 15,211	$ (36,667)	$ (24,888)
Foreign	690	385	284
Income (loss) before provision for income taxes	$ 15,901	$ (36,282)	$ (24,604)

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

	Year Ended December 31,		
	2021	**2020**	**2019**
Current:			
Federal	$ —	$ —	$ —
State	174	75	86
Foreign	161	151	88
Total current tax expense	335	226	174
Deferred:			
Federal	—	(1,760)	(21)
State	—	(366)	(4)
Foreign	—	—	—
Total deferred income tax benefit	—	(2,126)	(25)
Income tax expense (benefit)	$ 335	$ (1,900)	$ 149

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,		
	2021	2020	2019
Income tax expense (benefit) at federal statutory rate [1]	$ 3,339	$ (7,619)	$ (5,167)
State income tax, net of federal benefit	(254)	(2,792)	(1,174)
Warrants revaluation	356	3,588	2,326
Research and development credits	(5,703)	(5,330)	(2,091)
Section 382 limitation	(97)	1,021	25,043
Stock-based compensation	(7,609)	(18,309)	(8,974)
Officers' compensation	4,024	2,612	3,133
Other	124	479	972
Change in valuation allowance	6,155	24,450	(13,919)
Income tax expense (benefit)	$ 335	$ (1,900)	$ 149

(1) For the years ended December 31, 2021, 2020 and 2019, the federal statutory tax rate was 21%.

Significant components of the Company's net deferred income tax assets at December 31, 2021 and 2020 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, 2021. 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 $146.4 million and $121.6 million at December 31, 2021 and 2020, 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,	
	2021	2020
Deferred tax assets:		
Net operating loss (NOL) carryforwards	$ 78,961	$ 86,898
Research and development tax credits carryforwards	16,761	11,261
Capitalized research and development expenses	5,135	6,840
Accrued compensation	28,970	24,038
Lease liabilities	8,012	6,112
Other	20,608	12,096
Total deferred tax assets	158,447	147,245
Deferred tax liabilities:		
Convertible senior notes	—	(11,224)
Fixed assets	(3,847)	(7,675)
Other	(8,177)	(6,719)
Total deferred tax liabilities	(12,024)	(25,618)
Less valuation allowance	(146,423)	(121,627)
Net deferred tax assets	$ —	$ —

As of December 31, 2021, the Company had accumulated federal and state NOL carryforwards of approximately $301.2 million, and $291.0 million, respectively, Of the total federal net operating loss carryforwards, approximately $112.1 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 $189.1 million will begin to expire in 2026, and state tax loss carryforwards continue to expire in 2022, unless previously utilized. The remaining California NOL carryforwards of $171.8 million will begin expiring in 2028. The Company has no foreign tax loss carryforwards as of December 31, 2021.

The Company also has federal and California research credit carryforwards of approximately $12.9 million and $15.5 million, respectively, as of December 31, 2021. The federal research credit carryforwards will begin expiring in 2038, 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, 2021, 2020 and 2019 (in thousands):

	Year Ended December 31,		
	2021	2020	2019
Gross unrecognized tax benefits at the beginning of the year	10,107	$ 6,580	$ 8,824
Increases related to current year positions	3,482	2,234	1,076
Increases (decreases) related to prior year positions	—	1,293	(3,320)
Gross unrecognized tax benefits at the end of the year	$ 13,589	$ 10,107	$ 6,580

As of December 31, 2021, the Company had $11.8 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, 2021 and 2020. 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.

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 insulin 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, Saudi Arabia 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, 2021, 2020 and 2019, 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 its products are shipped (in thousands).

	For the Year Ended December 31,		
	2021	2020	2019
United States	$ 524,907	$ 415,680	$ 302,084
International	177,892	83,150	60,221
Total Sales	$ 702,799	$ 498,830	$ 362,305

Sales to distributors accounted for 67%, 70%, and 73% of the Company's total domestic sales for the years ended December 31, 2021, 2020 and 2019, respectively. Sales to distributors accounted for 95%, 94%, and 92% of the Company's total international sales for the years ended December 31, 2021, 2020 and 2019, respectively.

12. Commitments and Contingencies

Legal and Regulatory Matters

In April 2020, the Company was named as a defendant in four federal class action lawsuits relating to a data breach it experienced in January 2020, each of which was subsequently dismissed.

In addition, in May 2020 the Company was named as a defendant in three California state court class action lawsuits arising from the same data breach. 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), California Consumer Privacy Act (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; (ii) the demurrer of the CCPA claim was sustained; and (iii) the demurrer of the UCL and contract claims were sustained with leave to amend the pending complaint. A second demurrer was heard by the Court on March 29, 2021 with the following outcome: (i) the demurrer of the CMIA claim was denied; and (ii) the demurrer of the UCL and contract claims were narrowed in scope to dismiss three plaintiffs for either failing to allege cognizable damages or injuries-in-fact, resulting in two remaining plaintiffs. Although the Company intends to vigorously defend against these claims, there is no guarantee that the Company will prevail. The Company presently is unable to determine the ultimate outcome of these lawsuits or determine the amount (or range) of possible losses associated with the lawsuits.

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 the County of San Diego. 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 case was brought as a class action and was later amended to also include a representative action under the California Private Attorney General Act, or PAGA. The 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. The parties recently agreed to resolve all claims in the lawsuit. The settlement of claims covered by the PAGA matter were approved by the Superior Court of the State of California in the County of San Diego on September 21, 2021 and settlement amounts were disbursed in 2021. In October 2021, a settlement of the class action related claims was preliminarily approved by an independent arbitrator mutually acceptable to both parties. The class action is intended to resolve the claims of the individual plaintiff, as well as the remaining members of the class, unless an individual class member submits a timely request for exclusion. The material terms of the settlement are set forth in a binding Memorandum of Agreement dated as of July 1, 2021, which is subject to the completion of a number of conditions, as well as final approval by the independent arbitrator. There is no guarantee that the conditions will be met or that final approval will be obtained. If the final class settlement is not approved, or if other conditions to approval of the settlement are not met, the case will continue and the Company will continue to vigorously defend against the claims.

From time to time, the Company is involved in various other legal proceedings, regulatory matters, and other disputes or claims arising from or related to the normal course of our business activities, including actions with respect to intellectual property, data privacy, employment, regulatory, product liability and contractual matters. Although the results of legal proceedings, disputes and other claims cannot be predicted with certainty, the Company believes it is not currently a party to any legal proceeding(s) which, if determined adversely to the Company, would, individually or taken together, have a material adverse effect on the Company's 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 the Company as a result of defense and settlement costs, diversion of management time and resources, and other factors.

Except as set forth above, as of December 31, 2021 and December 31, 2020, 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 merits of the claims raised or the outcome, legal proceedings, regulatory matters, and other disputes and claims may have an adverse impact on the Company because of as a result of defense and settlement costs, diversion of management time and resources, and other factors.

Letters of Credit

The Company leases general office space, laboratory, manufacturing and warehouse facilities, and equipment under noncancelable operating leases for use in our operations (see Note 6, "Leases"). In connection with one of the operating leases, the Company has a $4.9 million unsecured irrevocable standby letter of credit arrangement with a bank, under which the landlord of the building is the beneficiary. The Company is required to maintain the standby letter of credit throughout the term of the lease, which is currently expected to expire in April 2035.

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 consist primarily of purchase order commitments for raw materials used in the production of insulin pumps and cartridges, and finished goods infusion sets. Cancellation of outstanding purchase orders is generally allowed under the standard terms of our purchase order agreements, but may require payment of costs incurred through the date of cancellation. At December 31, 2021, obligations under our purchase agreements totaled approximately $255 million, of which approximately $251 million is scheduled to be received and become payable within one-year.

13. Fourth Quarter Financial Data (Unaudited)

The financial information for the three months ended December 31, 2021 and 2020 presented in the following table reflects all normal recurring adjustments that are, in the opinion of management, necessary for a fair statement of the results of the interim periods (in thousands, except per share data):

	For the Quarter Ended	
	December 31, 2021	December 31, 2020
Sales	$ 209,996	$ 168,065
Gross profit	$ 113,729	$ 90,556
Operating expenses	$ 100,991	$ 71,894
Operating income	$ 12,738	$ 18,662
Net income	$ 10,808	$ 17,000
Basic net income per share	$ 0.17	$ 0.27
Diluted net income per share	$ 0.16	$ 0.22

The numerator and denominator of the basic and diluted net income per share computations are calculated as follows for the three months ended December 31, 2021 and 2020:

	For the Quarter Ended	
(in thousands)	December 31, 2021	December 31, 2020
Net income	$ 10,808	$ 17,000
Less: change in fair value of common stock warrants	32	(2,819)
Net income - diluted	$ 10,840	$ 14,181
Weighted average shares outstanding - basic	63,650	62,249
Dilutive common share equivalents:		
Options to purchase common stock	1,877	2,984
Unvested restricted stock units	227	133
Warrants to purchase common stock	170	308
Awards to be granted under the ESPP	3	4
Convertible senior notes (if-converted)	—	—
Weighted average shares outstanding - diluted	65,927	65,678

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, 2021, 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, 2021.

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, 2021, 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 (2013 Framework) (the COSO criteria). Based on this assessment, our management concluded that, as of December 31, 2021, 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, 2021 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, 2021, 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, 2021, 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, 2021 and 2020, the related consolidated statements of operations and comprehensive income (loss), stockholders' equity, and cash flows, for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 22, 2022 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 22, 2022

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 2022 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, 2021, 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 Accountant 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).	10-K	001-36189	24-Feb-21	3.2	
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 dated May 15, 2020 by and 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 the 2006 Stock Incentive Plan.	S-1	333-191601	7-Oct-13	10.4	

10.3*	Form of Restricted Stock Purchase Agreement under the 2006 Stock Incentive 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 Amended and	10-Q	001-36189	30-Jul-2020	10.1
10.7*	Form of Stock Option Agreement under the Amended and Restated 2013 Stock Incentive Plan.	S-1/A	333-191601	1-Nov-13	10.7
10.8*	Form of Stock Option Agreement under the Amended and Restated 2013 Stock Incentive 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. 2021 Sr. Management Cash Bonus Plan.	10-Q	001-36189	5-May-2021	10.2
10.11*	Employee Offer Letter, dated June 28, 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 January 29, 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 11, 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 Tandem Diabetes Care, Inc. and Leigh	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.	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,	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.	10-K	001-36189	24-Feb-21	10.24
10.25†	Commercialization Agreement, dated November 20, 2020, by and between Tandem Diabetes Care, Inc. and DexCom, Inc.	10-K	001-36189	24-Feb-21	10.25
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, dated September 2, 2020 by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 ROSELLE STREET, LLC	10-Q	001-36189	5-Nov-2020	10.1

10.33	Fifth Amendment to Lease dated September 2, 2020 by and between Tandem Diabetes Care, Inc. and ARE-11025/11075 ROSELLE STREET, LLC	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	
10.35†	Commercialization Agreement, dated January 14, 2022, by and between Tandem Diabetes Care, Inc. and Unomedical A/S.					X
10.36	Lease Agreement dated May 10, 2021 by and Between Tandem Diabetes Care, Inc. and ONE DEL MAR LLC					X
10.37	Second Amendment to Lease dated March 11, 2021 by and between Tandem Diabetes Care, Inc. and TREA PACIFIC PLAZA, LLC	10-Q	001-36189	5-May-2021	10.2	
10.38	Office Lease dated September 15, 2021 by and between Tandem Diabetes Care, Inc. and Kilroy	10-Q	001-36189	3-Nov-2021	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					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 22, 2022

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 John F. Sheridan	President, Chief Executive Officer and Director (Principal Executive Officer)	February 21, 2022
/s/ LEIGH A. VOSSELLER Leigh A. Vosseller	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 21, 2022
/s/ DICK P. ALLEN Dick P. Allen	Lead Independent Director	February 21, 2022
/s/ KIM D. BLICKENSTAFF Kim D. Blickenstaff	Chair of the Board	February 21, 2022
/s/ PEYTON R. HOWELL Peyton R. Howell	Director	February 21, 2022
/s/ KATHLEEN MCGRODDY-GOETZ Kathleen McGroddy-Goetz	Director	February 21, 2022
/s/ REBECCA B. ROBERTSON Rebecca B. Robertson	Director	February 21, 2022
/s/ DOUGLAS A. ROEDER Douglas A. Roeder	Director	February 21, 2022
/s/ RAJWANT S. SODHI Rajwant S. Sodhi	Director	February 21, 2022
/s/ CHRISTOPHER J. TWOMEY Christopher J. Twomey	Director	February 21, 2022

Board of Directors

Kim Blickenstaff
Chair

Dick Allen
Lead Independent Director

John Sheridan
President and CEO

Peyton Howell
Member

Kathleen McGroddy-Goetz, Ph.D.
Member

Rebecca Robertson
Member

Douglas Roeder
Member

Rajwant Sodhi
Member

Christopher Twomey
Member

Executive Team

John Sheridan
President and
Chief Executive Officer

David Berger
Executive Vice President and
Chief Operating Officer

Elizabeth Gasser
Executive Vice President and
Chief Strategy Officer

Brian Hansen
Executive Vice President and
Chief Commercial Officer

Susan Morrison
Executive Vice President and
Chief Administrative Officer

Leigh Vosseller
Executive Vice President and
Chief Financial Officer

TANDEM Diabetes Care

NASDAQ GLOBAL MARKET | TNDM

CORPORATE HEADQUARTERS

11075 Roselle Street
San Diego, CA 92121
(877) 801-6901
tandemdiabetes.com

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Ernst & Young LLP
4370 La Jolla Village Drive, #500
San Diego, CA 92122

TRANSFER AGENT

American Stock Transfer
& Trust Company, LLC
6201 15th Avenue
Brooklyn, NY 11219
astfinancial.com

DATE & TIME

Annual Stockholder Meeting

The annual meeting of Tandem Diabetes Care stockholders will be held virtually on **Wednesday, May 25, 2022 at 3:00 pm (Pacific).**

Stockholder Inquiries
Stockholders may obtain copies of our news releases, Securities and Exchange Commission filings, including Forms 10-K, 10-Q, and 8-K, and other Company information by accessing our website at investor.tandemdiabetes.com or by contacting Investor Relations at (858) 366-6900.