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, 2022
or

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

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

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐
Indicate by check if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See definitions of "large accelerated filer, "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	x	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒
As of June 30, 2022, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $3.8 billion based on the closing price for the common stock of $59.19 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, 2023, there were 64,528,059 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement on Schedule 14A for the 2023 Annual Meeting of Stockholders, or of an amendment to this Form 10-K, 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.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the fiscal year ended December 31, 2022, 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, cybersecurity threats, macroeconomic pressures or uncertainties 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

References within this Annual Report to "Tandem," "we," "our," "us," "management," or the "Company" refer to Tandem Diabetes Care, Inc., together with its wholly-owned subsidiaries in the United States, Canada and the Netherlands.

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 robust ecosystem and 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. Today, the t:slim X2 Insulin Delivery System (t:slim X2) is our flagship technology solution. In the four-year period ended December 31, 2022, we shipped approximately 420,000 t:slim X2 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. Approximately 290,000 of these pumps were shipped to customers in the United States and 130,000 were shipped to customers outside the United States. Our products are currently available in approximately 25 countries outside the United States.

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. The majority of our customers use the t:slim X2 with continuous glucose monitoring (CGM) integration. This allows the t:slim X2 to receive CGM sensor readings, which can then be used in our automated insulin dosing (AID) algorithms, including our Control-IQ technology. Control-IQ is an advanced hybrid-closed loop feature designed to help increase a user's time in their targeted glycemic range. Multiple studies have demonstrated that use of Control-IQ technology provides people across all demographics with improved clinical outcomes that are both immediate and sustained. 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.

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) that has allowed approximately 200,000 people to update their t:slim X2 software from a personal computer. This offering is a competitive advantage that allows us to bring our customers clinical and lifestyle enhancements, such as new developments in our AID technology, CGM integrations and mobile app features. In July 2022, we launched a new pump software update through TDU to allow all t:slim X2 pump users in the United States to bolus insulin using our smartphone app that is available on compatible iOS and Android devices.

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

We are focused on developing diabetes solutions that expand our portfolio of insulin pump offerings, provide even greater personalization to our AID algorithms, expand our AID indications, and that further improve the user experience with our diabetes management systems, data product offerings and services we provide.

Diabetes and the Insulin Therapy Management Market

Diabetes is a chronic, life-threatening disease for which there is no known cure.

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 use insulin or produce enough insulin. It's a progressive condition, and a person in the advanced stages of living with type 2 diabetes often requires intensive insulin therapy.

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-dependent)	*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

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. Preventing and managing fluctuations in blood glucose levels between hypoglycemia, or low blood glucose levels, and hyperglycemia, or high blood glucose levels, is often time consuming and stressful to people with diabetes and their loved ones.

There are two primary therapies used by people with insulin-dependent diabetes, Multiple Daily Injection (MDI) and insulin pumps. 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, durable device, a disposable cartridge filled with insulin by the user, and a disposable infusion set to administer insulin into the person's body. This system is typically known as a durable pump and the device itself is expected to last for multiple years. By comparison, there are also disposable pumps which combine the pump mechanism, battery and electronics with the cartridge and infusion set into a body-worn patch. These pumps are entirely disposed of by the user every 3-days.

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 approximately 25 countries outside the United States in which our insulin pump is available.

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.

Our Technology: Improving the Lives of People with Insulin-Dependent 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 living 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. 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. 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)

- Control-IQ advanced hybrid-closed loop technology: This AID feature is designed to help increase a user's time in targeted glycemic range (70-180 mg/dL), and is used by the majority of our customers worldwide. 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 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

This tool allows pump users to update their pump 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 t:slim X2 customers in the United States multiple different software updates for no-cost. 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. 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 analysis of clinical outcomes data. 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 as of the end of 2022, there were approximately 300,000 downloads of our t:connect 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

Sugarmate is a popular mobile app that is designed to help people 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.

Our Strategy & Products Under Development

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 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. We believe our positively different approach to diabetes management 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.

In support of this strategy, 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

The Tandem Mobi is approximately half the size of our t:slim X2 pump, and is designed for people who seek even greater discretion and flexibility with the use of their insulin pump. Its features include full pump-control from our mobile application, a 200-unit cartridge, an on-pump bolus button, inductive charging, and an AID algorithm.

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. It will allow a Mobi pump to be worn completely on the user's body with no tubing. A goal of this design is to allow people living with diabetes to customize the way they wear their pump with each cartridge change, switching between tubed and tubeless wear configurations, to best suit their personal preferences and lifestyle.

Sigi

This ergonomic, rechargeable patch pump is being designed to reduce the burden of managing diabetes through its use of pre-filled insulin cartridges and compatibility with AID technology. This replaces our early-stage development of a disposable tubeless solution that was previously under development.

Extended Wear Infusion Sets

Infusion sets provide additional choice and flexibility to people living with diabetes. Our goals for infusion set innovations focus on solutions that extend wear time and enhance user experience, while reducing occlusions, body burden and waste. In support of this effort, we are currently developing unique extended wear infusion set technology.

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 continuing to drive innovation in our algorithms, emphasizing automation, personalization and simplification to continue to improve therapeutic outcomes and provide a positive patient experience. We have recently completed clinical studies to support expanding the indications of our Control-IQ technology to include people with type 1 diabetes ages 2 to 5 years old. Additionally, we are initiating a pivotal study to support expanding indications to include 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: We have agreements with Dexcom to extend our current collaboration to include integration with their G7 CGM technology. Following integrated product development work, this will be the fourth generation of Dexcom CGM that we intend to integrate with our devices.

Abbott CGM: We have an agreement with Abbott Laboratories (Abbott), to develop and commercialize integrated diabetes solutions that combine Abbott's FreeStyle Libre 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. Our key objectives include making these insights easy to understand, making the data available in real time, and providing the information in a flexible format with mobile or web apps. In addition, we are working to integrate health-related information from third-party sources and to 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 be deployed globally. This application enhances clinical data visualization, and provides added interface customization for users to personalize how they engage with their data and for healthcare providers to better manage their care. 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.

Markets and Distribution Methods

The t:slim X2 insulin delivery system is now available in approximately 25 countries worldwide. In the United States and Canada, we employ a direct sales and clinical organization. This organization is augmented by individuals in our internal customer sales support organization, who follow up with existing customers who are approaching their insurance renewal date to aid in the renewal process and on leads generated through promotional activities. Outside the United States, we have contracted with distributors who have substantial responsibility for sales, marketing and customer support efforts.

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. Generally, our five largest distributors account for approximately 40% of consolidated sales. We believe our distributors in the United States carry minimal inventory at any given time. Outside the United States, 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.

Third-Party Reimbursement

In the United States, customer orders are typically fulfilled by billing third-party payors on behalf of our customers, or by using our network of distributors who then bill third-party payors on our customers' behalf. Typically, customers are eligible for insurance reimbursement for the purchase of 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.

We are accredited by the Community Health Accreditation Program and are an approved Medicare provider. 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. 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 use distribution channels so our customers' orders can be serviced. While we have been working to increase our sales in the United States through our direct third-party payor contracts, the percentage is currently less than half of total sales. Outside of the United States and Canada, our distribution partners 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. Over the course of the last two years, we have been transitioning our t:slim cartridge manufacturing to an experienced third-party contract manufacturer to provide us additional flexibility in scaling our business while creating additional leverage. We also use external third parties to sterilize 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 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.

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, 2022, our patent portfolio includes numerous issued patents and pending patent applications in the U.S. and other countries, which in the aggregate, we believe to be important to our business. Patents are generally effective for 20 years from the date the earliest application was filed, and in some cases may be extended. Our issued patents as of December 31, 2022 are set to expire over a range of years, from 2024 to 2041, subject to any extensions. We also have various registered U.S. trademarks, registered European Community trademarks, and other trademark registrations and pending trademark applications in other countries and regions of the world. In addition, we have entered into exclusive and non-exclusive licenses in the ordinary course of business relating to a wide array of technologies or other intellectual property rights or assets.

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 two primary companies that manufacture insulin delivery devices. 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.

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. 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 U.S. Federal Food, Drug and Cosmetic Act (FDCA), also referred to as a 510(k) clearance, or approval from the FDA through the premarket approval (PMA) process. We have obtained clearance on multiple devices in both Class II and Class III, including Control IQ and the tslim:X2.

510(k) Clearance. To obtain 510(k) clearance for any of our potential future devices (or for certain modifications to devices that have previously received 510(k) clearance), we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device. The FDA's 510(k) clearance pathway generally takes three to 12 months from the date the application is completed but can take significantly longer. A 510(k) application must be supported by extensive data, including technical information, labeling, human factors data and potentially clinical data to meet any Special Controls. After a medical device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a significant change in its intended use, requires a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to make this determination initially, but if the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained and assess significant regulatory fines or penalties for failure to submit the requisite 510(k) or PMA application(s).

There are three 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.

PMA Application: 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. 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.

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. 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.

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.

Licensure. In the United States, several states require that durable medical equipment (DME) providers be licensed 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 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. We have obtained the right to affix the CE Mark to the t:slim X2 Insulin Delivery System, which allows us to distribute this product throughout the European Union and in other countries that recognize the CE Mark. In addition, we have Health Canada approval to sell the t:slim X2 in Canada.

A range of anti-bribery and anti-corruption laws, as well as industry specific laws and codes of conduct, apply to the medical device industry and interactions with government officials and entities and healthcare professionals. These laws include the U.K. Bribery Act and similar antibribery laws in other jurisdictions in which we operate. Such laws generally prohibit U.S.-based companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business to foreign officials, or in the case of the U.K. Bribery Act, to any person.

General Data Protection Regulation. The General Data Protection Regulation ("GDPR") is a comprehensive update to the data protection regime in the European Economic Area that imposes requirements relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third-party processors. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including fines and penalties for noncompliance.

Environment, Social and Governance

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 include driving economic efficiencies and process improvement, with environmental impact in mind.

Additional information about our Environmental, Social and Governance practices can be found on our website within the "Investor Center" section. 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.

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, 2022, we had approximately 2,600 regular full-time employees, who primarily work in the United States, Canada, or Europe. 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. 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.

In both 2021 and 2022, we conducted employee engagement surveys through Gallup, a leading global consulting firm on employee engagement. More than 90% of our employees participated in both years, 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.

In 2022, we earned the Great Place to Work Certification, a prestigious award based entirely on results from in-depth employee surveys around their experience working at the Company. This certification is the most definitive "employer-of-choice" recognition that companies aspire to achieve and is recognized worldwide by employees and employers alike and is the global benchmark for identifying and recognizing outstanding employee experience.

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. More than half of our employees are female, including 40% 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, which we continued and expanded during 2022. 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.

Organizational Development

Attracting, developing and retaining employees is critical to our longer-term success. 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 95% 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 2022, more than 450 employees participated in our leadership development programs.

Competitive Total Rewards

Our compensation program is designed to align employee compensation with our performance and to provide the proper incentives to attract, retain, and motivate employees to achieve superior results. The structure of our compensation program balances incentive earnings for both short-term and long-term performance.

- We provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge, and geographic location.
- We engage internationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our executive compensation and benefit programs and to provide benchmarking.
- We align our executives' long-term equity compensation with our stockholders' interests.
- Annual increases and incentive compensation are based on our performance as well as each individual's contribution to the results achieved and are documented through our talent management process as part of our annual review process.

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.

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.

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.

Throughout the COVID-19 global pandemic, we were deemed an essential healthcare business under applicable governmental orders, and our manufacturing and warehousing sites continued operating during the COVID-19 pandemic. As such, we invested in creating physically safe work environments for our employees through the implementation of new protocols, trainings and communications.

Information about our Executive Officers

Name	Age	Title
John F. Sheridan	67	President and Chief Executive Officer
David B. Berger	53	EVP and Chief Operating Officer
Rick A. Carpenter	59	Chief Technical Officer
Elizabeth A. Gasser	47	EVP and Chief Strategy Officer
Brian B. Hansen	55	EVP and Chief Commercial Officer
Shannon M. Hansen	57	SVP, General Counsel, Chief Compliance Officer and Secretary
James Leal	59	SVP, Operations
Susan M. Morrison	43	EVP and Chief Administrative Officer
Leigh A. Vosseller	50	EVP, Chief Financial Officer, and Treasurer

Further detailed information about our executive officers not referenced or set forth above, is provided in our definitive Proxy Statement for our 2022 Annual Meeting of Stockholders and will be included in our definitive Proxy Statement for our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

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*. Copies of our filings with the SEC are available free of charge on our website within the "Investor Center" section as soon as reasonably practicable after having been electronically filed with or furnished to the SEC. 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 Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report.

Summary of Risk Factors

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 Industry

- We have incurred significant operating losses since inception and may not achieve sustained profitability.
- We 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.
- Our ability to maintain and grow our revenue depends in part on attracting and retaining customers.
- Our or our business partners' failure to successfully compete may negatively affect our financial condition.
- Competitive products or technologies may render our products obsolete or less desirable.
- Failure of our products to achieve market acceptance could negatively impact our business and operating results.
- Failure to secure or retain adequate coverage or reimbursement for our products by third-party payors could adversely affect our business.
- Concerns regarding the safety or efficacy of our products could limit sales.
- If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.
- Our failure to successfully complete clinical trials and development-stage testing could prevent us from obtaining regulatory approvals for or commercializing our products.
- We depend on a limited number of third-party suppliers for certain components and products.
- Our inability to attract or retain key personnel could adversely affect our ability to execute our business strategy.

Risks Related to Our International Operations

- Commercializing our products internationally may result in a variety of risks associated with international operations that could materially adversely affect our business.
- Failure to obtain regulatory authorization in foreign jurisdictions will prevent us from marketing our products internationally.
- Our sales and profits are subject to decline in response to foreign currency exchange rate fluctuation.

Risks Related to Macroeconomic Conditions and External Factors

- Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results.
- Public health threats, such as the COVID-19 global pandemic, could materially impact our operations and the global economy.
- Climate change or other extreme weather conditions and related regulations may have a long-term impact 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 Privacy and Security

- A security breach or disruption to our information technology systems could damage our relationships, expose us to litigation or regulatory proceedings, or harm our reputation.
- Our violation of privacy or security laws could subject us to penalties and harm our reputation or business.

Risks Related to Legal and Intellectual Property

- 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, personal information, or trade secrets, or are in breach of non-competition or non-solicitation agreements.

Risks Related to Our Regulatory Environment

- Our products and operations are subject to extensive governmental regulation, and failure to comply with requirements could cause our business to suffer.
- New products or modifications to our existing products may require new regulatory approvals, or require us to cease marketing or recall modified products.
- A recall or suspension of our products could have a significant negative impact on us.

General Risks

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

Risks Related to Our Indebtedness

- We have incurred a significant amount of indebtedness and the agreements governing such indebtedness may restrict our financial flexibility and affect our ability to operate our business.
- Our 1.50% Convertible Senior Notes due 2025 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.

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, 2022, we had an accumulated deficit of $729.2 million. To date, we have funded our operations primarily through cash collected from product sales, private and public offerings of our equity securities, and debt financing. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing and business operations, and the research and development 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 on an annual basis 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 in the United States and the more than 25 countries outside the United States in which our insulin pump is available. 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, general economic conditions, 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, reliability or cybersecurity of any of our products, or any component thereof, particularly in connection with the launch of additional mobile app features and functionality and other software products; 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.

Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results.

Our operations and performance depend in part on worldwide economic and political conditions. Many of the jurisdictions in which our products are sold have experienced and could continue to experience unfavorable general economic conditions, such as a recession or economic slowdown, which could negatively affect the affordability of, and consumer demand for, our products. Under difficult economic conditions, consumers may seek to modify spending priorities and reduce discretionary spending by delaying purchases of our products, which could reduce our profitability and could negatively affect our overall financial performance. Other financial uncertainties in our major markets and unstable political conditions in certain markets, including civil unrest and governmental changes, could undermine global consumer confidence and reduce consumers' purchasing power, thereby reducing demand for our products. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition, and results of operations.

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. 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, our sales and operating results have been adversely impacted, and we anticipate that they will continue to be impacted and subject to unpredictable variability in future periods. 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. 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 adapting to a hybrid work model, and we may experience additional costs as our employees return to work, or as we respond to general labor shortages and heightened competition for employees with specialized skills.

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. 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. In addition, varying COVID-19 case rates can limit our in-person access to healthcare provider offices and also result in staffing shortages in the practices we serve. Collectively, 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, Becton Dickinson and Company recently completed the spin off its diabetes care business as a separate publicly-traded company, Embecta. 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 offers 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. Further, we have 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 or unfavorable changes in general economic conditions.

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 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. 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 in the United States and the more than 25 countries outside the United States in which our insulin pump is available through 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 other than Canada, as that process is managed by local distributors. 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 markets outside of United States. 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.

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 in the United States 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 in the United States have 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, 2022, our two largest independent distributors in the United States collectively comprised approximately 20% of our worldwide sales, and our three largest independent distributors outside of the United States collectively comprised approximately 50% of our total sales outside the United States. 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 and data infrastructure, including by acquiring insurance, employing back-up generators, adopting health and safety protocols, implementing cybersecurity protections, and utilizing off-site storage of computer data. However, vandalism, terrorism, unplanned power outages, cyberattacks 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 of our manufacturing and warehousing operations.

We continue to scale our business operations and add manufacturing requirements for products currently under development. We have outsourced the majority of our t:slim cartridge manufacturing demand to an experienced third-party contract manufacturer. 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 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, adoption of new work models and requirements about when or how often employees work on site or remotely may present new challenges. As certain jobs and employers increasingly operate remotely, competition for talent may change in ways that cannot be fully predicted at this time. Moreover, 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 and in June 2022 for users in all geographies except Australia and New Zealand, though we continue to work towards restoring service for users in those geographies. 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 International Operations

Commercializing our products outside of the United States may result in a variety of risks associated with international operations that could materially adversely affect our business.

Our sales in the approximately 25 countries in which our products are offered outside the United States, which accounted for approximately 27% of our total sales during 2022, are accompanied by certain financial and other risks related to international business markets, including:

- local product preferences and differing regulatory requirements for product approvals;
- 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 E.U. member state directives;
- reduced protection for our intellectual property rights in certain countries outside the U.S. than exists in the U.S.;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation and workforce instability, and political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws, such as the Foreign Corrupt Practices Act;
- foreign taxes, including withholding of payroll taxes; and
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country.

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.

Failure to obtain any required regulatory authorization in foreign jurisdictions will prevent us from marketing our products in international markets.

We sell our products in approximately 25 countries outside the United States and may seek to commence commercial sales of our products in additional geographies in the future. As we continue to expand our operations outside of the United States and launch new products, we are increasingly subject to additional regulatory and legal requirements in the international markets. 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.

Because our business is global our sales and profits may fluctuate or decline in response to changes in foreign currency exchange rates or other international risks.

Activities outside the United States accounted for approximately 27% of our total sales during 2022. Foreign currency fluctuations could result in volatility of our revenue. In addition, we are exposed to transaction risk because we incur some of our sales and expenses in currencies other than the U.S. dollar. Our most significant currency exposures are to the Canadian dollar, the Euro and Swiss franc, and the exchange rates between these currencies and the U.S. dollar may fluctuate substantially. We do not actively hedge our exposure to currency rate fluctuations. The strengthening of the U.S. dollar would likely negatively impact our results. We price some of our products in U.S. dollars, and thus changes in exchange rates can make our products more expensive in some offshore markets and reduce our sales. Inflation could also make our products more expensive and increase the credit risks to which we are exposed. Future foreign currency fluctuations could favorably or unfavorably impact and increase the volatility of our revenue, profitability, and stock price. These and other risks may have a material adverse effect on our business, financial condition and results of operations as a whole.

Risks Related to Macroeconomic Conditions and External Factors

Uncertainty in current global economic and political conditions could adversely affect our ability to predict product demand and impact our financial results and makes it more likely that our actual results could differ materially from expectations.

Our operations and performance depend in part on worldwide economic and political conditions. Many of the jurisdictions in which our products are sold have experienced and could continue to experience unfavorable general economic conditions, such as a recession or economic slowdown, including as a result of political instability and military hostilities in certain geographies, concerns over the potential downgrade of U.S. sovereign debt and continued sovereign debt, monetary and financial uncertainties in Europe and other geographies, and domestic and global inflationary trends, any of which could negatively affect the affordability of, and consumer demand for, our products. Under difficult economic conditions, consumers may seek to modify spending priorities and reduce discretionary spending by delaying purchases of our products, which could reduce our profitability and could negatively affect our overall financial performance. Other financial uncertainties in our major markets and unstable political conditions in certain markets, including civil unrest and governmental changes, could undermine global consumer confidence and reduce consumers' purchasing power, thereby reducing demand for our products. We cannot predict the reoccurrence of any economic slowdown or the strength or sustainability of the economic recovery, worldwide, in the United States, or in our industry. These and other economic factors could have a material adverse effect on our business, financial condition, and results of operations.

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 has impacted our sales and operating results, and we anticipate that they will continue to be impacted and subject to unpredictable variability in future periods. Further, certain development activities, such as human factors studies associated with our product development efforts and activities supporting 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 pandemic, which impacted our development timelines and regulatory strategies. These delays could have a negative impact on our product commercialization efforts and the future demand for our products.

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 incidence of disease could have a material adverse impact on the operations of our suppliers, which could prevent them from timely delivering products to us or supporting our requirements for manufacturing-related equipment. 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 or potential future public health threats on our business and operations is 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.

Climate change or other extreme weather conditions and related regulations may have a long-term impact on our business.

Climate-related events, including the increasing frequency of extreme weather events and their impact on the U.S., Mexico, Canada, and other major regions' critical infrastructure along with potential related regulations, have the potential to disrupt our business, our third-party suppliers, and/or the business of our customers. For example, a portion of our office facilities located in San Diego are in an area that is prone to flooding, which has occasionally caused temporary disruptions to our business operations and our third-party contract manufacturers are located in regions subject to natural disasters, including earthquakes, hurricanes, floods, fires and other catastrophic events. We strive to partner with organizations that mitigate their business risks associated with climate change. However, we recognize that inherent risks related to climate change, other extreme weather conditions and related regulations exist wherever global business is conducted. While these dangers currently have a low-assessed risk of disrupting our normal business operations, they pose a potential long-term impact on our business.

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.

As of December 31, 2022, we had $616.9 million in cash, cash equivalents and short-term investments. Our management expects the continued growth of our business, including the expansion of our customer service infrastructure to support our growing base of customers, our plans to continue expanding commercial sales of our products outside of the United States, the growth of our manufacturing and warehousing operations, and the increase of our facility footprint to accommodate additional headcount and 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:

- revenue generated by sales of our products, as well as the gross profits and gross margin we realize from such sales;
- the costs associated with maintaining and expanding an appropriate sales, marketing, clinical and customer service infrastructure;
- expenses associated with developing and commercializing our proposed products or technologies, including capital expenditures we make to maintain or enhance our manufacturing operations and distribution capabilities;
- the cost of obtaining and maintaining regulatory clearance or approval for our products and our manufacturing facilities, and of ongoing compliance with other legal and regulatory requirements;
- 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; and

- general and administrative expenses.

As a result of these and other factors we may in the future seek 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 Privacy and Security

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 compromise 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.

The efficient operation of our business depends on our information technology and communication systems, as well as those of our suppliers, contract manufacturers, distributors and other 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. These systems 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. These risks may have further increased in the second half of 2022 when we enabled users to control insulin boluses through the mobile app. 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. As this is a rapidly evolving area, compliance with any future requirements, regulations, and evolving threat models may require the investment of additional resources in the form of capital, personnel or technology.

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 identify, investigate and mitigate potential threats through ongoing maintenance and enhancement of software applications, 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 a few employees' email accounts through a cyber-attack commonly known as "phishing." As a result, we have been defending a lawsuit entitled *Joseph Deluna et al. v. Tandem Diabetes Care, Inc.*, which was filed in the Superior Court of the State of California in the County of San Bernardino. On November 28, 2022, the court granted our motion for summary adjudication on the plaintiffs' allegations that we violated the Confidentiality of Medical Information Act. On February 8, 2023, the plaintiffs asked the court to dismiss their remaining two claims with prejudice, which terminated the case at the Superior Court. The plaintiffs have to decide whether to appeal the Court's decision granting our motion for summary adjudication.

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 laws in the United States and outside the United States 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) and California Privacy Rights Act (CPRA), 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, transfer, 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 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, CCPA, CPRA, 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 use 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.

Risks Related to Legal and Intellectual Property

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. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. 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. 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.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties, which may be difficult, expensive and time consuming. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is subject to rapid change and constant evolution and, consequently, intellectual property protection in our industry can be uncertain. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially valuable. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, or are invalid or unenforceable, and could award attorneys' fees. 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 common, and we may be subject to litigation that could cause us to incur substantial costs and divert the attention of management from our business.

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 markets outside of United States 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 current products or products under development. 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 could require us to do one or more of the following:

- stop selling current products, developing new products or using technology that allegedly infringes third-party intellectual property;
- attempt to obtain a license to intellectual property from the third parties, which may not be available on reasonable terms or at all
- incur significant royalty payments and legal expenses; or
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing.

We do not maintain insurance to cover the expense or any liability that may arise from an intellectual property dispute. Any litigation or claim against us may cause us to incur substantial costs, divert the attention of management from our business and harm our reputation. Further, as we launch new products, increase our sales and expand the geographic regions in which we commercialize our products we believe the likelihood 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 trade secrets or other proprietary information of our competitors.

Many of our employees were previously employed at other medical device companies, including those that are our competitors or could become our competitors. We may be subject to claims that we, or our employees, have used or disclosed trade secrets or other proprietary information. In addition, we may be subject to allegations that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Even if we successfully defend against these claims, any resulting litigation could cause us to incur substantial costs, divert the attention of management from our business and harm our reputation. If our defense of those allegations fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or key personnel. A loss of key personnel or intellectual property rights could limit our ability to commercialize products, which could have an adverse effect on our business.

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 medical device industry. We are subject to product liability lawsuits alleging that component failures, manufacturing defects, design defects, or inadequate disclosure of product-related risks or information resulted in an unsafe condition, injury or death to customers. The risk of product liability claims 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. In addition, the misuse of our products or the failure of customers to adhere to operating guidelines could cause significant harm to customers, which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls could cause us to incur substantial costs, divert the attention of management from our business, harm our reputation and adversely affect our ability to attract and retain customers.

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 have substantial deductibles. In addition, we expect the cost of our product liability insurance will increase as our sales increase. 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 and make it more difficult to obtain insurance coverage in the future.

Risks Related to Our 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 (510(k) or approval of a pre-market approval (PMA) application from the FDA, unless an exemption from pre-market review applies. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, which may be exacerbated if the FDA or other regulatory authority changes its clearance and approval policies, and we may not be able to obtain these clearances for our proposed products or approvals on a timely basis or at all, including as a result of:

- 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; or the
- failure of the manufacturing process or facilities we use to meet applicable requirements.

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. Further, 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. Our failure to appropriately respond to these findings and take corrective action, or 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, product recalls, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future 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.

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.

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 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 we only recently commenced offering our Control-IQ technology in Australia. 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.

The U.S. has numerous federal and state laws pertaining to healthcare fraud and abuse. Violations of these laws are punishable by criminal and civil sanctions, including, imprisonment, significant monetary penalties and exclusion from participation in federal funded programs such as Medicare and Medicaid.

Healthcare fraud and abuse regulations are complex and evolving. Minor irregularities can potentially give rise to claims. The laws that may affect our ability to operate include:

- the federal and state Anti-Kickback Statutes, which prohibit, 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, persons from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to Medicare, state Medicaid programs, or other third-party payors;

- federal and state physician self-referral laws, such as the Stark Law, which 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 which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Our relationships with healthcare providers and other third parties are subject to scrutiny under these laws. 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. Federal government agencies continue to issue proposed and final rules implementing additional process, controls and guidelines for compliance under these laws with which we will be required to comply. We cannot predict the impact of any changes in these laws and whether they might be retroactive. Further, 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. Adjusting to new regulatory guidelines and responding to investigations can be time and resource-consuming and can divert management's attention from our core business. Additionally, if we settle an investigation, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. All of the foregoing 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. Our current or future activities could be subject to challenge under these laws. Any of these challenges could have a material adverse effect on our reputation, business, financial condition and operating results.

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. For example, the Affordable Care Act has substantially changed the way healthcare is financed by both governmental and private insurers and encourages improvements in the quality of healthcare items and services. In the future, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. 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.

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.

General Risks

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

The trading price of our common stock has been and will continue to be volatile in response to a variety of factors, including the following:

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

- 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, divestitures or partnerships by us, our competitors or our collaboration partners;
- regulatory approval of our products or the products of our competitors or collaboration partners, 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;
- financial and operating results relative to the expectations of securities analysts and other market participants and the issuance of securities analysts' reports or recommendations;
- threatened or actual litigation, regulatory proceedings, or government investigations; and
- general political or economic conditions, including the impacts and disruptions caused by the COVID-19 global pandemic.

In addition, the trading price of our common stock may fluctuate substantially due to other factors, including the numerous risks and uncertainties described in this section. Fluctuations in our stock price may negatively affect the liquidity of our common stock, which could further impact our stock price. Further, our common stock may be susceptible to significant price and volume fluctuations as a result of stock market dynamics, which may impact our common stock without regard to our financial condition or operating performance.

Anti-takeover provisions in our organizational documents and Delaware law may delay or prevent a change of control, which could reduce our stock price and prevent our stockholders from removing our current board of directors.

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 a staggered board of directors whereby the board is currently divided into three classes, although our board and stockholders have approved the phased declassification of the board of directors such that the board structure will be completely declassified by our 2024 annual meeting of stockholders;
- 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 also 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 ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2022, we had accumulated federal and state net operating loss (NOL) carryforwards of approximately $193.1 million, and $255.9 million, respectively. Of the total federal NOL carryforwards, approximately $95.6 million were generated after January 1, 2018, and therefore do not expire. The NOL generated after January 1, 2018, is subject to an 80% limitation. The remaining federal NOL carryforwards of $97.5 million will begin to expire in 2033, and state tax loss carryforwards continue to expire. 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, which 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.

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, which could harm our business and result in a decline in 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 adequate controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations, or to prevent the circumvention of our controls or fraud. 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 SEC rules and 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, may require prospective or retroactive changes to our consolidated financial statements, or may identify other areas for further attention or improvement. Any failure to implement appropriate internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and result in a decline in the trading price of our common stock.

Risks Related to Our Indebtedness

We have incurred a significant amount of indebtedness, and the agreements governing such indebtedness subject us to required debt service payments, as well as financial and operational covenants, any of which may restrict our financial flexibility and affect our ability to operate our business.

From time to time, we have financed our liquidity needs under various credit arrangements and we may borrow additional funds in the future. For example, in May 2020, we completed the offering of $287.5 million principal amount of 1.50% Convertible Senior Notes due 2025 (the Notes), which are governed by the terms of an indenture. The Notes are our senior unsecured obligations. In addition, in May 2022, we entered into a revolving line of credit agreement, which provides us with an available principal borrowing amount of $100.0 million (the Line of Credit). While there are currently no borrowings outstanding under the Line of Credit, we may request advances thereunder and use the proceeds for general corporate purposes. The Line of Credit is secured by a first priority security interest in substantially all of our assets.

The Notes and the Line of Credit contain certain debt service requirements, and financial and operational covenants, as applicable. Pursuant to the Notes, interest is payable in cash semi-annually at a rate of 1.50% per year. In addition, any future advances under the Line of Credit will bear interest at an annual rate calculated as determined pursuant to the Line of Credit with interest on outstanding advances payable quarterly. During the term of the Line of Credit, we are also required to maintain compliance with two financial maintenance covenants: a minimum consolidated interest coverage ratio and a maximum consolidated net leverage ratio. The Line of Credit also contains customary operating covenants, subject to certain exceptions.

Our failure to comply with certain obligations under the Notes and the Line of Credit, or inability to make required debt service payments, could result in an event of default. A default, if not cured or waived, could result in acceleration of the

indebtedness, which could have a material adverse effect on our business, financial condition and liquidity. Further, if our indebtedness is accelerated, we cannot be certain that cash will be available to pay the indebtedness and we may not have the ability to refinance the indebtedness on terms satisfactory to us or at all.

In addition, our current or future level of indebtedness could affect our business, operations and strategy in several important ways, including the following:

- we may be required to dedicate a portion of our current liquidity or cash flow from operations to interest payments, limiting the availability of cash for other purposes;
- the covenants contained in the Line of Credit or future agreements governing indebtedness may limit our ability to borrow additional funds, refinance indebtedness or make certain investments;
- debt covenants may affect our flexibility in planning for, and reacting to, changes in the economy and our industry;
- a high level of indebtedness may increase our vulnerability to adverse economic and competitive conditions; and
- a high level of indebtedness may limit our ability to obtain additional financing in the future or negatively impact the terms on which additional financing may be obtained.

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 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 under 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.

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 the Notes, or to refinance the Notes depends on our future business operations and liquidity, which are subject, to numerous risks and uncertainties, including, market acceptance of our products, regulatory approval for our products, and the competitive environment in which we operate. 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. If we are unable to generate sufficient 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. 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 under 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 from incurring additional indebtedness or refinancing our existing indebtedness in the future. 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 sufficient cash or be able to obtain financing to repurchase the Notes upon a fundamental change, or to settle conversions 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 the Notes or settle conversions of the Notes. In addition, our ability to repurchase the Notes or to pay cash upon conversions of the Notes may be limited 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.

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.

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 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 governing the Notes) 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. 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. 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 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. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings. 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.

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, 2022, we leased facilities with an aggregate total of approximately 417,000 square feet, as follows:

United States

- 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, commenced in March 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.

- 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 2028.

- 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 Lease: 31,372 square feet of general office space located on High Bluff Drive, in San Diego, California, which is scheduled to expire in March 2024.

- 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.

Outside the United States

- 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.

Except as set forth below under the caption *"Commitments and Contingencies - Legal and Regulatory Matters"* in Part II, Item 8, Subsection 13 of this Annual Report, as of December 31, 2022, 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.

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, 2022		
First Quarter	$ 150.64	$ 100.00
Second Quarter	$ 123.96	$ 52.69
Third Quarter	$ 70.81	$ 42.90
Fourth Quarter	$ 58.82	$ 33.51
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

Holders of Record

As of February 17, 2023, there were approximately 44 holders of record of our common stock. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans, as set forth under the caption "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters" in Part III, Item 12 of this Annual Report, 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, 2022 and 2021.

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 the "Consolidated Financial Statements and Supplementary Data" in Part II, Item 8 of this Annual Report. 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 of this Annual Report.

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 robust ecosystem and 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. Today, the t:slim X2 Insulin Delivery System is our flagship technology solution. In the four-year period ended December 31, 2022, we shipped approximately 420,000 t:slim X2 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. Approximately 290,000 of these pumps were shipped to customers in the United States and 130,000 were shipped to customers outside the United States. Our products are currently available in approximately 25 countries outside the United States.

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. The majority of our customers use the t:slim X2 with continuous glucose monitoring (CGM) integration. This allows the t:slim X2 to receive CGM sensor readings, which can then be used in our automated insulin dosing (AID) algorithms, including our Control-IQ technology. Control-IQ is an advanced hybrid-closed loop feature designed to help increase a user's time in their targeted glycemic range. Multiple studies have demonstrated that use of Control-IQ technology provides people across all demographics with improved clinical outcomes that are both immediate and sustained. 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.

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) that has allowed approximately 200,000 people to update their t:slim X2 software from a personal computer. This offering is a competitive advantage that allows us to bring our customers clinical and lifestyle enhancements, such as new developments in our AID technology, CGM integrations and mobile app features. In July 2022, we launched a new pump software update through TDU to allow all t:slim X2 pump users in the United States to bolus insulin using our smartphone app that is available on compatible iOS and Android devices.

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

COVID-19 Global Pandemic Impact and Considerations

Information about the COVID-19 global pandemic impact and considerations is set forth above under the caption *"Risk Factors"* in Part I, Item 1A of this Annual Report and is incorporated herein by reference.

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

The Tandem Mobi is approximately half the size of our t:slim X2 pump, and is designed for people who seek even greater discretion and flexibility with the use of their insulin pump. Its features include full pump-control from our mobile application, a 200-unit cartridge, an on-pump bolus button, inductive charging, and an AID algorithm.

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. It will allow a Mobi pump to be worn completely on the user's body with no tubing. A goal of this design is to allow people living with diabetes to customize the way they wear their pump with each cartridge change, switching between tubed and tubeless wear configurations, to best suit their personal preferences and lifestyle.

Sigi

This ergonomic, rechargeable patch pump is being designed to reduce the burden of managing diabetes through its use of pre-filled insulin cartridges and compatibility with AID technology. This replaces our early-stage development of a disposable tubeless solution that was previously under development.

Extended Wear Infusion Sets

Infusion sets provide additional choice and flexibility to people living with diabetes. Our goals for infusion set innovations focus on solutions that extend wear time and enhance user experience, while reducing occlusions, body burden and waste. In support of this effort, we are currently developing a unique extended wear infusion set technology.

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 continuing to drive innovation in our algorithms, emphasizing automation, personalization and simplification to continue to improve therapeutic outcomes and provide a positive patient experience. We have recently completed clinical studies to support expanding the indications of our Control-IQ technology to include people with type 1 diabetes ages 2 to 5 years old. Additionally, we are initiating a pivotal study to support expanding indications to include 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: We have agreements with Dexcom to extend our current collaboration to include integration with their G7 CGM technology. Following integrated product development work, this will be the fourth generation of Dexcom CGM that we intend to integrate with our devices.

Abbott CGM: We have an agreement with Abbott Laboratories (Abbott), to develop and commercialize integrated diabetes solutions that combine Abbott's FreeStyle Libre 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. Our key objectives include making these insights easy to understand, making the data available in real time, and providing the information in a flexible format with mobile or web apps. In addition, we are working to integrate health-related information from third-party sources and to 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 be deployed globally. This application enhances clinical data visualization, and provides added interface customization for users to personalize how they engage with their data and for healthcare providers to better manage their care. 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.

Pump Shipments

From inception in 2012 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 began selling our t:slim X2 insulin pump in select geographies outside the United States and our technology solutions are now available in approximately 25 countries worldwide. We consider the number of insulin pump units shipped 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. In the past four years, we have shipped approximately 420,000 insulin pumps worldwide, which is representative of our estimated global in-warranty installed customer base. Our ending estimated worldwide installed base has increased approximately 29% year over year.

At the end of the typical four-year reimbursement cycle, customers may be eligible for the purchase of a new insulin pump, subject to the rules and requirements of their primary insurance payor. While warranties generally expire four years from the original pump shipment date, those customers that renew typically purchase a subsequent pump within one year from the date of warranty expiration. The majority of our insulin 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 escalating number of additional 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.

Approximately 290,000 pumps were shipped to customers in the United States in the past four years, which aligns with the standard four-year warranty period. Pump shipments to customers in the United States by fiscal quarter for the current year and previous five years, which aligns more closely with our typical renewal cycle, were as follows:

	United States Pump Unit Shipments for Each of the Three Months Ended in Respective Years				
	March 31	June 30	September 30	December 31	Total
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
2022	18,658	20,818	20,394	23,684	83,554

Since commencing sales outside the United States in the third quarter of 2018, we shipped approximately 130,000 pumps and our products are now available in approximately 25 countries. We are only beginning to complete a full four-year reimbursement cycle in certain of our markets outside of the United States. Pump shipments to customers outside the United States by fiscal quarter were as follows:

	Outside the United States Pump Unit Shipments for Each of the Three Months Ended in Respective Years				
	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
2022	9,437	11,296	12,113	11,939	44,785

Trends and Uncertainties Impacting Financial Results

Our financial condition and operating results have historically fluctuated on a quarterly or annual basis. We expect these periodic fluctuations will continue to be impacted by a number of trends and uncertainties, including the following:

Regulatory Approvals

- When there are anticipated, and actual, regulatory approvals for our products, or our competitors' products, customers may reconsider their purchasing decisions and take additional time to consider FDA approval prior to making their purchase, which could adversely impact our revenue and results of operations. Similarly, our sales outside the United States are subject to local government regulations. The requirements and the timeline to

receive these approvals substantially vary from country to country and may impact our ability to expand our international customer base and increase our cost of sales.

- The failure to receive regulatory clearances and approvals may lead to product recalls or the suspension of our products. Even if a clinical trial meets the required success criteria, the FDA may not accept the results of the trial as sufficient to prove the product's safety and efficacy. Our competitors are also vulnerable to these uncertainties, which may affect our customer base and sales.

Product Launches

- We expect our business to be impacted by the introduction of new products, treatment techniques or technologies for the treatment of diabetes by us or our competitors. Customers may defer their purchasing decisions if they believe a new product may be launched in the future. The success of our products is variable and we believe it correlates to market acceptance, anticipated product launches and commercial availability. We currently believe our recently announced Tandem Choice program, and its related financial and accounting impact, my continue to materially impact our business going forward.

- Our revenue and results of operations may be impacted by the failure to secure or retain adequate coverage or reimbursement for our current and future products from third-party payors. Our competitors are also vulnerable to these uncertainties, which may affect our customer base and sales.

Foreign Markets

- We have expanded our business and launched new products in select geographies outside the United States. The ordering patterns of our distributors outside the United States is highly variable from period to period, particularly as our distributors continue to gain familiarity with the markets they are operating. The commencement of operations of our European distribution center in the third quarter also led to downward adjustments to inventory levels from our distributors in late 2022 and early 2023.

Seasonality

- Seasonality in the United States is associated with annual insurance deductibles and coinsurance requirements of the medical insurance plans used by our customers and the customers of our distributors. In the United States, we experience a higher volume of pump shipments in the third and fourth quarters due to the nature of the reimbursement environment. Other factors that may impact sales across the year include the timing of winter, summer and other seasonal holidays, particularly in our markets outside the United States.

Macroeconomic Factors

- Global economic and market uncertainty, such as recessionary concerns, inflation, changes in discretionary spending and increased interest rates have impacted our customers' purchasing decisions and the buying patterns of our distributors.

- The lingering effects of COVID-19 have continued to disrupt our relationship with suppliers, third-party manufacturers, healthcare providers, distributors and our existing or potential customers. We are experiencing higher costs as we navigate these global supply chain challenges.

Components of Results of Operations

Sales

We offer products for people with insulin-dependent diabetes in approximately 25 countries. The t:slim X2 insulin pump is our flagship pump platform. Our other products include disposable insulin cartridges and infusion sets, as well as our complementary t:connect, TDU and mobile application products. Our primary customers are the end customers who use our products, non-exclusive distribution partners whose level of service varies based on geography, the healthcare professionals who prescribe our products and the healthcare systems or payors who provide insurance coverage and access to our products. Our sales may fluctuate from period to period, particularly due to seasonality in the United States associated with the timing of insurance deductible resets, which generally result in the lowest percent of sales the first quarter of each calendar year and the highest percent in the fourth quarter.

In September 2022, the Company began offering the Tandem Choice Program to eligible t:slim X2 customers to provide a pathway to ownership of its newest hardware platform for a fee when available. Tandem Choice expires on December 31, 2024. The accounting treatment for Tandem Choice is complex. Initially, the program requires the deferral of some portion of sales for shipments of eligible pumps beginning in the third quarter of 2022. No election is made by the customer at the time of the initial sale, nor does the right offered to the customer impact the economics associated with how or when the initial pump sale is reimbursed. If a customer elects to participate in Tandem Choice at a future date beginning with the launch of our next generation hardware platform, we will recognize the existing deferral, incremental fees received and the associated costs of providing the new hardware at the time of fulfillment. Any remaining deferrals will be recognized at program expiration. At this time, we are not able to estimate the financial impact for the duration of Tandem Choice.

Cost of Sales

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. When taking into consideration the differences in reimbursement levels and cost structure, pumps have, and are expected to continue to have, a higher gross profit and 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.

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 have approximately 110 sales territories in the United States, which are generally maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel. Other significant SG&A expenses typically include those incurred for 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.

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 and non-cash stock-based compensation. 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.

Acquired In-process Research and Development (IPR&D) Expenses

Acquired IPR&D reflects costs of external research and development projects acquired directly in a transaction other than a business combination, that do not have an alternative future use.

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, interest earned on our cash equivalents and short-term investments, and changes in the fair value of certain common stock warrants which were issued in October 2017 and expired in October 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 federal, state and foreign cash tax expense as a result of taxable income anticipated or incurred in those jurisdictions.

Results of Operations

(in thousands, except percentages)	Year Ended December 31, 2022	2021	2020
Sales:			
United States	$ 588,765	$ 524,907	$ 415,680
Outside the United States	212,452	177,892	83,150
Total sales	801,217	702,799	498,830
Cost of sales	388,231	326,584	238,310
Gross profit	412,986	376,215	260,520
Gross margin	52 %	54 %	52 %
Operating expenses:			
Selling, general and administrative	335,681	261,508	204,903
Research and development	139,114	92,054	63,574
Acquired in-process research and development	31,039	—	—
Total operating expenses	505,834	353,562	268,477
Operating income (loss)	(92,848)	22,653	(7,957)
Other income (expense), net:			
Interest income and other, net	6,057	674	1,567
Interest expense	(6,208)	(6,040)	(12,805)
Change in fair value of common stock warrants	147	(1,386)	(17,087)
Total other expense, net	(4)	(6,752)	(28,325)
Income (loss) before income taxes	(92,852)	15,901	(36,282)
Income tax expense (benefit)	1,742	335	(1,900)
Net income (loss)	$ (94,594)	$ 15,566	$ (34,382)

Comparison of Years Ended December 31, 2022 and 2021

Sales. For the year ended December 31, 2022, sales were $801.2 million, which included $212.5 million of sales outside the United States. For the year ended December 31, 2022, we deferred $3.5 million of pump sales as the result of our Tandem Choice program which launched in the third quarter of 2022. For the year ended December 31, 2021, sales were $702.8 million, which included $177.9 million of sales outside the United States.

The increase in worldwide sales of $98.4 million in 2022, as compared to 2021, was driven by a 30% increase in pump-related supply sales, primarily due to 29% growth in our ending estimated worldwide installed base of customers.

Sales by product in the United States were as follows (in thousands):

	Year Ended December 31, 2022	2021	% Change
Pump	$ 329,061	$ 319,898	3%
Infusion sets	181,578	140,387	29%
Cartridges	80,187	63,375	27%
Other	1,488	1,247	19%
Adjustment for Tandem Choice program	(3,549)	—	—%
Total Sales in the United States	$ 588,765	$ 524,907	12%

Pump shipments in the United States were flat compared to the prior year while pump sales benefited from an improvement in average selling prices due in part to price increases, as well as a decrease in sales through the distribution channel. Pump shipments were driven by continued demand for our t:slim X2 insulin pump with Control-IQ technology even with the presence of new competitive product launches during the year. We also faced challenging marketplace dynamics and economic conditions brought on by the global pandemic and a deteriorating macroeconomic environment, with inflation and the threat of recession beginning to impact pump purchasing decisions. Sales of pump-related supplies increased primarily due to a 22% increase in our ending estimated installed base of customers in the United States. Sales to distributors accounted for 65% and 67% of our total sales in the United States for the years ended December 31, 2022 and 2021, respectively. Sales in the United States for the year ended December 31, 2022 were also reduced by a deferral of $3.5 million as the result of the launch of our Tandem Choice program in the third quarter. No comparable program existed in 2021.

Sales by product outside the United States were as follows (in thousands):

	Year Ended December 31,		
	2022	2021	% Change
Pump	$ 102,846	$ 96,458	7%
Infusion sets	76,912	57,063	35%
Cartridges	31,973	23,509	36%
Other	721	862	(16)%
Total Sales Outside the United States	$ 212,452	$ 177,892	19%

Pump shipments outside the United States were flat compared to the prior year, with the increase in pump sales attributable to an increase in average selling prices due in part to price increases, as well as positive fluctuations associated with variations in the geographical mix. Sales of pump-related supplies benefited from a 46% increase in our ending estimated installed base of customers outside the United States. The ordering patterns of our distributors outside the United States for pumps and supplies has been, and may continue to be, highly variable from period to period as distributors continue to gain familiarity with the markets in which they operate and the acceptance of our products in those markets evolves. This variability has been compounded by the differing levels of impact from the global pandemic with regard to access to both physicians and customers, as well as shipping logistics. We also commenced operations of a centralized distribution center in the third quarter of 2022, which resulted in modest disruption to ordering patterns in the fourth quarter as a result of the affected European distributors adjusting their inventory levels for the reduced transit time. We expect that this will continue to impact sales levels of pumps and supplies in Europe through the middle of 2023. Sales to distributors accounted for 96% and 95% of our total sales outside the United States for the years ended December 31, 2022 and 2021, respectively.

Cost of Sales and Gross Profit. Our cost of sales for the year ended December 31, 2022 was $388.2 million, resulting in gross profit of $413.0 million, compared to cost of sales of $326.6 million and gross profit of $376.2 million for the year ended December 31, 2021. The gross margin for 2022 was 52%, compared to 54% in 2021.

The increase in our gross profit for the year ended December 31, 2022, was primarily the result of the $98.4 million increase in total sales, driven by increased supply sales. Gross profit and gross margin benefited from an increase in average selling prices as well as improvement in manufacturing efficiencies and leverage of fixed overhead, offsetting the pressure from product mix. The gross margin decline in 2022 was related primarily to certain COVID-related pressures, as well as the introduction of the Tandem Choice program. Gross margin was pressured by more than 1 percentage point from increased pump material costs due to the use of alternative sourcing for raw materials to reduce the risk of component shortages in the near-term and higher freight costs we experienced in 2022. We anticipate that the pressure from increased supply chain and material costs experienced in 2022 will continue into the first half of 2023 as we continue to navigate the challenges of the global pandemic and the economic environment. The impact on gross margin from the Tandem Choice program will fluctuate through the expiration of the program based on the timing of availability of a new hardware platform and the number of eligible customers who ultimately elect to participate.

Selling, General and Administrative Expenses. SG&A expenses increased 28% to $335.7 million for the year ended December 31, 2022, from $261.5 million for the same period in 2021. Employee-related expenses for our SG&A functions comprise the majority of SG&A expenses. The increase compared to 2021 was primarily the result of a $43.8 million increase in salaries, incentive compensation, non-cash stock based compensation, and other employee benefits due primarily to an increase in personnel to expand the number of sales territories in the United States from approximately 95 in 2021 to 110 in 2022, and provide continued support services for our growing installed customer base. Discretionary expenses included an increase of $21.5 million, of which a $12.4 million non-recurring charge for facilities consolidation was recorded in the fourth quarter of 2022, and $9.1 million of lease expenses were incurred throughout the year during the construction phase of our new Tech Center facility (see Note 6, “Leases”). We also experienced an $11.6 million increase in other non-employee discretionary spending, primarily attributable to equipment, outside services, and travel.

Research and Development Expenses. R&D expenses increased 51% to $139.1 million for the year ended December 31, 2022, from $92.1 million for the same period in 2021. The increase in R&D expenses was primarily the result of an increase of $32.4 million in salaries, incentive compensation, non-cash stock based compensation, and other employee benefits due to an increase in personnel to support our product development efforts. We also experienced a $15.0 million increase in other non-employee discretionary spending, including outside consulting and services, clinical trial expenses, information technology and equipment costs attributable to R&D.

Acquired In-Process Research and Development Expenses. Acquired IPR&D expenses of $31.0 million for the year ended December 30, 2022 represented the value of assets acquired, and acquisition related expenses in connection with our acquisition of Capillary Biomedical (see Note 12, “Acquisitions”).

Other Income (Expense). Total other expense, net for the year ended December 31, 2022 was $4,000, compared to $6.8 million in 2021. Other expense for 2022 primarily consisted of $6.2 million of interest expense which included the amortization of debt issuance costs related to our Convertible Senior Notes, offset by $6.1 million of interest income earned on our cash equivalents and short-term investments. Other expense for 2021 consisted primarily of $6.0 million of interest expense which included amortization of debt issuance costs related to our Notes, and an $1.4 million revaluation loss from the change in the fair value of certain warrants, offset by $0.7 million of interest income earned on our cash equivalents and short-term investments. Interest income increased in 2022 primarily due to the higher interest rate environment as compared to 2021.

Income Tax Expense (Benefit). We recognized income tax expense of $1.7 million on a pre-tax loss of $92.9 million for the year ended December 31, 2022, compared to income tax expense of $0.3 million on a pre-tax gain of $15.9 million for the same period in 2021. The income tax expense for the year ended December 31, 2022 was primarily attributable to federal, 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, 2021 was primarily attributable to state and foreign income tax expense as a result of current taxable income in those jurisdictions.

Comparison of Years Ended December 31, 2021 and 2020

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

The increase in worldwide sales of $204.0 million in 2021, as compared to 2020, was primarily 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 ending estimated worldwide installed base of customers.

Sales by product in the United States were as follows (in thousands):

	Year Ended December 31,		
	2021	2020	% Change
Pump	$ 319,898	$ 269,856	19%
Infusion sets	140,387	99,743	41%
Cartridges	63,375	45,342	40%
Other	1,247	739	69%
Total Sales in the United States	$ 524,907	$ 415,680	26%

Pump sales in the United States 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 impacted the availability of both customers and healthcare providers. Sales of pump-related supplies increased primarily due to a 39% increase in our ending estimated installed base of customers in the United States. Sales to distributors accounted for 67% and 70% of our total sales in the United States for the years ended December 31, 2021 and 2020, respectively.

Sales by product outside the United States were as follows (in thousands):

	Year Ended December 31,		
	2021	2020	% Change
Pump	$ 96,458	$ 44,851	115%
Infusion sets	57,063	28,016	104%
Cartridges	23,509	9,884	138%
Other	862	399	116%
Total Sales Outside the United States	$ 177,892	$ 83,150	114%

Pump sales outside the United States 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 continued 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 ending estimated installed base of customers outside the United States. The ordering patterns of our distributors outside the United States 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 differing levels of impact from the global pandemic with regard to access to both physicians and customers. Sales to distributors accounted for 95% and 94% of our total sales outside the United States 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 pump sales outside the United States 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 installed base of customers outside the United States. 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 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 a $17.1 million revaluation loss from the change in the fair value of certain warrants, and $12.8 million of interest expense which included the amortization of debt discount and debt issuance costs related to our Notes. 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. 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.

Liquidity and Capital Resources

At December 31, 2022, we had $616.9 million in cash and cash equivalents and short-term investments. In addition, we had a total available balance of $95.1 million at December 31, 2022 under our Revolving Line of Credit (the Line of Credit), which expires in May 2025 (see Note 7, "Debt"). We believe that our cash and cash equivalents, short-term investments, borrowing availability under the Line of Credit, and future cash flows from operations will be sufficient to fund our ongoing core business activities.

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.

Our historical cash outflows have primarily been associated with cash used for operating activities such as research and development activities, sales, marketing and commercialization of our products worldwide, expansion of clinical and customer support organizations, the acquisition of intellectual property, equity investments and acquired assets, capital expenditures and debt service costs.

The following table shows a summary of our cash flows for the years ended December 31, 2022, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2022	**2021**	**2020**
Net cash provided by (used in):			
Operating activities	$ 50,464	$ 111,359	$ 24,669
Investing activities	33,168	(186,876)	(296,056)
Financing activities	16,877	51,932	314,438
Effect of foreign exchange rate changes on cash	827	153	387
Net increase (decrease) in cash and cash equivalents	$ 101,336	$ (23,432)	$ 43,438

Operating activities. Net cash provided by operating activities was $50.5 million for the year ended December 31, 2022, compared to cash provided of $111.4 million and $24.7 million, respectively, for the years ended December 31, 2021 and 2020.

The reduction in net cash provided by operating activities for 2022 compared to 2021 was primarily a result of the $110.2 million increase in net loss, as well as net working capital changes. Working capital changes during 2022, primarily consisted of increases in inventories, accounts receivable, accounts payable, and operating leases and other current liabilities. Accounts receivable increased to $114.7 million at December 31, 2022 from $110.7 million at December 31, 2021, as a result of higher sales in the fourth quarter of 2022 as compared to the fourth quarter of 2021. Inventories increased to $111.1 million at December 31, 2022 from $68.6 million at December 31, 2021.

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 net 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.

Investing activities. Net cash provided by investing activities was $33.2 million for the year ended December 31, 2022, which was primarily related to $569.5 million in proceeds from maturities and redemptions of short-term investments, offset by $467.7 million of purchases of short-term investments, $34.1 million in purchases of property and equipment, $25.7 million for the acquisition of Capillary Biomedical, including $1.0 million of transaction costs, and $8.9 million cash paid for purchases of intangible assets and strategic investments. 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 purchases of intangible assets and strategic investments, offset by $570.0 million in proceeds from maturities and redemptions 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 redemptions of short-term investments.

Financing activities. Net cash provided by financing activities was $16.9 million for the year ended December 31, 2022, which primarily consisted of proceeds from the issuance of common stock under our stock plans. 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.

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 proceeds from the issuance of equity awards pursuant to employee stock plans;
- fluctuations in gross margins and operating margins; and
- fluctuations in working capital, including changes in accounts receivable, inventories, accounts payable, employee-related liabilities, and operating lease liabilities.

Both our primary short-term and long-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.
- acquisition and subsequent integration of businesses, products and technologies.

Indebtedness

Convertible Senior Notes

In May 2020, we 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 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 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, 2022 are as follows (in thousands):

	Total	2023	2024	2025
Principal amount of convertible senior notes[(1)]	$ 287,500	$ —	$ —	$ 287,500
Contractual interest	10,782	4,313	4,313	2,156
Total	$ 298,282	$ 4,313	$ 4,313	$ 289,656

(1) The Convertible Senior Notes may be settled in cash, shares of our common stock, or a combination of cash and shares of our common stock, at our election.

Promissory Note Payable

In connection with our acquisition of Capillary Biomedical, Inc. (see Note 12, “Acquisitions”), we assumed $4.7 million of long-term debt. The promissory note accrues interest at the rate of 5% per year, becomes due and payable upon the first sale or license of the commercialized product, and is included as a component of other long-term liabilities on the consolidated balance sheet at December 31, 2022.

Contractual Obligations & Off-Balance Sheet Arrangements

Contractual Obligations

Operating Lease Obligations

We lease 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, 2022, see Note 6 “Leases” to the consolidated financial statements in Part II, Item 8 of this Annual Report.

Purchase Order Commitments

We have 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, 2022, see Note 13 “Commitments and Contingencies” to the consolidated financial statements in Part II, Item 8 of this Annual Report.

Acquisition-related Contingent Consideration

In connection with our acquisition of AMF Medical SA completed in January of 2023 (see Note 15, “Subsequent Event” to the consolidated financial statements in Part II, Item 8 of this Annual Report), the total consideration includes cash paid at the closing of the transaction and additional contingent earnout payments. The additional earnout payments of up to CHF 129.6 million, in aggregate, become payable upon the achievement of certain milestones and are comprised of a payment of up to CHF 38.4 million upon the successful completion of key development milestones over the next two years, and a payment of up to CHF 91.2 million upon obtaining regulatory clearance of an automated controller enabled (ACE) pump by the United States Food and Drug Administration.

Off-Balance Sheet Arrangements

As of December 31, 2022, 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 13 “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 “Summary of Significant Accounting Policies” 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.

For purposes of evaluating the Tandem Choice Program, we have determined that the ability for a customer to upgrade to a new technology, represents a material right because the pricing inherent in such option provides the customer with a discount that is incremental to the range of discounts that would otherwise be granted for the related goods and services to comparable customers. The standalone selling price for the Choice Right was estimated based on the adjusted market assessment approach and contemplates the likelihood that the respective option will be exercised.

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, 2021 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 to be 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 U.S. Treasury securities, U.S. Government-sponsored enterprise securities, commercial paper and corporate debt 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. 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, 2022 were primarily due to the recent increase in market interest rates. 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, 2022, 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. In addition, we have a sales and marketing office in Canada and, beginning in 2022, a distribution center in the Netherlands. Our sales to customers in the United States are made in U.S. dollars. With the exception of sales from our distribution center in the Netherlands and a portion of our sales in Canada, our sales to customers outside of the United States are currently made to independent distributors under agreements denominated in U.S. dollars. Accordingly, we believe our exposure to foreign currency rate fluctuations is currently limited to our operations in Canada and the Netherlands, where fluctuations in the rate of exchange between the U.S. dollar and the local currency could adversely affect our financial results. As we expand and further develop our operations in markets outside the United States, particularly in Europe, we will be exposed to additional foreign currency exchange rate risk. 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. 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, 2022 and 2021 and for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, 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, 2022 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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, 2023 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit 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 $36.5 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 the expected warranty replacement rates.

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 the significant assumption of replacement rates, 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. This assumption is affected by actual customer experience and changes in this assumption 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 this determination and management's significant assumption 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 the significant assumption underlying the warranty reserve, 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 assumption related to replacement rates, including review for contrary evidence. Evaluating management's significant assumption involved evaluating the historical claims data utilized by management in estimating the replacement rates. We involved our valuation professionals to assist in the assessment of the estimation methodology and the significant assumption used in determining the warranty reserve. 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. We performed sensitivity analyses of the significant assumption to evaluate the impact of changes in the warranty reserve that would result from changes in the assumption.

/s/ Ernst & Young LLP

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

San Diego, California
February 22, 2023

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

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 172,517	$ 71,181
Short-term investments	444,384	552,630
Accounts receivable, net	114,717	110,725
Inventories	111,117	68,551
Prepaid and other current assets	7,241	8,433
Total current assets	849,976	811,520
Property and equipment, net	68,552	50,386
Operating lease right-of-use assets	110,626	27,503
Other long-term assets	23,631	15,728
Total assets	$ 1,052,785	$ 905,137
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 55,730	$ 28,032
Accrued expenses	9,595	9,419
Employee-related liabilities	38,682	51,556
Operating lease liabilities	13,121	9,279
Deferred revenue	18,837	10,182
Other current liabilities	29,325	23,388
Total current liabilities	165,290	131,856
Convertible senior notes, net - long-term	283,232	281,467
Operating lease liabilities - long-term	123,524	23,922
Deferred revenue - long-term	16,874	16,940
Other long-term liabilities	23,918	17,840
Total liabilities	612,838	472,025
Commitments and contingencies (Note 13)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 64,513 and 63,833 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively.	65	64
Additional paid-in capital	1,170,888	1,068,259
Accumulated other comprehensive loss	(1,817)	(616)
Accumulated deficit	(729,189)	(634,595)
Total stockholders' equity	439,947	433,112
Total liabilities and stockholders' equity	$ 1,052,785	$ 905,137

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,		
	2022	**2021**	**2020**
Sales	$ 801,217	$ 702,799	$ 498,830
Cost of sales	388,231	326,584	238,310
Gross profit	412,986	376,215	260,520
Operating expenses:			
Selling, general and administrative	335,681	261,508	204,903
Research and development	139,114	92,054	63,574
Acquired in-process research and development expenses	31,039	—	—
Total operating expenses	505,834	353,562	268,477
Operating income (loss)	(92,848)	22,653	(7,957)
Other income (expense), net:			
Interest income and other, net	6,057	674	1,567
Interest expense	(6,208)	(6,040)	(12,805)
Change in fair value of common stock warrants	147	(1,386)	(17,087)
Total other expense, net	(4)	(6,752)	(28,325)
Income (loss) before income taxes	(92,852)	15,901	(36,282)
Income tax expense (benefit)	1,742	335	(1,900)
Net income (loss)	$ (94,594)	$ 15,566	$ (34,382)
Other comprehensive income (loss):			
Unrealized loss on short-term investments	$ (2,233)	$ (693)	$ (20)
Foreign currency translation gains (losses)	1,032	(143)	118
Comprehensive income (loss)	$ (95,795)	$ 14,730	$ (34,284)
Net income (loss) per share - basic	$ (1.47)	$ 0.25	$ (0.56)
Net income (loss) per share - diluted	$ (1.47)	$ 0.24	$ (0.56)
Weighted average shares used to compute basic net income (loss) per share	64,146	63,000	60,990
Weighted average shares used to compute diluted net income (loss) per share	64,146	64,349	60,990

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		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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 under 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 gains	—	—	—	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 under 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 losses	—	—	—	(143)	—	(143)
Net income	—	—	—	—	15,566	15,566
Balance at December 31, 2021	63,833	$ 64	$ 1,068,259	$ (616)	$ (634,595)	$ 433,112
Exercise of stock options	280	1	9,130	—	—	9,131
Vesting of restricted stock units, net of shares withheld for taxes	131	—	(4,374)	—	—	(4,374)
Issuance of common stock under Employee Stock Purchase Plan	263	—	12,713	—	—	12,713
Exercise of common stock warrants	6	—	83	—	—	83
Stock-based compensation expense	—	—	85,077	—	—	85,077
Unrealized loss on short-term investments	—	—	—	(2,233)	—	(2,233)
Foreign currency translation gains	—	—	—	1,032	—	1,032
Net loss	—	—	—	—	(94,594)	(94,594)
Balance at December 31, 2022	64,513	$ 65	$ 1,170,888	$ (1,817)	$ (729,189)	$ 439,947

(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 7, "Debt").

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,		
	2022	**2021**	**2020**
Operating Activities			
Net income (loss)	$ (94,594)	$ 15,566	$ (34,382)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization expense	14,330	13,845	10,451
Amortization of debt discount and issuance costs	1,896	1,727	10,096
Provision for expected credit losses	4,782	2,333	3,016
Lease termination and impairment charges	7,567	—	—
Change in fair value of common stock warrants	(147)	1,386	17,087
Amortization of premium (discount) on short-term investments	4,187	365	(1,296)
Benefit for deferred income taxes	—	—	(2,126)
Stock-based compensation expense	84,918	60,752	58,431
Acquired in-process research and development expenses	31,039	—	—
Other	1,135	1,013	(19)
Changes in operating assets and liabilities:			
Accounts receivable, net	(7,830)	(30,980)	(38,837)
Inventories	(42,452)	(4,954)	(15,361)
Prepaid and other current assets	(58)	(1,570)	(2,427)
Other long-term assets	(1,207)	1,313	129
Accounts payable	24,493	10,275	1,118
Accrued expenses	(461)	4,640	(3,256)
Employee-related liabilities	(12,869)	17,399	5,339
Deferred revenue	8,358	10,611	7,029
Operating leases and other current liabilities	25,445	6,217	5,789
Other long-term liabilities	1,932	1,421	3,888
Net cash provided by operating activities	50,464	111,359	24,669
Investing Activities			
Purchases of short-term investments	(467,652)	(733,388)	(497,076)
Proceeds from maturities and redemptions of short-term investments	569,492	570,023	233,314
Purchases of property and equipment	(34,097)	(14,180)	(27,408)
Acquisition, including in-process research and development, net of cash acquired	(25,720)	—	—
Purchases of intangible assets and strategic investments	(8,855)	(9,331)	(4,886)
Net cash provided by (used in) investing activities	33,168	(186,876)	(296,056)
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	17,469	51,340	66,866
Proceeds from exercise of common stock warrants	83	592	2,950
Other financing activities	(675)	—	—
Net cash provided by financing activities	16,877	51,932	314,438
Effect of foreign exchange rate changes on cash	827	153	387
Net increase (decrease) in cash and cash equivalents	101,336	(23,432)	43,438
Cash and cash equivalents at beginning of period	71,181	94,613	51,175
Cash and cash equivalents at end of period	$ 172,517	$ 71,181	$ 94,613
Supplemental disclosures of cash flow information			
Interest paid	$ 4,313	$ 4,313	$ 2,707
Income taxes paid	$ 411	$ 260	$ 177
Supplemental schedule of non-cash investing and financing activities			
Operating lease right-of-use assets obtained in exchange for operating lease obligations	$ 114,003	$ 15,191	$ 11,022
Purchase of property and equipment included in accounts payable	$ 4,237	$ 1,034	$ 1,082
Intangible costs in accounts payable and other long-term liabilities	$ 515	$ 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 United States, Canada and the Netherlands.

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 has an advanced algorithm for managing insulin delivery, 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 mobile app and cloud-based diabetes management application (t:connect), and the Tandem Device Updater, a Mac- and PC-compatible tool which offers and supports remote 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.

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 United States, Canada, and the Netherlands. All significant intercompany balances and transactions have been eliminated in consolidation.

The functional currency of the Company's foreign subsidiaries is their respective local currency. The Company translates the financial statements of its foreign subsidiaries 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.

Reclassifications

Deferred revenue long-term, which was reported as a component of other long-term liabilities in 2021, is now separately reported on the consolidated balance sheet. The Company also reclassified the 2021 liability of $0.1 million related to common stock warrants (see Note 5, "Fair Value Measurements"), which was previously reported separately, to other current liabilities on the Company's consolidated balance sheet. In addition, certain prior year balances on the consolidated statements of cash flows have been reclassified to conform to the current year presentation.

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, 2022, except for adding the accounting policies related to an asset acquisition and the recently launched Tandem Choice technology access program (Tandem Choice), which are included herein.

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, 2022, 2021 and 2020.

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, including credit risks as a result of the coronavirus pandemic, recessionary concerns, changes in discretionary spending, increased interest rates, and other macroeconomic factors. 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 the percentages of total sales and accounts receivable, net for customers who accounted for 10% or more of the respective amounts for the periods presented:

	Total Sales			Accounts Receivable, net	
	Year Ended December 31,			December 31,	
	2022	2021	2020	2022	2021
Distributor B	11.6 %	11.9 %	15.9 %	12.8 %	11.2 %
Distributor C	*	*	12.9 %	*	*
Distributor D	*	*	*	10.4 %	*

* 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 (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 measures the fair value of its convertible senior notes for disclosure purposes. The Company estimated the fair value of its convertible senior notes to be $260.5 million and $430.0 million at December 31, 2022 and December 31, 2021, respectively, based on Level 2 quoted market prices as of those dates.

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 and related equipment are amortized over the lesser of the estimated useful lives of the assets or the remaining lease term, unless there is a transfer of title or purchase option that is reasonably certain to be exercised. Maintenance and repair costs are expensed as incurred.

Operating Lease Right-of-Use Assets and Liabilities

Operating 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.

Intangible Assets Subject to Amortization

Finite-lived intangible assets (see Note 4, “Composition of Certain Financial Statement Items”) 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.

Impairment of Long-Lived Assets

Long-lived assets, such as property and equipment, right-of-use lease assets, and acquired intangible assets subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require a long-lived asset or asset group be tested for possible impairment, the Company first compares undiscounted cash flows expected to be generated by that asset or asset group to its carrying amount. If the carrying amount of the long-lived asset or asset group is not recoverable on an undiscounted cash flow basis, an impairment is recognized to the extent that the carrying amount exceeds its fair value. Fair value is determined using unobservable (Level 3) inputs, including discounted cash flow models, future estimated sublease income, and third-party independent appraisals, as considered necessary. There is uncertainty in the projected undiscounted future cash flows used in the Company’s impairment review analysis, which requires the use of estimates and assumptions. If actual performance does not achieve the projections, or if the assumptions used change in the future, the Company may be required to recognize additional impairment charges in future periods. Other than the impairment of operating lease right-of-use assets recognized in the fourth quarter of 2022 (see Note 6, “Leases”), there were no impairments of long-lived assets, including acquired intangible assets, during the years ended December 31, 2022 and 2021.

Strategic Investments

During the third quarter of 2022, the Company made an investment of Swiss Francs (“CHF”) 8.0 million, or $8.3 million, in AMF Medical SA (“AMF Medical”), a privately held company. The investment is included as a component of other long-term assets on the consolidated balance sheet at December 31, 2022. On January 19, 2023, the Company completed the acquisition of AMF Medical, pursuant to the terms of the Purchase Agreement entered into on December 13, 2022 (see Note 15, “Subsequent Event”).

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 as of the date of investment. The investment is carried at cost minus impairment, if any, adjusted for changes in observable prices and is included as a component of other long-term assets on the consolidated balance sheets. The Company monitors 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.

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.

Tandem Choice Program

In September 2022, the Company announced and launched a new technology access program, (Tandem Choice) that provides eligible, in-warranty t:slim X2 customers in the United States with the flexibility to obtain the newest hardware platform when it is commercially available. Participating customers have the right to purchase the alternative Tandem pump for a fee (the Choice Right). The Tandem Choice expires on December 31, 2024.

For purposes of evaluating the Tandem Choice, in accordance with ASC 606, the Company has determined that the ability for a customer to upgrade to a new technology, represents a material right because the pricing inherent in such option provides the customer with a discount that is incremental to the range of discounts that would otherwise be granted for the related goods and services to comparable customers. The standalone selling price for the Choice Right was estimated based on the adjusted market assessment approach and contemplates the likelihood that the respective option will be exercised. At December 31, 2022, $6.8 million was allocated to the material right and recorded in current deferred revenue on the consolidated balance sheet.

Sales Returns

The Company offers a 90-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 $0.5 million and $0.6 million at December 31, 2022 and 2021, 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. 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. Insulin pumps returned to the Company may be refurbished and redeployed. Experience has shown that initial data for any given pump version may be insufficient; therefore, the Company’s process relies on long-term historical averages until sufficient data are available. As actual experience becomes available, the Company uses the data to update the historical averages. The Company may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to revised future expectations of performance based on enhanced hardware components, or new features and capabilities that may become available through Tandem Device Updater. Warranty expense is recorded as a component of cost of sales in the consolidated statements of operations.

The following table provides a reconciliation of the changes in product warranty liabilities for the years ended months ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Balance at beginning of the period	$ 30,401	$ 22,075	$ 16,724
Provision for warranties issued during the period	32,699	27,604	21,135
Settlements made during the period	(25,447)	(18,768)	(13,736)
Decreases in warranty estimates	(1,116)	(510)	(2,048)
Balance at end of the period	$ 36,537	$ 30,401	$ 22,075

As of December 31, 2022 and December 31, 2021, total product warranty reserves were included in the following consolidated balance sheet accounts (in thousands):

	December 31, 2022	December 31, 2021
Other current liabilities	$ 17,280	$ 13,076
Other long-term liabilities	19,257	17,325
Total warranty reserve	$ 36,537	$ 30,401

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 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, and the awardee's continuing service through the measurement date, 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. At each reporting period, the Company reassesses 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 licensing, development and commercialization agreements, and other indirect costs.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development (IPR&D) expenses reflect the costs of externally developed IPR&D projects acquired directly in a transaction other than a business combination that do not have an alternative future use, including the initial costs of rights to IPR&D projects. The acquired IPR&D is expensed on acquisition date. Future costs to develop these IPR&D projects are recorded in research and development expenses on the consolidated statements of operations as incurred.

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 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'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 to be 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. The Company includes interest and penalties related to income taxes, including unrecognized tax benefits, within income tax expense.

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 or loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net income (loss) per share reflects the potential dilution that would occur if securities exercisable for or convertible into common stock were exercised for or converted into common stock. Dilutive common share equivalents are comprised of 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 the years ended December 31, 2022, 2021 and 2020, the numerator and denominator of the diluted net income (loss) per share computation were calculated as follows (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Net income (loss) - basic and diluted	$ (94,594)	$ 15,566	$ (34,382)
Weighted average shares outstanding - basic	64,146	63,000	60,990
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	64,146	64,349	60,990

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

	Year Ended December 31,		
	2022	2021	2020
Options to purchase common stock	1,138	3,124	5,021
Unvested restricted stock units	1,118	—	78
Warrants to purchase common stock	194	1	379
Awards granted under the ESPP	8	—	3
Convertible senior notes (if-converted)	2,554	2,554	1,605
	5,012	5,679	7,086

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, 2022 and December 31, 2021 (in thousands):

At December 31, 2022	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
U.S. Treasury securities	$ 213,105	$ 3	$ (1,947)	$ 211,161
Commercial paper	112,812	6	(208)	112,610
U.S. Government-sponsored enterprises	100,602	21	(615)	100,008
Corporate debt securities	18,218	—	(104)	18,114
Supranational bonds	2,504	—	(13)	2,491
Total	$ 447,241	$ 30	$ (2,887)	$ 444,384

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
U.S. Government-sponsored enterprises	50,773	1	(88)	50,686
Corporate debt securities	58,881	—	(45)	58,836
Supranational bonds	3,003	—	—	3,003
Total	$ 553,254	$ 15	$ (639)	$ 552,630

The contractual maturities of available-for-sale debt securities as of December 31, 2022, were as follows (in thousands):

	Years to Maturity		
At December 31, 2022	Within One Year	One to Two Years	Estimated Fair Value
U.S. Treasury securities	$ 202,855	$ 8,306	$ 211,161
Commercial paper	112,610	—	112,610
U.S. Government-sponsored enterprises	73,292	26,716	100,008
Corporate debt securities	13,190	4,924	18,114
Supranational bonds	2,491	—	2,491
Total	$ 404,438	$ 39,946	$ 444,384

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, 2022 were primarily due to the recent increase 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 record an allowance for credit losses related to its available-for-sale debt securities at December 31, 2022.

4. Composition of Certain Financial Statement Items

Accounts Receivable

Accounts receivable, net consisted of the following at December 31, 2022 and December 31, 2021 (in thousands):

	December 31,	
	2022	2021
Accounts receivable	$ 119,044	$ 114,974
Less: allowance for credit losses	(4,327)	(4,249)
Accounts receivable, net	$ 114,717	$ 110,725

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, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Balance at beginning of the period	$ 4,249	$ 3,857	$ 3,304
Provision for expected credit losses	4,782	2,333	3,016
Write-offs and adjustments, net of recoveries	(4,704)	(1,941)	(2,463)
Balance at end of the period	$ 4,327	$ 4,249	$ 3,857

Inventories

Inventories consisted of the following at December 31, 2022 and December 31, 2021 (in thousands):

	December 31,	
	2022	2021
Raw materials	$ 39,207	$ 26,911
Work-in-process	18,571	16,612
Finished goods	53,339	25,028
Total inventories	$ 111,117	$ 68,551

Property and Equipment

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

	December 31,	
	2022	2021
Leasehold improvements	$ 35,828	$ 25,245
Office furniture and equipment	13,772	9,943
Computer equipment and software	12,330	11,544
Manufacturing and scientific equipment	62,797	52,823
Total cost	124,727	99,555
Less: accumulated depreciation and amortization	(56,175)	(49,169)
Total property and equipment, net	$ 68,552	$ 50,386

Depreciation and amortization expense related to property and equipment was $12.3 million, $11.7 million, and $9.2 million for the years ended December 31, 2022, 2021, and 2020, 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, 2022 and 2021, which were included in other long-term assets on the consolidated balance sheets, were as follows (in thousands):

	December 31,	
	2022	2021
Intangible assets, gross amount	$ 12,502	$ 12,502
Accumulated amortization	(7,875)	(5,866)
Intangible assets, net	$ 4,627	$ 6,636
Weighted average remaining amortization period (in months)	30	41

Amortization expense related to intangible assets subject to amortization amounted to $2.0 million, $2.2 million and $1.2 million for the years ended December 31, 2022, 2021 and 2020, 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 three succeeding years is $1.9 million for 2023, $1.9 million for 2024, and the remaining $0.9 million in 2025, all of which will be recorded in selling, general and administrative expense in the consolidated statement of operations.

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, 2022 and December 31, 2021, and indicates the fair value hierarchy of the valuation techniques used by the Company to determine such fair value (in thousands):

	Fair Value Measurements at December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[(1)]	$ 150,742	$ 150,742	$ —	$ —
U.S. Treasury securities	211,161	211,161	—	—
Commercial paper	112,610	—	112,610	—
U.S. Government-sponsored enterprises	100,008	—	100,008	—
Corporate debt securities	18,114	—	18,114	—
Supranational bonds	2,491	—	2,491	—
Total assets	$ 595,126	$ 361,903	$ 233,223	$ —

	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[2]	$ 147	$ —	$ —	$ 147
Total liabilities	$ 147	$ —	$ —	$ 147

(1) Generally, cash equivalents include money market funds and investments with a maturity of three months or less from the date of purchase.
(2) Included in other current liabilities on the Company's consolidated balance sheet.

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 included outstanding Series A warrants to purchase 1,000 shares of the Company's common stock, issued by the Company in connection with the public offering of common stock in October 2017 and which expired in October 2022. The fair value of the outstanding Series A common stock warrants was remeasured at each financial reporting date using a Black-Scholes pricing model with any changes in fair value being recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive income (loss). The assumptions used to estimate the fair values of the outstanding Series A warrants at December 31, 2021 were as follows:

	December 31, 2021
Risk-free interest rate	0.3 %
Dividend yield	0.0%
Expected volatility	39.1 %
Expected term (in years)	0.8

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, 2022, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Balance at beginning of period	$ 147	$ 14,261	$ 23,509
(Gain) loss recognized from the change in fair value of common stock warrants	(147)	1,386	17,087
Common stock warrants exercised during the period	—	(15,500)	(26,335)
Balance at end of period	$ —	$ 147	$ 14,261

6. Leases

The Company's leases consist of operating leases for general office space, research and development, manufacturing and warehouse facilities, and equipment. These noncancellable operating leases have initial lease terms from two years to thirteen years. Leases with an initial term of 12 months or less (Short-term Lease) are expensed as incurred and are not recorded as right-of-use leased 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 before 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.

Vista Sorrento Lease

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 operating lease right-of-use 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.

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 occupying 77,458 square feet of leased space, located on Roselle Street in San Diego, California, that is scheduled to expire in May 2023. 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 initial lease term Phase I Commencement Date occurred in March 2022 when the Company was tendered possession of the Phase I portion of the Premises, and rent payments commenced in September 2022 (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 Tech Center Lease term expires in April 2035. The Company has two options to extend the term of the lease, with each option providing for an additional period of five years. The Tech Center Lease term was determined assuming the renewal options would not be exercised.

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 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 following the Phase I Rent Commencement Date, and for the Phase II portion of the Premises for months two through five following the Phase II Rent Commencement Date. The Company recognized operating lease right-of-use assets and corresponding operating lease liabilities of $107.5 million on the consolidated balance sheet on the Phase I Commencement Date in the first quarter of 2022.

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 property the Company previously occupied subject to a sublease agreement. The lease term began in April 2022 following the termination of the High Bluff sublease in March 2022, and is scheduled to expire in March 2024. The Company recognized operating lease right-of-use assets and corresponding operating lease liabilities of $3.0 million on the consolidated balance sheet on the Commencement Date in the second quarter of 2022.

Barnes Canyon Lease

In November 2022, the Company exercised its one-time option to extend the term of the lease covering 48,880 square feet of general office, manufacturing and warehouse space located on Barnes Canyon Road in San Diego, California (Barnes Canyon Lease) for an additional five years from November 2023 to November 2028. The Company recognized operating lease right-of-use assets and corresponding operating lease liabilities of $3.0 million on the consolidated balance sheet in the fourth quarter of 2022 related to the Barnes Canyon Lease term extension.

Lease Termination and Impairment Charges

During the fourth quarter of 2022, the Company recorded $12.4 million of lease termination and impairment charges primarily related to our customer and technical support office space in Boise, Idaho. The $12.4 million charge consisted of a $6.7 million loss on disposal of fixed assets, including leasehold improvements, furniture and fixtures, $3.8 million net loss on lease termination, and $1.9 million impairment of operating lease right-of-use assets, and is recorded as a component of selling, general and administrative expenses in the consolidated statement of operations.

Supplemental Lease Disclosure Information

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

	Year Ended December 31,		
	2022	**2021**	**2020**
Operating lease cost	$ 18,432	$ 8,627	$ 7,514
Loss on lease termination and right-of-use asset impairment charge	5,699	—	—
Short-term lease cost	142	90	219
Total lease cost	$ 24,273	$ 8,717	$ 7,733

Maturities of operating lease liabilities at December 31, 2022 were as follows (in thousands):

Years Ending December 31,	
2023	$ 13,133
2024	17,198
2025	17,023
2026	17,068
2027	17,333
Thereafter	103,844
Total undiscounted lease payments	185,599
Less: amount representing interest	(48,954)
Present value of operating lease liabilities	136,645
Less: current portion of operating lease liabilities	(13,121)
Operating lease liabilities - long-term	$ 123,524

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

	December 31, 2022	December 31, 2021
Weighted-average remaining lease term (in years)	10.8	5.0
Weighted-average discount rate used to determine operating lease liabilities	5.3 %	5.6 %

Cash paid for amounts included in the measurement of lease liabilities, representing operating cash flows from operating leases, was $16.7 million, which included a $4.8 million lease termination payment, $9.5 million, and $8.2 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Lease For Which Accounting Has Not Yet Commenced

As of December 31, 2022, the Commencement Date for Phase II of the Tech Center Lease had not yet occurred. Accordingly, the consolidated balance sheet at December 31, 2022 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, 2022 does not include any lease costs, related to Phase II of 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 Phase II of the Tech Center Lease.

The Company currently estimates that Phase II Commencement Date will occur in the first quarter of 2025, at which time the Phase II operating lease right-of-use assets and liabilities will be recorded. Future minimum payments for monthly base rent due under Phase II of the Tech Center Lease, are currently estimated to total $34.7 million from 2025 through 2035, subject to a number of factors, including the actual Commencement Date of Phase II. Because the incremental borrowing rate will not be available until the Phase II Commencement Date, we are not yet able to determine the Phase II operating lease right-of-use assets and liabilities.

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 governing the Notes. 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 before 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 before 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.

In accounting for the issuance of the Notes in 2020, 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 recorded as a debt discount, which was being amortized to interest expense. 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 Company adopted the new standard 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. As of January 1, 2021, the Notes are accounted for as a single liability measured at amortized cost, as no other embedded features require bifurcation and recognition as derivatives.

The net carrying amount of the Notes on the consolidated balance sheets consisted of the following (in thousands):

	December 31, 2022	December 31, 2021
Principal amount	$ 287,500	$ 287,500
Unamortized debt issuance costs	(4,268)	(6,033)
Net carrying amount	$ 283,232	$ 281,467

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, 2022, the if-converted value of the Notes did not exceed the principal amount. As of December 31, 2021, the if-converted value of the Notes exceeded the principal amount by $96.9 million.

As of December 31, 2022, the unamortized debt issuance costs of $4.3 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 2.3 years.

The following table details interest expense related to the Notes recognized for the years ended December 31, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Contractual interest expense	$ 4,313	$ 4,313	$ 2,707
Amortization of debt issuance costs	1,896	1,727	652
Amortization of debt discount (1)	N/A	N/A	9,446
Total interest expense	$ 6,209	$ 6,040	$ 12,805

(1) The debt discount was reversed upon the adoption of ASU No. 2020-06.

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.

Line of Credit

On May 18, 2022, the Company entered into a three-year Revolving Line of Credit Agreement that provides the Company with a maximum principal borrowing amount of $100.0 million (the Line of Credit), reduced by any letters of credit issued and outstanding under a $15.0 million letter of credit sub-limit. The Line of Credit allows the Company to request advances thereunder, and to use the proceeds of such advances for general corporate purposes, including working capital and capital expenditures. The Line of Credit matures on the earlier of (i) May 18, 2025 or (ii) the Springing Maturity Date, unless renewed at maturity upon approval by the Company's board of directors and the lender. The Springing Maturity Date is any date during the 91 days prior to the May 1, 2025 maturity date of the Company's Convertible Senior Notes, that the Company does not satisfy a predefined liquidity threshold. During the term of the Line of Credit, the Company is required to maintain compliance with two financial maintenance covenants: a minimum consolidated interest coverage ratio and a maximum consolidated net leverage ratio. The Company was in compliance with these financial maintenance covenants as of December 31, 2022. The Line of Credit is secured by a first priority security interest in substantially all of the assets of the Company and its subsidiaries.

Advances drawn under the Line of Credit bear interest at an annual rate of (1) the SOFR Rate (as defined in the Line of Credit); plus (2) an applicable credit spread adjustment ranging from 0.10% to 0.25%; plus (3) an applicable margin ranging from 1.25% to 2.00%, and each advance will be payable on the Maturity Date with the interest on outstanding advances payable quarterly. The Credit Agreement also includes a commitment fee ranging from 0.20% to 0.35% per annum on the average daily unused amount of the Line of Credit, payable quarterly. The Company may, at its option, prepay any borrowings under the Line of Credit, in whole or in part at any time before the maturity date, without premium or penalty.

As of December 31, 2022, the Company’s outstanding borrowings and available balance under the Line of Credit were as follows (in millions):

Maximum principal borrowing amount	$	100.0
Less:		
Outstanding borrowings		—
Outstanding letters of credit		4.9
Total available balance	$	95.1

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, 2022 (in thousands):

Shares reserved for issuance upon conversion of Convertible Senior Notes	2,554
Shares underlying outstanding warrants	194
Shares underlying outstanding stock options	4,442
Shares underlying unvested restricted stock units	1,834
Shares authorized for issuance pursuant to awards granted under the ESPP	953
Shares authorized for future equity award grants	119
Total	10,096

Common Stock Warrants

Warrants outstanding to purchase shares of the Company's common stock as of December 31, 2022 were as follows:

Issue Date	Exercise Price Per Share	Warrants Outstanding	Expiration Date of Warrants Outstanding
March 2017	$23.50	193,788	March 2027

Each warrant allows the holder to purchase one share of the Company's common stock at the exercise price per share of the warrant. The Company issued 5,678 shares and 155,517 shares of its common stock, respectively, upon the exercise of warrants during the years ended December 31, 2022, and 2021, 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.

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. Stock options granted before the second quarter of 2022 generally vest over a four-year period as to 25% of the underlying shares on the first anniversary of the grant date, with the balance of the options vesting monthly over the following three years. Stock options granted during the second quarter of 2022 and thereafter vest over a three-year period as to 33% of the underlying shares on the first anniversary of the grant date, with the balance of the options vesting monthly over the following two 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	(214,876)	$ 76.29		$ 6,963
Outstanding at December 31, 2021	4,814,846	$ 57.08	7.07	$ 452,081
Granted	83,008	$ 65.28		
Exercised	(280,275)	$ 32.58		$ 13,473
Canceled/forfeited/expired	(175,266)	$ 77.93		$ 2,143
Outstanding at December 31, 2022	4,442,313	$ 57.95	6.12	$ 30,236
Vested and expected to vest at December 31, 2022	4,423,803	$ 57.87	6.12	$ 30,236
Exercisable at December 31, 2022	3,701,918	$ 54.08	5.82	$ 30,234

Restricted Stock Units

Restricted stock units (RSUs) have a grant value equal to the closing price of the Company's common stock on the award date. RSUs granted before March 2022 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. RSUs granted in March 2022 and thereafter generally vest over a three-year period based on continued service to the Company as to 33% of the underlying shares on the first anniversary of the award, with the balance of the RSUs vesting quarterly over the following two years. In addition, the Company granted 53,662 and 25,674 performance-based RSUs during the years ended December 31, 2022 and 2021, respectively. 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.

The following table summarizes RSU activities, which includes performance-based RSUs, for the 2013 Plan:

	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)	$ 82.34	
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	(32,148)	$ 87.21	
Unvested awards outstanding at December 31, 2021	610,731	$ 95.08	$ 91,927
Granted	1,542,859	$ 67.09	
Vested	(202,215)	$ 91.99	
Canceled/forfeited	(117,543)	$ 84.20	
Unvested awards outstanding at December 31, 2022	1,833,832	$ 72.57	$ 82,431
Awards expected to vest at December 31, 2022	1,797,999	$ 72.62	$ 80,820

The aggregate fair value of RSUs that vested during the years ended December 31, 2022, 2021 and 2020 was $12.7 million, $5.1 million, and $0.2 million, respectively, which represents the market value of the Company's common stock on the date the RSUs vested. The number of RSUs vested includes shares of common stock the Company withheld on behalf of employees to satisfy the minimum statutory tax withholding requirements. RSUs that are expected to vest are net of estimated future forfeitures.

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, 2022 and 2021, 262,936 shares and 172,694 shares of our common stock, respectively, were purchased under the ESPP for proceeds of $12.7 million and $11.1 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,		
	2022	2021	2020
Cost of sales	$ 7,685	$ 6,434	$ 8,210
Selling, general and administrative	57,196	43,567	41,563
Research and development	20,037	10,751	8,658
Total stock-based compensation expense	$ 84,918	$ 60,752	$ 58,431

The total stock-based compensation expense capitalized as part of the cost of the Company's inventories was $1.1 million at December 31, 2022, and $1.0 million at December 31, 2021.

At December 31, 2022, the total unamortized stock-based compensation expense of approximately $143.9 million will be recognized over the remaining weighted average vesting term of approximately 2.3 years.

The Company estimates the fair value of stock options using the Black-Scholes option-pricing model on the grant date. The assumptions used in the Black-Scholes option-pricing model were as follows:

	Stock Options		
	Year Ended December 31,		
	2022	2021	2020
Weighted average grant date fair value (per share)	$ 42.16	$ 56.89	$ 54.20
Risk-free interest rate	2.7 %	1.0 %	0.6 %
Dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	72.0 %	75.1 %	74.6 %
Expected term (in years)	5.8	6.1	6.1

The Company records stock-based compensation expense associated with the ESPP using the Black-Scholes option-pricing model. Valuations are performed on the grant date at the beginning of the purchase period, which generally occurs in May and November of each year. The assumptions used in the Black-Scholes option-pricing model for the ESPP were as follows:

	ESPP		
	Year Ended December 31,		
	2022	2021	2020
Weighted average grant date fair value (per share)	$ 21.89	$ 38.19	$ 36.83
Risk-free interest rate	3.4 %	0.2 %	0.2 %
Dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	56.9 %	44.2 %	60.3 %
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 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 was estimated based on a weighted-average of the Company's actual historical volatility of its common stock measured over the expected term.

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 total amount contributed by the Company to the 401(k) plan was $4.2 million for the year ended December 31, 2022. The Company did not provide a matching contribution prior to 2022.

10. Income Taxes

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

	Year Ended December 31,		
	2022	2021	2020
United States	$ (94,033)	$ 15,211	$ (36,667)
Foreign	1,181	690	385
Income (loss) before provision for income taxes	$ (92,852)	$ 15,901	$ (36,282)

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

	Year Ended December 31,		
	2022	2021	2020
Current:			
Federal	$ 216	$ —	$ —
State	1,228	174	75
Foreign	298	161	151
Total current tax expense	1,742	335	226
Deferred:			
Federal	—	—	(1,760)
State	—	—	(366)
Foreign	—	—	—
Total deferred income tax benefit	—	—	(2,126)
Income tax expense (benefit)	$ 1,742	$ 335	$ (1,900)

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,		
	2022	2021	2020
Income tax expense (benefit) at federal statutory rate [(1)]	$ (19,499)	$ 3,339	$ (7,619)
State income tax, net of federal benefit	(926)	(254)	(2,792)
Warrants revaluation	(31)	356	3,588
Research and development credits	(6,263)	(5,703)	(5,330)
Section 382 limitation	—	(97)	1,021
Stock-based compensation	2,282	(7,609)	(18,309)
Officers' compensation	2,931	4,024	2,612
Acquired IPR&D expenses	6,518	—	—
Other	962	124	479
Change in valuation allowance	15,768	6,155	24,450
Income tax expense (benefit)	$ 1,742	$ 335	$ (1,900)

(1) For the years ended December 31, 2022, 2021 and 2020, the federal statutory tax rate was 21%.

Significant components of the Company’s net deferred income tax assets at December 31, 2022 and 2021 are shown in the table 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, 2022. 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 $162.7 million and $146.4 million at December 31, 2022 and 2021, respectively, was recorded to offset the net deferred tax asset as realization of such asset is uncertain. However, the amount of the deferred tax asset considered realizable 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,	
	2022	2021
Deferred tax assets:		
Net operating loss (NOL) carryforwards	$ 54,598	$ 78,961
Research and development tax credits carryforwards	22,400	16,761
Capitalized research and development expenses	29,760	5,135
Accrued compensation	34,378	28,970
Lease liabilities	32,738	8,012
Other	20,927	20,608
Total deferred tax assets	194,801	158,447
Deferred tax liabilities:		
Operating lease right-of-use assets	(26,505)	(6,637)
Fixed assets	(4,467)	(3,847)
Other	(1,103)	(1,540)
Total deferred tax liabilities	(32,075)	(12,024)
Less valuation allowance	(162,726)	(146,423)
Net deferred tax assets	$ —	$ —

As of December 31, 2022, the Company had accumulated federal and state NOL carryforwards of approximately $193.1 million, and $255.9 million, respectively, Of the total federal net operating loss carryforwards, approximately $95.6 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 $97.5 million will begin to expire in 2033, and state tax loss carryforwards continue to expire in 2023, unless previously utilized. The remaining California NOL carryforwards of $169.5 million will begin expiring in 2031. The Company had no foreign tax loss carryforwards as of December 31, 2022.

The Company also has federal and California research credit carryforwards of approximately $18.1 million and $20.1 million, respectively, as of December 31, 2022. 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, 2021 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, 2022, 2021 and 2020 (in thousands):

	Year Ended December 31,		
	2022	2021	2020
Gross unrecognized tax benefits at the beginning of the year	$ 13,589	$ 10,107	$ 6,580
Increases related to current year positions	3,403	3,482	2,234
Increases (decreases) related to prior year positions	(6)	—	1,293
Gross unrecognized tax benefits at the end of the year	$ 16,986	$ 13,589	$ 10,107

As of December 31, 2022, the Company had $15.0 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, 2022, 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 foreign and state jurisdictions. Prior to 2018, the losses were all attributable to the United States. 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. In the United States and Canada, the Company also uses 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, 2022, 2021 and 2020, 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):

	Year Ended December 31,		
	2022	**2021**	**2020**
United States	$ 588,765	$ 524,907	$ 415,680
Outside the United States	212,452	177,892	83,150
Total Sales	$ 801,217	$ 702,799	$ 498,830

Sales to distributors accounted for 65%, 67%, and 70% of the Company's total United States sales for the years ended December 31, 2022, 2021 and 2020, respectively. Sales to distributors accounted for 96%, 95%, and 94% of the Company's total sales outside the United States for the years ended December 31, 2022, 2021 and 2020, respectively.

12. Acquisitions

Capillary Biomedical Acquisition

On July 21, 2022, the Company acquired Capillary Biomedical, Inc. (Capillary Biomedical) an infusion set developer, for total cash consideration of $24.7 million, and the assumption of $4.7 million of long-term debt. The debt becomes due and payable upon the first sale or license of the commercialized product, and is included as a component of other long-term liabilities on the consolidated balance sheet at December 31, 2022. Capillary Biomedical's extended-wear infusion set technology is currently in development and is not yet commercially available. The Company funded the purchase price using existing cash balances. The transaction was accounted for as an asset acquisition as substantially all the value of the gross assets were concentrated in a single asset. The Company recorded a $31.0 million charge representing the value of acquired in-process research and development assets with no alternative future use, and acquisition related expenses, on its consolidated statements of operations in acquired in-process research and development expenses. The Company's results of operations for the year ended December 31, 2022 included the operating results of Capillary Biomedical since the date of acquisition, the amounts of which were not material.

13. Commitments and Contingencies

Legal and Regulatory Matters

In May 2020, we were named as a defendant in three California state court class action lawsuits arising from a phishing incident that occurred in January 2020. Collectively, these lawsuits sought 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 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 alleged violations of the Confidentiality of Medical Information Act (CMIA), CCPA, California's Unfair Competition Law (UCL), and breach of contract. We filed a demurrer on all claims, which was heard by the Court on October 20, 2020, and our demurrer to the CCPA claim was sustained. The plaintiffs filed a motion for class certification on January 7, 2022 and we filed a motion for summary adjudication on the CMIA claim on April 7, 2022. On February 8, 2023, the Court granted plaintiffs' request to dismiss their remaining two claims with prejudice, and dismissed the motion for class certification, terminating the case in the Superior Court. The plaintiffs have to decide whether to appeal the Court's decision granting our motion for summary adjudication.

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

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

Letters of Credit

In connection with one of the Company's operating leases (see Note 6, "Leases"), the Company has a $4.9 million unsecured irrevocable standby letter of credit arrangement with a bank (see Note 7, "Debt"), 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 expires 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, 2022, obligations under our purchase agreements totaled approximately $351.4 million, of which approximately $320.3 million is scheduled to be received and become payable within one-year.

14. Fourth Quarter Financial Data (Unaudited)

The financial information for the three months ended December 31, 2022 and 2021 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, 2022	December 31, 2021
Sales	$ 220,502	$ 209,996
Gross profit	$ 115,523	$ 113,729
Operating expenses	$ 133,300	$ 100,991
Operating income (loss)	$ (17,777)	$ 12,738
Net income (loss)	$ (15,852)	$ 10,808
Basic net income (loss) per share	$ (0.25)	$ 0.17
Diluted net income (loss) per share	$ (0.25)	$ 0.16

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, 2022 and 2021 (in thousands):

	For the Quarter Ended	
	December 31, 2022	December 31, 2021
Net income (loss) - basic	$ (15,853)	$ 10,808
Less: change in fair value of common stock warrants	—	32
Net income (loss) - diluted	$ (15,853)	$ 10,840
Weighted average shares outstanding - basic	64,384	63,650
Dilutive common share equivalents:		
Options to purchase common stock	—	1,877
Unvested restricted stock units	—	227
Warrants to purchase common stock	—	170
Awards to be granted under the ESPP	—	3
Weighted average shares outstanding - diluted	64,384	65,927

15. Subsequent Event

AMF Medical Acquisition

On December 10, 2022, the Company, entered into a Share Purchase Agreement (the “Purchase Agreement”) with AMF Medical SA, a corporation organized and existing under the laws of Switzerland (“AMF Medical”), and its shareholders to acquire all of the registered shares of AMF Medical (the “Transaction”), the privately held Swiss developer of the Sigi Patch Pump. The Sigi Patch Pump, designed to be an ergonomic, rechargeable patch pump that reduces the burden of managing diabetes through its use of pre-filled insulin cartridges, is under development and not commercially available.

On January 19, 2023, the Company completed the acquisition of AMF Medical, pursuant to the terms of the Purchase Agreement. The total aggregate consideration for the Transaction includes a previous strategic investment of Swiss Francs (“CHF”) 8.0 million paid in the third quarter of 2022 (see Note 2, “Strategic Investments”), a cash payment of CHF 62.4 million paid at the closing of the Transaction, and additional contingent earnout payments. The additional earnout payments of up to CHF 129.6 million, in aggregate, become payable upon the achievement of certain milestones and are comprised of a payment of up to CHF 38.4 million upon the successful completion of key development milestones over the next two years, and a payment of up to CHF 91.2 million upon obtaining regulatory clearance of an automated controller enabled (ACE) pump by the United States Food and Drug Administration. The Company funded the initial closing payment using existing cash balances, and is in the process of determining the accounting treatment for the acquisition.

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, 2022, 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, 2022.

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, 2022, 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, 2022, 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, 2022 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 (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended December 31, 2022 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, 2022, 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, 2022, 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, 2022 and 2021, 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, 2022, and the related notes and our report dated February 22, 2023 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, 2023

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 under the caption “Business” in Part I, Item 1 of this Annual Report.

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 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, 2022, 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	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	
4.7	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 Restated 2013 Stock Incentive Plan.	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. 2022 Sr. Management Cash Bonus Plan.	10-Q	001-36189	4-May-2022	10.1
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 Vosseller.	S-1	333-222553	16-Jan-18	10.25
10.19*	Form of Indemnification Agreement.	S-1	333-191601	7-Oct-13	10.11
10.20	Confidential Intellectual Property Agreement, dated July 10, 2012, by and between Tandem Diabetes Care, Inc. and Smiths Medical ASD, Inc.	S-1/A	333-191601	8-Nov-13	10.20

10.21**	Development Agreement, dated June 4, 2015 by and between Tandem Diabetes Care, Inc. and DexCom, Inc.	10-Q/A	001-36189	9-Nov-18	10.5	
10.22†	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	
10.23†	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	
10.24	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	
10.25	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	
10.26	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	
10.27	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	
10.28	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	
10.29	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	
10.30†	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	
10.31†	Commercialization Agreement, dated January 14, 2022, by and between Tandem Diabetes Care, Inc. and Unomedical A/S.	10-K	001-36189	2-Feb-2022	10.35	
10.32	Office Lease dated September 15, 2021 by and between Tandem Diabetes Care, Inc. and Kilroy Realty L.P.	10-Q	001-36189	3-Nov-2021	10.1	
10.33†	Share Purchase Agreement by and Between Tandem Diabetes Care, Inc., and AMF Medical					X
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***	18 U.S.C. Section 1350 Certification by Chief Executive Officer of Tandem Diabetes Care, Inc.	X
32.2***	18 U.S.C. Section 1350 Certification by Chief Financial Officer of Tandem Diabetes Care, Inc.	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.

*** Certification pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended; furnished herewith.

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, 2023

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 22, 2023
/s/ LEIGH A. VOSSELLER Leigh A. Vosseller	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 22, 2023
/s/ DICK P. ALLEN Dick P. Allen	Lead Independent Director	February 22, 2023
/s/ KIM D. BLICKENSTAFF Kim D. Blickenstaff	Chair of the Board	February 22, 2023
/s/ MYOUNGIL CHA Myoungil Cha	Director	February 22, 2023
/s/ PEYTON R. HOWELL Peyton R. Howell	Director	February 22, 2023
/s/ JOAO PAULO FALCAO MALAGUEIRA Joao Paulo Falcao Malagueira	Director	February 22, 2023
/s/ KATHLEEN MCGRODDY-GOETZ Kathleen McGroddy-Goetz	Director	February 22, 2023
/s/ REBECCA B. ROBERTSON Rebecca B. Robertson	Director	February 22, 2023
/s/ RAJWANT S. SODHI Rajwant S. Sodhi	Director	February 22, 2023
/s/ CHRISTOPHER J. TWOMEY Christopher J. Twomey	Director	February 22, 2023

Share Purchase Agreement

dated as of December 10, 2022
by and among

each of the individuals and entities listed in Annex B (each a **Seller** and collectively the **Sellers**)

and

Tandem Diabetes Care, Inc.
11075 Roselle Street
San Diego, CA 92121
United States of America (the **Buyer**)

[***]

[***]
[***]
[***]
[***]

[***] and [***]

AMF Medical SA
Rue des Jordils 38
1025 St.-Sulpice
Switzerland

Table of Contents

Recitals

A. AMF Medical SA (the **Company**) is a corporation organized and existing under the laws of Switzerland, registered under identification number CHE-378.435.207, with its registered office at Rue des Jordils 38, 1025 St.-Sulpice, Switzerland. As of the date of this Agreement, the Company has a share capital of CHF 283,156.00, divided into 283,156 registered shares with a nominal value of CHF 1 each.

B. As of the date of this Agreement, the Sellers are the legal and beneficial owners of (i) all 283,156 registered shares in the Company with a nominal value of CHF 1 each (the **Issued Shares**, and each an **Issued Share**) and (ii) all 38,469 options to acquire registered shares in the Company with a nominal value of CHF 1 each (the **Options**, each an **Option**, and the shares in the Company to be issued upon exercise of such Options in accordance with the terms of this Agreement prior to the Closing Date, the **Option Shares** and each an **Option Share**, and together with the Issued Shares, the **Shares** and each a **Share**), as further set forth in Annex B.

C. Each Seller intends to sell and transfer to the Buyer such number of Shares as set forth opposite his, her or its name in Annex B, and the Buyer intends to buy and accept the Shares from the Sellers, on the terms and subject to the conditions contained in this Agreement (the **Transaction**).

D. As of the date of this Agreement, the Buyer is the holder of a convertible loan with a principal amount of CHF 8,000,000 on the terms and subject to the conditions contained in the Convertible Loan Agreement by and between the Company and the Buyer dated as of July 29, 2022 (the **Convertible Loan Agreement**), as amended by the Term Sheet dated as of October 26, 2022 (the **Term Sheet**).

E. Prior to the execution of this Agreement, the Sellers have given access to the Buyer and its Representatives, and the Buyer and its Representatives have reviewed, analyzed and assessed (the **Due Diligence Review**), legal, financial, accounting, tax, operational, commercial and other information in relation to the Company and the Company's business, including, without limitation, based on the information uploaded to the online data room hosted by Datasite on behalf of the Sellers under the name "Sparrow" (the **Data Room**) (as saved to an electronic data storage device in the form as existing as of December 7, 2022 and made available to the Buyer by the Sellers at the signing of this Agreement) (the **Data Room Documents**). The Buyer has further had the opportunity to discuss with the Sellers and their Representatives and the Management of the Company and clarify with them any matters pertaining to the Company and the Company's business.

Now, therefore, the Sellers, the Buyer and, where applicable, [***] and the Company (each a **Party**, and collectively the **Parties**) agree as follows:

1. Definitions and Interpretation

Capitalized terms used in this Agreement have the meanings assigned to such terms (a) in the body of this Agreement and referenced in Annex 1 to this Agreement, or (b) in Annex 1. For purposes of this Agreement, the interpretational rules set forth in Annex 1 shall apply.

2. Sale and Purchase of the Shares

2.1 Object of the Sale

(a) On the terms and subject to the conditions of this Agreement, each Seller hereby agrees to sell, individually and not jointly with the other Sellers, and at the Closing, to transfer to the Buyer the full legal and beneficial ownership of the Shares, free and clear of any Liens, as set forth opposite such Seller's name on Annex B, with all rights attached or accruing to such Shares as of the Closing, and the Buyer hereby agrees to purchase and accept from the Sellers the Shares.

(b) Each Seller, subject to and as of the Closing, (i) unconditionally and irrevocably waives all rights of pre-emption, redemption, first offer, first refusal, transfer, tag along and drag along and any other similar rights as holder of Shares that each Seller may have under the second restated and amended shareholders' agreement dated as of August 13, 2021 by and among the Sellers (the **Shareholders' Agreement**) and (ii) agrees to terminate the Shareholders' Agreement, including Section 15 (*Non-Compete and Non-Solicitation*), effective as of the Closing, except for Section 1 (*Definitions*), Section 13 (*Confidentiality*), Section 16 (*Miscellaneous*) and Section 17 (*Governing Law and Arbitration*).

2.2 Preliminary Consideration Payable at the Closing

(a) The consideration for the Shares payable by the Buyer to the Sellers at the Closing in accordance with Section 4.3.2 (the **Preliminary Closing Consideration**) is equal to:

(i) CHF 62,400,000 (Swiss Francs sixty-two million four hundred thousand) (the **Headline Price**),

(ii) *minus* the Estimated Net Debt, established in accordance with Section 2.2(c),

(iii) (1) if the Estimated Net Working Capital (established in accordance with Section 2.2(c)) exceeds the Net Working Capital Target Amount, *plus* the amount of such excess, or (2) if the Estimated Net Working Capital (established in accordance with Section 2.2(c)) is less than the Net Working Capital Target Amount, *minus* the amount of such shortfall,

(iv) *minus* the Estimated Pre-Closing Taxes, established in accordance with Section 2.2(c), and

(v) *minus* the Estimated Company Transaction Expenses, established in accordance with Section 2.2(c).

subject to the adjustments pursuant to Section 2.3. Once established in accordance with Section 2.2(c), but not later than five (5) Business Days prior to the Closing Date, the Sellers shall deliver to the Buyer a statement (the **Closing Payment Statement**) containing (i) the Preliminary Closing Consideration including separate line items regarding the Estimated Net Debt, the Estimated Net Working Capital, the Estimated Pre-Closing Taxes, and the Estimated Company Transaction Expenses, (ii) the allocation to each of the Sellers based on the Ownership Percentage, (ii) the Estimated Closing Employee Payroll Taxes Amount in connection with the Closing Purchase Price and its allocation to each Seller who is subject to Closing Payroll Taxes, (iii) the Sellers' Advisor Closing Fees Amount, (iv) the Sellers' Legal Fees Amount, and (v) the wire instructions for the payments to be made by the Buyer at the Closing in accordance with Section 4.3.2.

(b) The Buyer shall deduct from the respective portion of the Preliminary Closing Consideration that is payable to a Seller who is subject to Closing Payroll Taxes the relevant Estimated Closing Employee Payroll Taxes Amount, and pay these amounts to the Company in accordance with Section 4.3.2.

(c) The Sellers shall estimate in good faith the Net Debt, the Net Working Capital, the Pre-Closing Taxes and the Company Transaction Expenses (the latter, for the avoidance of doubt including the Sellers' Advisor Closing Fees Amount and the Sellers' Legal Fees Amount) as at the Cut-off Date as well as the Estimated Closing Employee Payroll Taxes Amount (the **Estimates**) for purposes of calculating the Preliminary Closing Consideration and deliver the Estimates to the Buyer no later than seven (7) Business Days prior to the anticipated Closing, together with reasonable documentation supporting the calculation of the Estimates. If the Buyer disagrees with the Estimates as proposed by the Sellers, the matter shall be escalated to the Sellers' Representative and the Chief Strategy Officer and General Counsel of the Buyer (or an individual or individuals of equivalent standing within the Buyer's organization), acting on behalf of the Buyer, who shall between them agree on the Estimates to be used for purposes of the Closing. Absent agreement on the Estimates within two (2) Business Days of the referral of the matter to the individuals identified in the preceding sentence, the Estimates established by the Sellers corrected in accordance with the reasonable objections of the Buyer shall be used for purposes of calculating the Preliminary Closing Consideration (which shall, for the avoidance of doubt, be subject to the adjustments pursuant to Sections 2.3 and 2.4).

2.3 Determination of Adjustments

2.3.1 Principles

(a) The Final Net Debt, the Final Net Working Capital, the Final Pre-Closing Taxes and the Final Company Transaction Expenses as well as the Closing Employee Payroll Taxes Amount shall be determined by establishing the Final Closing Accounts and the Final Adjustment in accordance with this Section 2.3 and Section 2.4.

(b) The Preliminary Closing Consideration, as adjusted in accordance with this Section 2.3 and Section 2.4 (other than with respect to the Closing Employee Payroll Taxes Amount), shall be referred to hereinafter as the **Closing Purchase Price**.

2.3.2 Procedural Matters

(a) No later than forty-five (45) Business Days following the Closing Date, the Buyer shall deliver to the Sellers' Representative the Company's financial statements as of the Cut-off Date and established in accordance with the manner described in Section 2.3 (the **Proposed Closing Accounts**, and upon becoming final and binding in accordance with this Section 2.3 the **Final Closing Accounts**), and determine based thereon the Final Net Debt, the Final Net Working Capital, the Final Pre-Closing Taxes, the Final Company Transaction Expenses as well as the Closing Employee Payroll Taxes Amount, and the balance of the adjustments pursuant to this Section 2.3 and Section 2.4 (the **Proposed Adjustment**, and upon becoming final and binding in accordance with this Section 2.3 the **Final Adjustment**).

(b) The Buyer shall procure that the Sellers' Representative and its advisors are given full access (during ordinary business hours) to the books and records of the Company for the purposes of reviewing the Proposed Closing Accounts and the Proposed Adjustment.

(c) Unless the Sellers' Representative gives written notice (the **Notice of Objection**) to the Buyer within thirty (30) Business Days following receipt of the Proposed Closing Accounts and the Proposed Adjustment that it disagrees with any specific item of the Proposed Closing Accounts or the Proposed Adjustment, stating in such notice in reasonable detail the reasons for the objections and including specific proposals for adjustment of each disputed item in the Proposed Closing Accounts and the Proposed Adjustment, the Proposed Closing Accounts and the Proposed Adjustment shall be deemed final and binding on the Parties for all purposes.

(d) The Parties shall endeavor to resolve in good faith any objection stated in the Notice of Objection within twenty (20) Business Days after the Buyer's receipt of the Notice of Objection. If the Parties are unable to do so, either Party may refer the matter to an accounting firm which is independent from the Sellers, the Buyer, and their Affiliates, and which is based in Switzerland with an international reputation such as BDO AG, Deloitte AG, Ernst & Young AG, KPMG AG or PricewaterhouseCoopers AG, to be agreed upon by the Parties, or, if the Parties cannot agree on an accounting firm within fifteen (15) Business Days after the Buyer's receipt of the Notice of Objection, such an accounting firm appointed by the Zurich Chamber of Commerce upon request by either the Buyer or the Sellers (the accounting firm appointed in accordance with this Section 2.3.2(d) hereinafter referred to as the **Appraiser**).

(e) The Appraiser shall establish independently, on behalf of the Parties and on the terms set forth in this Section 2.3 and Section 2.4, the Final Closing Accounts and the Final Adjustment. In so doing, the Appraiser shall serve as an expert (*Schiedsgutachter*), as that term is defined in article 189 of the Swiss Code of Civil Procedure (*Schweizerische Zivilprozessordnung*), and not as an arbitrator, and his or her determination of any subject matter falling within the scope of his or her mandate shall be final and binding on the Parties, except in the event of a manifest error on the part of the Appraiser (in which case the relevant part of his or her determination shall be void and the matter be remitted to the Appraiser for correction).

(f) The Parties shall procure that the Appraiser will be furnished with all documents and information relating to the establishment of the Final Closing Accounts and the Final Adjustment as the Appraiser may reasonably request.

(g) The Appraiser shall determine only:

(i) whether the specific items of the Proposed Closing Accounts or the Closing Employee Payroll Taxes Amount, as applicable, that are disputed by the Sellers' Representative in their Notice of Objection are accurate and in accordance with this Section 2.3, and if not, what alterations are to be made to the Proposed Closing Accounts or the Closing Employee Payroll Taxes Amount, as applicable, in order to correct the relevant inaccuracy of any such specific item; and

(ii) based on the Final Closing Accounts or the Closing Employee Payroll Taxes Amount, as applicable, established by the Appraiser in accordance with the above, the Final Adjustment in accordance with this Section 2.3 and Section 2.4.

For the avoidance of doubt, the Appraiser shall, where necessary for the determinations pursuant to Section 2.3.2(a), upon consultation, where required or considered appropriate by the Appraiser, of an independent legal expert appointed by the Appraiser, decide over disputes by the Parties on legal questions in connection with the establishment of the Final Closing Accounts and the Final Adjustment, including, but not limited to, the proper construction and interpretation of this Agreement.

(h) The Appraiser shall make his or her determination pursuant to Section 2.3.2 as soon as reasonably practicable, but no later than thirty (30) Business Days from the date of his or her appointment.

(i) The procedure as determined by the Appraiser shall comply with the requirements of due process; in particular, the Appraiser shall:

(i) give the Parties a reasonable opportunity to make written and oral presentations to him or her;

(ii) require that each Party provide the other with a copy of any written presentations at the same time as they are made available to the Appraiser;

(iii) permit each Party to be present while oral submissions are being made by the other Party or while evidence is gathered by the Appraiser, including meetings and discussions with the employees of the Company; and

(iv) conduct the proceedings in English.

(j) Each Party and the Appraiser shall, and shall procure that its accountants, assistants and other advisors shall, keep all information and documents provided to them pursuant to this Section 2.3 confidential and shall not use the same for any other purpose, except for disclosure or use in connection with the preparation of the Final Closing Accounts or the Closing Employee Payroll Taxes Amount, the proceedings before the Appraiser or otherwise in connection with the determination of the Final Adjustment.

(k) The costs and expenses (including VAT) of the Appraiser shall be equitably apportioned by the Appraiser based on the extent to which the Sellers, on the one hand, and the Buyer, on the other hand, is determined by the Appraiser to be the prevailing party in the resolution of such disputed matter. All other costs and expenses shall be borne by the Party incurring them.

(l) Notwithstanding anything to the contrary in this Section 2.3, either Party may refer the matter to dispute resolution pursuant to Section 12.2 at any time before the Parties and the Appraiser have reached agreement on the terms of engagement of the Appraiser.

2.3.3 General Principles Applicable to the Closing Accounts

(a) The Proposed Closing Accounts and the Final Closing Accounts shall be drawn up:

(i) in accordance with the policies and practices set forth in this Agreement;

(ii) so far as not inconsistent with the above, in accordance with Swiss Code of Obligations as such standards are applied pursuant to the accounting principles, procedures and practices adopted in the Financial Statements, applied on a consistent basis (but with correctness prevailing over consistency);

(iii) so as to avoid double counting (whether positive or negative) of any item to be included therein.

(b) The Closing Accounts shall be drawn up as at the Cut-off Date.

(c) The Closing Accounts shall be expressed in CHF and amounts in other currencies shall be translated into CHF pursuant to Section 6.4.

2.3.4 Computation of Net Debt

(a) So far as not inconsistent with Section 2.3.4(b) and Section 2.3.4(c) below, Net Debt shall mean the difference of the following Cash and Debt items, each as shown in the Final Closing Accounts as established in accordance with this Section 2.3:

	Line Item or Reference in Financial Statements
	Other Loans (interest bearing) (if any), but excluding the Grenke leasing debt for equipment

Minus	Cash and cash equivalent
Minus	Deposits / BCV Rent Guarantee
Minus	VAT current account - other receivables

(b) Amounts to be included within Cash and Debt by reference to line items referred to above shall be included consistently with the accounting principles and practices adopted in the Financial Statements, applied on a consistent basis (but with correctness prevailing over consistency).

(c) For the purposes of calculating the Net Debt:

(i) Cash shall include the aggregate exercise price payable by the Sellers holding Options upon exercise prior to Closing.

(ii) Cash shall, however, not include the amount equal to dividends from the Company to the Sellers distributed after the Cut-off Date but prior or on the Closing and that thus are not reflected in the Final Closing Accounts as having been distributed.

(iii) Debt shall not include any amounts under the Convertible Loan Agreement.

2.3.5 Computation of Net Working Capital

(a) So far as not inconsistent with Section 2.3.5(b) and Section 2.3.5(c) below, Net Working Capital shall mean the aggregate sum of the following items, as shown in the Final Closing Accounts as established in accordance with this Section 2.3:

	Line Item or Reference in Financial Statements
	Debtors – trade accounts receivable
Plus	Inventories
Plus	Prepaid expenses
Minus	Creditors – trade accounts payable
Minus	Accrued expenses
Minus	Other payables

(b) The computation of the Net Working Capital shall exclude items which are a direct consequence of the transactions contemplated by this Agreement, including, without limitation, provisions or Liabilities for Taxes arising as a result of the Closing to the extent such items have been deducted separately from the Preliminary Closing Consideration or are to be deducted separately for the calculation of the Closing Purchase Price.

(c) The Net Working Capital shall be calculated so as to avoid double counting with the Net Debt.

2.3.6 Computation of Pre-Closing Taxes

(a) For the sake of clarity, Pre-Closing Taxes shall comprise:

(i) federal, cantonal (Canton of Vaud) and communal corporate income taxes (if any) to be calculated based on profit/loss after taxes as shown in the Final Closing Accounts;

(ii) cantonal (Canton of Vaud) and communal capital taxes to be calculated based on the Company's equity (*i.e.*, the taxable equity correspondence to share capital, legal reserve

from capital contributions, other reserves (if any) and retained earnings) as per the Final Closing Accounts; and

(iii) any withholding taxes due in connection with the distribution of dividends from the Company to the Sellers that occur after the Cut-off Date but prior or on the Closing and thus are not reflected in the Closing Financial Accounts as having been distributed;

in each case in accordance with the applicable statutory tax rate under applicable Law.

(b) For the avoidance of doubt, Pre-Closing Taxes shall not include any Closing Payroll Taxes.

2.3.7 Computation of Closing Payroll Taxes

The Closing Employee Payroll Taxes Amount and the Closing Employer Payroll Taxes Amount (the latter which forms part of the Company Transaction Expenses) shall be calculated in accordance with the applicable withholding or contribution rates under applicable Law on the basis of the Closing Purchase Price.

2.4 Adjustment Payments

2.4.1 Net Debt, Pre-Closing Taxes and Company Transaction Expenses Adjustment

(a) If the sum of (i) the Final Net Debt, (ii) the Final Pre-Closing Taxes, and (iii) the Final Company Transaction Expenses is greater than the sum of (i) the Estimated Net Debt, (ii) the Estimated Pre-Closing Taxes, and (iii) the Estimated Company Transaction Expenses, the Preliminary Closing Consideration shall be decreased by the amount of such excess, and the Sellers shall, subject to and in accordance with Sections 2.4.3 and 2.4.4, pay that amount to the Buyer in accordance with their Ownership Percentage.

(b) If the sum of (i) the Final Net Debt, (ii) the Final Pre-Closing Taxes, and (iii) the Final Company Transaction Expenses is less than the sum of (i) the Estimated Net Debt, (ii) the Estimated Pre-Closing Taxes, and (iii) the Estimated Company Transaction Expenses, the Preliminary Closing Consideration shall be increased by the amount of such shortfall, and the Buyer shall, subject to and in accordance with Sections 2.4.3 and 2.4.4, pay that amount to the Sellers in accordance with their Ownership Percentage.

2.4.2 Net Working Capital Adjustment

(a) If the Final Net Working Capital is greater than the Estimated Net Working Capital, the Preliminary Closing Consideration shall be increased by the amount of such excess, and the Buyer shall, subject to and in accordance with Sections 2.4.3 and 2.4.4, pay that amount to the Sellers in accordance with their Ownership Percentage.

(b) If the Final Net Working Capital is less than the Estimated Net Working Capital, the Preliminary Closing Consideration shall be decreased by the amount of such shortfall, and the Sellers shall, subject to and in accordance with Sections 2.4.3 and 2.4.4, pay that amount to the Buyer in accordance with their Ownership Percentage.

2.4.3 Closing Employee Payroll Taxes Amount Adjustment

(a) If the Closing Employee Payroll Taxes Amount is greater than the Estimated Closing Employee Payroll Taxes Amount, the Sellers who are subject to Closing Payroll Taxes shall, subject to and in accordance with Section 2.4.4, pay the respective amount to the Buyer or, upon direction of the Buyer, to the Company in accordance with their percentage as determined by the Company

pursuant to applicable Law. The Buyer shall procure that the Company uses such amounts only for payment of Closing Payroll Taxes, pays them promptly to the relevant Tax Authorities in full and final discharge of the relevant Tax liabilities, and prepares the necessary salary statements and other filings with Tax Authorities.

(b) If the Closing Employee Payroll Taxes Amount is less than the Estimated Closing Employee Payroll Taxes Amount, the Buyer shall, subject to and in accordance with Section 2.4.4, pay the respective amount to the Sellers who are subject to Closing Payroll Taxes in accordance with their percentage as determined by the Company pursuant to applicable Law, provided that (i) the Closing Purchase Price is lower than the Preliminary Closing Consideration or (ii) the Company has obtained confirmation of either reimbursement or credit from the relevant Tax Authorities of the difference between the excessive Estimated Closing Employee Payroll Taxes Amount paid to the relevant Tax Authorities and the Closing Employee Payroll Taxes Amount.

2.4.4 Payment of the Adjustments

(a) All amounts required to be paid by the Parties pursuant to Section 2.4.1, Section 2.4.2 and Section 2.4.3 shall be aggregated or offset against each other, as applicable.

(b) The Final Adjustment determined pursuant to Section 2.4.4(a), plus the interest accrued thereon from and including the Closing Date to and excluding the date on which such balance and interest is paid pursuant to this Section 2.4.4(b), calculated in accordance with Section 6.3(a), shall be paid by or on behalf of the relevant Party by wire transfer of immediately available funds in CHF to the bank account(s) designated in writing by the Party entitled to receive such payment within ten (10) Business Days after the earlier of (i) the Proposed Adjustment becoming final and binding on the Parties pursuant to Section 2.3.2(c) and (ii) the delivery by the Appraiser of his or her determination of the Final Adjustment to the Parties pursuant to Section 2.3.2(e).

2.5 Earnout

2.5.1 Determination of Earnout Payments

(a) In addition to the Closing Purchase Price, the Sellers shall, subject to the terms and conditions set forth in this Section 2.5, be entitled to additional consideration of up to CHF 129,600,000 (Swiss Francs one hundred and twenty nine million six hundred thousand) payable by the Buyer in two installments (the **Earnout Payments**), subject to the achievement or completion by the Company of the milestone events set out in Annex 2.5.1(a) (the **Milestone Events**).

(b) [***]

2.5.2 Sellers' Information Rights

(a) No later than forty-five (45) Business Days following the end of each quarter, the first time on March 31, 2023, the Buyer shall, or shall cause the Company to, deliver to the Sellers' Representative, subject to reasonable confidentiality undertakings by the Sellers' Representative, quarterly status reports (the **Quarterly Reports**) describing in writing, in reasonable detail in the form as attached hereto as Annex 2.5.2(a): (i) the development status, the activities undertaken, in process, completed and planned, each with respect to achieving each of the two Milestone Events on a timely basis; and (ii) any problems or events that are likely to adversely impact the ability of the Company (or the relevant Affiliate of the Buyer) to achieve the Milestone Events or the timeline for such achievement. Following the Quarterly Report covering February 15, 2028, the Sellers shall not be entitled to any such reports anymore. The Sellers' Representative may disclose such information to the Sellers, subject to reasonable confidentiality undertakings. Notwithstanding the foregoing, the Sellers' Representative may at any time inform any Seller of

the general progress made by the Company (or the relevant Affiliate of the Buyer) in view of achieving the Milestone Events. The Sellers' Representative may request the Buyer to provide adequate supporting documentation in relation to the Quarterly Reports.

(b) Within twenty (20) calendar days after delivery of a Quarterly Report, if the Sellers' Representative requests a meeting (of up to five (5) hours in duration) with representatives of the Buyer and/or the Company to discuss the Quarterly Report, the Buyer shall make available for such a meeting (in person or by videoconference) at least one officer with operating responsibility for the activities of the Buyer related to the achievement of the Milestone Events with appropriate expertise. During such meetings, the Buyer and/or the Company shall also provide a general review of the development programs, testing and/or otherwise demonstrate product performance, and the activities performed and required to obtain FDA Clearance of the Sigi Patch Pump, as associated with the Milestone Events. The Buyer shall provide or cause the Company to provide written summaries of all such meetings to the Sellers' Representative.

(c) In addition to the Quarterly Reports, the Buyer shall inform the Sellers' Representative within thirty (30) calendar days upon becoming aware of: (i) any actions and decisions by any regulatory authority that will adversely impact the timing of achievement of the Milestone Events and/or the ability of the Company (or the relevant Affiliate of the Buyer) to achieve a Milestone Event; and (ii) any other material events associated with the Milestone Events that will adversely impact the timing of achievement of the Milestone Events and/or the ability of the Company (or the relevant Affiliate of the Buyer) to achieve a Milestone Event, and provide, or cause the Company to provide, the Sellers' Representative with summaries of any newly proposed development plans and study and testing designs, as well as summaries of the final version of such proposed development plans and study and testing designs. Section 2.5.2(b) shall apply *mutatis mutandis*.

(d) In addition, the Buyer shall, or cause the Company to, keep reasonable documentation substantiating all efforts to achieve the Milestone Events until the tenth (10th) anniversary of the Closing Date.

(e) Upon reasonable notice following receipt of the Quarterly Reports or other information provided to the Sellers' Representative pursuant to Section 2.5.2(c) and upon signing a confidentiality agreement with terms reasonably satisfactory to the Buyer, the Sellers shall have the right, at their own cost, to appoint one (1) expert (the **Sellers' Expert**) to: (i) review all such information provided to the Sellers' Representative; (ii) examine the current development status, the activities undertaken, in process, completed and planned with a view to achieving the Milestone Events, and any problems or events that have occurred or may occur which are likely to adversely impact the ability of the Company (or the relevant Affiliate of the Buyer) to achieve the Milestone Events; (iii) request and review all such other information reasonably required in order to perform the aforementioned examination; and (iv) perform such other activities as the Sellers' Expert deems reasonably necessary or desirable to assess the progress made toward achievement of the Milestone Events; provided that: (A) the selection of Sellers' Expert shall be subject to the prior approval of the Buyer and the Company (which shall not be unreasonably withheld); and (B) the Sellers' Expert shall report its findings to the Sellers' Representative.

2.5.3 Payment of Earnout Payments

(a) The Buyer shall notify the Sellers within fifteen (15) Business Days after achievement of each of the two Milestone Events (each such notice, a **Milestone Notice**). Within forty-five (45) calendar days following a Milestone Notice, the Buyer shall pay

(i) the relevant Earnout Payment *minus* the Earnout Employer Payroll Taxes Amount and the Earnout Employee Payroll Taxes Amount in accordance with Section 2.5.3(b) and *minus*

the Sellers' Earnout Advisor Fees Amount by wire transfer of immediately available funds in CHF to the accounts designated by the Sellers' Representative;

(ii) the Earnout Employer Payroll Taxes Amount and the Earnout Employee Payroll Taxes Amount in accordance with Section 2.5.3(b); and

(iii) the Sellers' Earnout Advisor Fees Amount by wire transfer of immediately available funds to the account designated by SVB Securities LLC.

(b) The Buyer shall deduct (i) from each Earnout Payment an amount equal to the Earnout Employer Payroll Taxes Amount and (ii) from the respective portion of the relevant Earnout Payment that is payable to a Seller who is subject to Earnout Payroll Taxes the relevant Earnout Employee Payroll Taxes Amount, and pay these amounts to the Company. The Buyer shall procure that the Company uses such amounts only for payment of Earnout Payroll Taxes, pays them promptly to the relevant Tax Authorities in full and final discharge of the relevant Tax liabilities, and prepares the necessary salary statements and other filings with Tax Authorities.

(c) Once a Milestone Event has been achieved, an Earnout Payment may not be withheld or reclaimed based on subsequent events or concerns arising after the relevant Milestone Event has first been achieved, except for any claim of the Buyer against the relevant Seller pursuant to this Agreement.

2.5.4 Procedural Matters

If the Parties do not agree as to whether a Milestone Event has been achieved or the Buyer used Commercially Reasonable Efforts in accordance with Section 2.5.1(b), each Party may initiate the following dispute resolution procedure:

(a) Upon written notice of a dispute regarding the achievement of a Milestone Event by either the Sellers' Representative or the Buyer, the Buyer's Chief Strategy Officer and the Sellers' Representative shall each use good faith and reasonable best efforts to reach an agreement on the matter within fifteen (15) Business Days of notice of dispute having been given.

(b) If the Buyer's Chief Strategy Officer and the Sellers' Representative cannot reach an agreement that is acceptable to the Sellers' Representative and the Buyer during the period set forth in Section 2.5.4(a) above, each Party may request by written notice to the other Party the escalation to the Buyer's CEO and the Sellers' Representative and to any Sellers specified in such notice, who shall each use good faith and reasonable best efforts to reach an agreement on the matter that is acceptable to all Parties within fifteen (15) Business Days following such written notice.

(c) If the Parties cannot reach an agreement that is acceptable to the Parties during the period set forth in Section 2.5.4(b) above, either Party may request by written notice to the other Party or Parties, respectively, that the matter be referred to an expert (the **Expert**) who shall be a person (employed or self-employed) who is independent from all Parties, has no conflict of interests with any of the Parties, has not acted as their or their Affiliates' advisor, board member or employee in the past, and who has at least ten (10) years' leadership experience in product development of, clinical use or assessment of and/or regulatory affairs responsibility for insulin delivery devices, and is generally well respected in the field.

(d) Within five (5) Business Days from the notice by the Party requesting the Expert procedure, the Sellers' Representative and the Buyer shall each submit a proposal for such Expert to the other (without, however, first contacting such proposed persons in this matter) who to the best knowledge of the proposing Party meet the requirements set out in Section 2.5.4(c) above. If the Sellers' Representative and the Buyer cannot agree on an Expert within ten (10) Business Days

from the notice by the Party requesting the Expert procedure, each Party may request the ICC International Centre for ADR of the International Chamber of Commerce (ICC) to appoint an Expert who meets the criteria in Section 2.5.4(c) above (such appointment being made in accordance with the Rules for the Appointment of Experts and Neutrals of the International Chamber of Commerce set forth in the ICC Expert Rules in force as from February 1, 2015, as amended).

(e) The Expert shall promptly review this Agreement and all relevant facts delivered by the Parties. The Expert shall make an independent evaluation of whether or not the Milestone Event has been achieved. Following its review, the Expert shall deliver a statement in English setting forth its determination of whether or not the Milestone Event has been achieved. The Expert shall act as an expert (*Schiedsgutachter*) as that term is defined in article 189 of the Swiss Code of Civil Procedure (*Schweizerische Zivilprozessordnung*), and not as arbitrator, and its determination of any matter falling within its jurisdiction shall, save for manifest error, be final and binding on the Sellers and the Buyer. In the event of a manifest error in the Expert's determination, the determination shall be returned to the Expert for correction, and any corrected determination shall be final and binding on the Sellers and the Buyer.

(f) The task of the Expert is limited to the factual determination as to whether the relevant Milestone Event has been achieved within the applicable timeframe or the Buyer used Commercially Reasonable Efforts in accordance with Section 2.5.1(b), as applicable, taking into account all facts and circumstances relating thereto. Any other question that may be in dispute in connection with the Milestone Event or otherwise shall be submitted to the dispute resolution procedure set out in Section 12.2.

(g) The Parties shall procure that the Expert will be furnished with all documents and information relating to the establishment of the achievement of the Milestone Event and with any information that the Expert may reasonably request, and the Parties agree to co-operate and assist the Expert as reasonably requested by the Expert. Such co-operation and assistance shall include (i) making available and permit copies to be taken of such books, records and work papers as may be relevant in connection with the Milestone Event and (ii) making available during office hours such personnel of the Parties and the Company, in each case, as may be reasonably required to conduct the determination by the Expert.

(h) The Expert shall make his or her determination as soon as reasonably practicable, but no later than forty-five (45) Business Days from the date of his or her appointment.

(i) The procedure as determined by the Expert shall comply with the requirements of due process; in particular, the Expert shall:

(i) give the Parties a reasonable opportunity to make written and oral presentations to him or her;

(ii) require that each Party provide the other with a copy of any written presentations at the same time as they are made available to the Expert;

(iii) permit each Party to be present while oral submissions are being made by the other Party or while evidence is gathered by the Expert, including meetings and discussions with the employees of the Company; and

(iv) conduct the proceedings in English.

(j) Each Party and the Expert shall, and shall procure that its assistants and other advisors shall, keep all information and documents provided to them pursuant to this Section 2.5 confidential and

shall not use the same for any purpose other than claiming and proving any rights or obligations under or in connection with this Agreement.

(k) Each Party shall be responsible for its own costs in this process. The costs and expenses (including VAT) of the Expert and any third party which the Expert consults pursuant to this Section 2.5 shall be borne by (i) the Buyer, if the Expert determines that the Milestone Event has been achieved or the Buyer did not use Commercially Reasonable Efforts in accordance with Section 2.5.1(b), as applicable, and (ii) the Sellers, if the Expert determines that the Milestone Event has not been achieved or the Buyer used Commercially Reasonable Efforts in accordance with Section 2.5.1(b), as applicable.

2.5.5 Acceleration of Earnout Payments

[***]

3. Actions Prior to Closing

3.1 General

(a) On the terms and subject to the conditions of this Agreement and except as otherwise expressly provided herein, the Sellers shall use their Commercially Reasonable Efforts:

(i) to cause the conditions precedent set forth in Section 4.2.1 and Section 4.2.2 to be satisfied on or before the Closing; and

(ii) to do all reasonable acts and things necessary (and within their power) to cause the Closing to occur.

(b) On the terms and subject to the conditions of this Agreement and except as otherwise expressly provided herein, the Buyer shall use its Commercially Reasonable Efforts to cause:

(i) the conditions precedent set forth in Section 4.2.1 and Section 4.2.3 to be satisfied on or before the Closing; and

(ii) its Affiliates to do all reasonable acts and things necessary (and within their power) to cause the Closing to occur.

(c) Each Party shall, and shall cause its or his or her Affiliates, Representatives and auditors, as applicable, to, (i) cooperate with the other Party, and (ii) promptly inform the other Party of any actions taken in view of the Closing.

3.2 Conduct Before Closing

3.2.1 Restricted Actions

(a) Unless either specifically provided for in this Agreement or contemplated in the Company's budget or business plan, as previously provided to Buyer, subject to changes necessary or advisable in connection with developments in the industry and/or material economic changes, each Seller shall (in each case to the extent possible through the exercise of his, her or its voting rights and subject to all applicable legal and regulatory requirements) ensure that the Company operates its business as a going concern, in the ordinary course of business and consistent with prior practice from the date of this Agreement through to and including the Closing Date.

(b) Notwithstanding the foregoing, each Seller shall not, and shall ensure (in each case to the extent possible through the exercise of his, her or its voting rights and subject to all applicable legal and regulatory requirements) that the Company does not take, or does not agree to take, any of the following actions (the **Restricted Actions**) from the date of this Agreement through to and including the Closing Date:

(i) do anything or omit to do anything that could interfere with the consummation of the transactions contemplated under this Agreement;

(ii) alter, amend or change the Articles of Association, the Shareholders' Agreement or any other similar governance documents of the Company, except as contemplated under this Agreement in connection with the exercise of the Options;

(iii) increase or decrease the share capital of the Company, except as contemplated under this Agreement in connection with the exercise of the Options;

(iv) authorize or create (by reclassification or otherwise) any new class or series of shares of the Company;

(v) issue, authorize or create any shares or related securities of the Company to any third party engaged in the development and commercialization of diabetes devices, including any manufacturer of continuous insulin infusion pumps or continuous glucose monitors;

(vi) redeem or repurchase any shares of the Company;

(vii) declare or pay any dividend or otherwise make a distribution to holders of any shares of the Company, other than the pre-closing distribution pursuant to Section 3.2.3;

(viii) increase the number of shares subject to issuance under any share plan or arrangement for the benefit of any service providers to the Company;

(ix) create, or hold capital stock in, any subsidiary that is not wholly owned (either directly or through one or more other subsidiaries) by the Company, or sell, transfer or otherwise dispose of any capital stock of any direct or indirect subsidiary of the Company, or permit any direct or indirect subsidiary to sell, lease, transfer, exclusively license or otherwise dispose (in a single transaction or series of related transactions) of all or substantially all of the assets of such subsidiary;

(x) liquidate, dissolve or wind-up the business and affairs of the Company, effect any deemed liquidation event (which shall include a merger or the sale, lease, transfer, exclusive license, or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary or subsidiaries of the Company, of all or substantially all the assets of the Company and its subsidiaries taken as a whole), or consent, agree or commit to any of the foregoing without conditioning such consent, agreement or commitment upon obtaining the approval required by this section;

(xi) grant, modify, dispose of or terminate any rights or enter into any agreement (including any license, assignment, Lien) relating to Intellectual Property Rights or otherwise permit any of its rights relating to Intellectual Property Rights to lapse;

(xii) grant, modify, dispose of or terminate any rights or enter into any agreement (including any license, assignment, Lien) relating to the Sigi Patch Pump or otherwise permit any of its rights relating to the Sigi Patch Pump to lapse;

(xiii) enter into any joint venture or partnership or profit-sharing arrangement;

(xiv) create, or authorize the creation of, or issue, or authorize the issuance of any debt security or create any lien or security interest, other than capital equipment leases in the ordinary course of business;

(xv) create, assume or increase any Debt other than short term trading indebtedness incurred or arising in the ordinary course of business;

(xvi) authorize or effect the acquisition or purchase of another entity, business line or assets of another entity or business line;

(xvii) sell, transfer or create any Lien (other than charges arising by operation of Law) on any assets of the Company (including any Intellectual Property of the Company) to or to the benefit of a third party (including a Seller);

(xviii) grant, create or allow to be created any Lien over any of his, her or its Shares;

(xix) make, increase or extend any financial loan or credit to any third party;

(xx) enter into, increase or extend any liability under any guarantee or indemnity in favor of any third party guaranteeing obligations of the Company in excess of CHF 25,000 per item;

(xxi) change accounting policies or procedures (including for Tax purposes), except as required by applicable Law;

(xxii) initiate, discontinue or settle any litigation or arbitration proceedings (i) where the amount claimed together with any costs incurred or likely to be incurred exceeds CHF 25,000 per item, or (ii) that would reasonably be expected to impose material nonmonetary obligations on the Company;

(xxiii) enter into, amend or give notice of termination of any Material Contracts with a total annual income or expenditure of more than CHF 100,000, or amend, waive, terminate or consent to the termination of any of the Company's rights thereunder;

(xxiv) enter into any other Material Contract that cannot be terminated in accordance with its terms (without any compensation being payable) on less than three (3) months' notice or terminate or vary the terms of any such existing Material Contract or material commitment;

(xxv) make or initiate any material changes to employee packages or compensation, other than the Transaction Bonus and the introduction of a supplemental executive pension plan;

(xxvi) make any capital expenditures or commitment thereof in excess of CHF 100,000 in the aggregate or fail to make any capital expenditures set forth in the Company's capital expenditure budget as in existence on the date hereof and made available to Buyer;

(xxvii) do anything that results in a Material Adverse Effect;

(xxviii) engage in any transaction with any Sellers and any of their Related Persons (excluding reasonable employment compensation, equity incentives and benefits approved by the board of directors of the Company prior to the date of this Agreement in exchange for services); or

(xxix) agree or commit to do any of the foregoing.

3.2.2 Buyer Convertible Loan

The Company and the Buyer agree to defer the Maturity Date as defined in the Convertible Loan Agreement to a date to be mutually agreed upon by the Company and the Buyer but that will not fall earlier than one (1) Business Day after the Closing Date.

3.2.3 Pre-Closing Distribution

The Sellers who are shareholders of the Company shall take all necessary steps to resolve a distribution to all shareholders of the Company immediately following the Exercise Date out of the Company's capital contribution reserves in an amount not to exceed the sum of (i) the Company's cash available as of the Cut-off Date (ii) *minus* CHF 50,000. The distribution shall be resolved based on the Company's audited year-end financial statements as of December 31, 2022 including the Company's auditor's confirmation explicitly confirming that the proposed distribution complies with the law and the Company's articles of association (the **Articles of Association**). The Company shall provide the Buyer with the drafts of the corporate documents including the Company's draft financial statements as of December 31, 2022 required in order to effect such distribution for prior review no later than three (3) Business Days, followed by the final drafts of these documents including the Company's audited financial statements as of December 31, 2022 (including the final auditors' confirmation about the dividend distribution) no later than one (1) Business Day, prior to the resolution of the distribution by the shareholders of the Company. Without limitation of the foregoing, each Seller agrees to grant, and hereby grants, to [***], each individually, with the right of substitution, all powers to represent such Seller at the ordinary general meeting of shareholders of the Company, even if a plenary meeting in the sense of article 701 CO be held, and to validly exercise such Seller's voting rights in favor of the proposals of the Company's board of directors regarding the following agenda items: (i) approval of Company's audited year-end financial statements as of December 31, 2022; (ii) appropriation of financial results for the year ended December 31, 2022; (iii) approval of the above distribution; (iv) granting discharge from liability to the members of the Company's board of directors and executive management in relation to financial year 2022; (v) re-election of all members of the Company's board of directors; and (vi) re-election of the Company's statutory auditors.

3.2.4 Access to the Company

Subject to any constraints under applicable Law, each Party shall use Commercially Reasonable Efforts to ensure that the Buyer is given reasonable access during ordinary business hours to the management, legal and financial advisors and auditors and records of the Company, at the Buyer's cost, to the extent this is necessary for the Buyer or its advisors to perform the obligations under this Agreement, *provided, however,* that such access shall not unreasonably interfere with the business and operations of the Company.

3.3 Exercise of Options

(a) Each Option Holder hereby (i) agrees to exercise his or her Options with effect as of such date that is after January 1, 2023 but prior to the Closing Date as determined by the Company (the **Exercise Date**), and (ii) undertakes to execute any documents, take all actions and make all payments required under the respective terms of the Options, and in connection with their exercise and settlement. Any Option Holder not having complied with his or her obligation under this Section 3.3 hereby agrees that such Options shall automatically be cancelled, terminated and forfeited without the payment of any consideration therefor with effect as of the Closing.

(b) The Company and each Option Holder agree that should Closing not occur, the exercise of the Options and the issuance of the Shares shall be reverted in a manner to be agreed between the Company and each Option Holder in good faith.

(c) Prior to the Closing, the Company shall update its Articles of Association in order to reflect the share capital of the Company and the new Shares issued out of the conditional capital (*bedingtes Kapital*) of the Company upon exercise of the Options and file for application with the commercial register to enter the amended Articles of Association in the commercial register. The Company shall provide the Buyer with the drafts of the corporate documents including the revised Articles of Association required for this purpose for prior review no later than five (5) Business Days prior to the meeting of the board of directors of the Company to be held in a session with a notary public in Switzerland ascertaining the issuance of Shares out of the conditional capital (*bedingtes Kapital*) and the amendment of the Articles of Association.

3.4 Closing Memorandum

No later than ten (10) Business Days prior to the anticipated Closing Date, the Sellers' legal counsel, in cooperation with the Buyer's legal counsel, shall prepare a closing memorandum describing the actions required to be taken at the Closing pursuant to Section 4.3 (the **Closing Memorandum**), substantially in the form attached hereto as Annex 3.4.

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4. Closing

4.1 Date and Place

(a) The Closing shall take place on January 19, 2023 or such other date as the Sellers' Representative and the Buyer may agree.

(b) The Closing shall take place at the offices of Homburger AG, Prime Tower, Hardstrasse 201, CH-8005 Zurich, Switzerland, or at such other location as the Sellers' Representative and the Buyer may agree.

(c) Neither the Sellers nor the Buyer shall be obliged to complete the sale or purchase of any of the Shares unless all of the Shares are sold and purchased simultaneously.

4.2 Conditions Precedent to the Closing

4.2.1 Conditions to the Obligations of Each Party

The obligations of the Buyer and each Seller to consummate the transactions contemplated under this Agreement shall be subject to the satisfaction or (where permitted) waiver by the Buyer and each Seller on or prior to the Closing Date of the following condition:

(a) No action shall be pending or threatened and no order, Law, injunction or decree of any court, administrative body or arbitration tribunal shall exist that has the effect of making illegal or otherwise preventing or prohibiting, or that seeks to enjoin, restrain, or impede the consummation of the Transaction.

4.2.2 Conditions to the Obligations of the Buyer

The obligation of the Buyer to consummate the transactions contemplated under this Agreement shall be subject to the satisfaction or waiver by the Buyer on or prior to the Closing Date of the following conditions:

(a) No Material Adverse Effect shall have occurred.

(b) The Fundamental Representations (as defined below) shall be true and correct in all respects as of the date of this Agreement and as of the Closing Date (except, in each case, to the extent such Fundamental Representations are made on and as of a specified date and shall continue on the Closing Date to be so true and correct as of the specified date).

(c) All Business Representations shall be true and correct in all material respects as of the date of this Agreement and as of the Closing Date (except, in each case, to the extent such Business Representations are made on and as of a specified date and shall continue on the Closing Date to be so true and correct in all material respects as of the specified date).

(d) Each Key Person shall have executed a revised employment agreement with the Company substantially in accordance with the terms set forth in Annex 4.2.2(d) (the **Employment Agreements**).

(e) Not more than 20% of all employees of the Company (excluding the Key Persons) shall have given notice of resignation between the date of this Agreement and the Closing Date, unless such employees have been replaced with or substituted by employees with comparable qualifications at comparable terms.

(f) The Sellers shall in all material respects have performed or complied with all obligations and covenants required by this Agreement to be performed or complied with by the Sellers by the Closing.

4.2.3 Conditions to the Obligations of the Sellers

The obligation of the Sellers to consummate the transactions contemplated under this Agreement shall be subject to the satisfaction or waiver by the Sellers of the following conditions:

(a) The Buyer Representations set forth in Section 7.3 shall be true and correct in all respects as of the date of this Agreement and as of the Closing Date.

(b) The Buyer shall in all material respects have performed or complied with all obligations and covenants required by this Agreement to be performed or complied with by the Closing.

4.2.4 Waiver of Conditions Not Satisfied

Prior to the Closing, each Party shall inform the other Party(ies) immediately upon becoming aware of any fact or matter that constitutes or could reasonably be expected to constitute a breach or non-satisfaction of the conditions set forth in Section 4.2.1, Section 4.2.2 or Section 4.2.3. At any time prior to the Closing, (a) the Sellers' Representative and the Buyer may jointly waive in writing in whole or in part the conditions set forth in Section 4.2.1, (b) the Buyer may waive in writing in whole or in part the conditions set forth in Section 4.2.2, and (c) the Sellers' Representative may waive in writing in whole or in part the conditions set forth in Section 4.2.3.

4.2.5 Right of Termination

(a) This Agreement may be terminated as follows:

(i) By the mutual written agreement of the Sellers and the Buyer.

(ii) By each Party by giving written notice to the other Party, if any of the conditions set forth in Section 4.2 is not satisfied (or waived) on or before February 28, 2023 (the **Long Stop**

Date); *provided* that any such non-satisfaction was not caused, or principally caused, by a material breach by the terminating Party of any of its or his or her obligations under the Agreement, and further *provided* that the Long Stop Date shall be extended (1) until March 31, 2023 if the European Commission informs the Buyer and/or any of the Sellers in the course of February 2023 that it invited the member states of the European Union (each a **Member State**) to make a referral request according to article 22 of the EU Merger Regulation or (2) until May 15, 2023 if the European Commission informs the Buyer and/or any of the Sellers in the course of February 2023, or, in case of an invitation to make a referral request referred to in paragraph (1) above, in the course of March 2023 about Member State(s) having made such referral request. Should the European Commission adopt a decision to examine the concentration or be deemed to have adopted a decision to examine the concentration (by expiry of the applicable statutory time limit to adopt such decision) until May 15, 2023, the Buyer and the Sellers may mutually agree on a further extension of the Long Stop Date.

(b) If this Agreement is terminated pursuant to Section 4.2.5(a)(ii), such termination shall be without Liability of any Party to the other Party(ies); *provided*, *however*, that if such termination is the result of a failure of a Party to fulfill any other obligation under this Agreement, such Party shall, notwithstanding any other provision of this Agreement, be liable for all losses incurred or sustained by the other Party as a result of such misconduct or failure; it being agreed and understood that, in addition to such Liability, (i) either Party shall be entitled to seek relief in the form of specific performance, injunctions or other interim measures and (ii) the other Party shall not oppose the granting of such relief on the basis that the Party seeking such relief may be made whole by the payment of a monetary amount. Nothing in this Section 4.2.5(b) shall be deemed to release any Party from any Liability for any breach by such Party of the terms and provisions of this Agreement.

(c) If this Agreement is terminated pursuant to this Section 4.2.5, upon the request of a Party, the other Party(ies) shall, and shall cause its Affiliates and its and their respective directors, officers, employees and advisors to, return or cause to be returned or destroyed (with certification thereof, if so requested by a Party) reasonably promptly all documents and information received from the requesting Party relating to the transactions contemplated hereby, whether so obtained before or after the date hereof, *provided* that (i) each advisor to such other Party may retain one copy for its files of each such document and information that it is required to retain in its capacity as professional advisor and (ii) each Party may keep copies of any computer records or files containing such information which have been created as a result of archiving or back-up procedures for legal, regulatory or internal compliance or governance purposes; *provided*, *however*, that any such advisor agrees to keep such document or information confidential.

(d) If this Agreement is terminated pursuant to this Section 4.2.5, this Agreement shall cease to be effective, except for the Surviving Provisions.

4.3 Closing Actions

4.3.1 Actions by the Sellers

At the Closing, the Sellers shall deliver to the Buyer the following documents:

(a) an original or a certified copy of any power of attorney under which any of the actions referred to in this Section 4.3.1 are executed, including (if applicable) evidence reasonably satisfactory to the Buyer of the authority of any Person signing on behalf of the respective Seller;

(b) assignment declarations as may be required under applicable Law to transfer the Shares and all rights associated therewith from the Sellers to the Buyer;

(c) originals of all corporate actions required under applicable Law and the Articles of Association to approve (i) the transfer of the Shares from the Sellers to the Buyer and (ii) the entry of the Buyer in the share register of the Company as owner of, and a shareholder with voting rights with respect to, the Shares;

(d) the Company's share register evidencing the Buyer as owner of, and a shareholder with voting rights with respect to, all (100%) of the Shares;

(e) a confirmation (as part of the Closing Memorandum) that the conditions set forth in Section 4.2.1 and Section 4.2.2 have been satisfied; and

(f) resignation letters in form and substance reasonably acceptable to the Buyer from each member of the board of directors of the Company, pursuant to which such member (i) declares his or her resignation as of the Closing Date as a member of the board of directors of the Company and (ii) waives any rights of any kind whatsoever he or she has against the Company arising out of, in connection with, or relating to his or her board membership.

4.3.2 Actions by the Buyer

At the Closing, the Buyer shall, or shall cause its Affiliates to, perform the following actions:

(a) deliver to the Sellers an original or a certified copy of any power of attorney under which any of the actions referred to in this Section 4.3.2 are executed, including evidence reasonably satisfactory to the Sellers of the authority of any Person signing on behalf of the Buyer;

(b) deliver the Preliminary Closing Consideration minus the Estimated Closing Employee Payroll Taxes Amount to the Sellers by wire transfer of immediately available funds to be credited on the same day, free and clear of any costs and charges, in accordance with the wire instructions set forth in the Closing Payment Statement;

(c) deliver the Estimated Closing Employee Payroll Taxes Amount to the Company by wire transfer of immediately available funds to be credited on the same day to the account of the Company designated by the Sellers, free and clear of any costs and charges, in accordance with the wire instructions set forth in the Closing Payment Statement, provided that the Buyer shall procure that the Company uses the Estimated Closing Employee Payroll Taxes Amount only for payment of Closing Payroll Taxes, and that the Buyer shall procure that the Company pays them promptly to the relevant Tax Authorities in full and final discharge of the relevant Tax liabilities;

(d) deliver the Sellers' Advisor Closing Fees Amount to SVB Securities LLC and the Sellers' Legal Fees Amount to Homburger AG by wire transfer of immediately available funds to be credited on the same day to the accounts designated by the Sellers, free and clear of any costs and charges, in accordance with the wire instructions set forth in the Closing Payment Statement;

(e) deliver to the Sellers a confirmation (as part of the Closing Memorandum) that the conditions set forth in Section 4.2.1 and Section 4.2.3 have been satisfied; and

(f) deliver to the Company a notification regarding beneficial ownership to the Shares as required by article 697j CO.

4.3.3 Concurrent Closing Actions

The closing actions of the Parties shall be effected concurrently with, and in exchange for (*Zug um Zug*), each other pursuant to article 82 CO. All documents and items delivered at the Closing pursuant to this

Section 4.3 shall be held by the recipient to the order of the person delivering the same until such time as Closing shall be deemed to have taken place. All documents to be delivered by the Parties at the Closing in accordance with this Section 4.3 shall be deemed to have been executed and delivered and shall cease to be held to the order of the Person delivering them and Closing shall be deemed to have occurred only if and when all such documents have been delivered in accordance with this Agreement (or their delivery waived by the Person entitled to receive the relevant document or item) and the electronic funds transfers in accordance with Sections 4.3.2(b), 4.3.2(c) and 4.3.2(d) have been received.

5. Other Covenants

5.1 Financing Undertakings

(a) The Buyer's obligations under this Agreement are not subject to any conditions regarding its or any other person's ability to obtain financing for the consummation of the Transaction.

(b) The Buyer undertakes that it has, and at the Closing will have, the necessary cash resources and/or definitive fundable loan agreements from its financing sources which together are sufficient to meet its obligations under this Agreement.

5.2 Press Releases and Other Public Announcements

From the date of this Agreement, all public announcements or press releases concerning any of the transactions contemplated by this Agreement shall only be issued after the Parties shall have consulted and agreed on the contents and timing of the relevant public announcement or press release. Notwithstanding the foregoing, nothing in this Agreement shall restrict or prohibit:

(a) any announcement or disclosure required by Law, any competent judicial or regulatory authority or any competent securities exchange or applicable securities Laws or stock exchange regulations (in which case the Parties shall endeavor in good faith to agree on the content of any such announcement or disclosure prior to its issuance); or

(b) the Buyer and the Sellers from making any disclosure to any of their respective Representatives, Affiliates or their Affiliates' Representatives who are required to receive such information to carry out their duties (conditional upon any such Person agreeing to keep such information confidential for so long as the Buyer and the Sellers are obligated to do so in accordance with this Section 5.2, any other provision of this Agreement or applicable Law).

5.3 No Claims Against Directors, Officers and Shareholders

(a) Neither the Buyer nor the Sellers shall make any claim against (i) any director, officer, consultant, employee or manager of the Company in connection with his or her acts or omissions as director, officer, consultant, employee or manager of the Company (the **Released Persons**) in the period prior to the Closing Date, and (ii) without prejudice to the Buyer's right to bring a claim against Sellers under and in accordance with the terms of this Agreement, the Sellers in connection with the Sellers' position as direct or indirect shareholders, directors, officers, consultants, employees or managers of the Company during the time until the Closing. Notwithstanding the foregoing, Sellers who are employed and entitled to a Transaction Bonus shall have the right to bring a claim against the Company in this regard.

(b) The Buyer shall (and shall procure that the Company shall), from and after the Closing Date and to the fullest extent permitted in accordance with applicable Laws, waive, release and discharge each Released Person and each Seller from any and all claims, demands, proceedings, causes of action, orders, obligations and liabilities arising out of any Pre-Closing Event (as defined below) which the Company has or may at any time have had against any Released Person or any Seller.

(c) For six (6) years from the Closing Date, the Buyer shall ensure that the Company (for so long as it remains part of the Buyer's group) maintains in force such "run-off" directors' and officers' liability insurance policies as will enable each Released Person who benefited from director's and officers' liability insurance policies as at the date of this Agreement to make claims arising out of any matter, cause or event occurring on or before the Closing Date (a **Pre-Closing Event**) under those policies on terms and conditions that are, on the whole, no less advantageous to the Released Person than the directors' and officers' liability insurance policies maintained by the Company on the date of this Agreement.

(d) The Buyer will procure that discharge is granted to each member of the board of directors and the executive management of the Company in office immediately prior to the Closing for any such matter, cause or event (i) promptly after Closing, but no later than ten (10) Business Days after the Closing Date, and (ii) again at the first ordinary shareholders' meeting of the Company following the Closing.

5.4 Covenant Not to Compete and Not to Solicit

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5.5 Document Retention and Access

The Buyer agrees to keep and cause the Company to keep all books and records of the Company that exist as of the Closing Date for the longer of (i) ten (10) years and (ii) the period required by applicable Law. During such period and without limitation to the generality of the foregoing, the Buyer shall procure during ten (10) years following the Closing that the Company grants the Sellers and their advisors access, during normal business hours, to such books and records as is necessary or appropriate in connection with any proceedings, Tax matter, preparation of financial statements, audit thereof, inquiry or dispute arising out of or in connection with this Agreement, any other matter requiring such access to safeguard the rights of any Seller and to perform the obligations under this Agreement or as otherwise reasonably requested by any Seller. The Buyer shall procure that any acquirer of the Company or of a material part of the Company's assets assumes the obligations set forth in this Section 5.5 such that the Sellers have a direct claim (*echter Vertrag zugunsten Dritter*) against any such acquirer.

5.6 Confidentiality

(a) The Amended and Restated Non-Disclosure and Clean Team Agreement executed by the Buyer and the Company on August 23, 2022 (the **Confidentiality Agreement**) shall remain in full force and effect until the Closing. Effective upon the Closing, the Confidentiality Agreement shall terminate.

(b) Each of the Sellers and the Buyer shall (and shall ensure that each of his, her or its Representatives shall) keep confidential the contents of this Agreement and other confidential information concerning the Company and shall not inform any third party of its content; it being understood and agreed that the foregoing confidentiality undertaking shall not restrict

(i) the Sellers or the Buyer from disclosing this Agreement or details of the transactions contemplated hereby for purposes of satisfying any of the conditions set forth in Section 4.2;

(ii) each Seller or the Buyer from pursuing his, her or its rights and exercising his, her or its remedies under this Agreement;

(iii) each Seller or the Buyer from a disclosure of information which is required by applicable Law (including applicable securities Laws or stock exchange regulations) or any competent judicial or regulatory authority (in which case the Parties shall endeavor in good faith to agree on the content of any such disclosure prior to it being made) or by any competent securities exchange;

(iv) each Seller or the Buyer from disclosure to a Tax Authority or Tax or other professional advisor in circumstances where such disclosure is reasonably necessary for the management of the Tax affairs of any Seller, any Affiliate of a Seller, the Buyer or any Affiliate of the Buyer;

(v) the Parties from disclosing information that is known to the public without any fault of, or breach of any confidentiality undertaking by, the disclosing Party or any of its Affiliates, or

(vi) the Sellers or the Buyer from a disclosure to their Representatives pursuant to Section 5.2(b).

6. Taxes, Costs, Expenses and Interest

6.1 Taxes

Except as expressly provided otherwise in this Agreement, each Party shall bear all Taxes incurred by or levied on it in connection with the transactions contemplated under this Agreement. Any duties imposed by applicable Law on the transfer of the Shares (*e.g.* transfer taxes (*Umsatzabgabe*)) shall be borne by the relevant Seller.

6.2 Costs and Expenses

Except as expressly provided otherwise in this Agreement, each Party shall bear his, her or its own costs and expenses (including advisory fees) incurred in the negotiation, preparation and completion of this Agreement.

6.3 Interest

(a) The interest rate to be applied to the interest calculation set forth in Section 2.4.4(b) shall be the three (3)-month Compounded SARON (as per the SIX Swiss Exchange Ltd page as at the date the relevant payment is due, at 6:00 p.m. Swiss time), *plus* one hundred (100) basis points *per annum* (calculated on the basis of the Day-Count Convention). If the applicable Compounded SARON is less than zero, the applicable Compounded SARON shall be deemed zero.

(b) If a Party defaults in the payment when due of any sum payable under this Agreement, such liability of such Party shall be increased to include interest on that sum from (and including) the date when the payment is due until (and excluding) the date of actual payment (whether before or after any judgment) at a rate of the three (3)-month Compounded SARON (as per SIX Swiss Exchange page as at the date the relevant payment is due, at 6:00 p.m. Swiss time), *plus* two hundred (200) basis points *per annum* (calculated on the basis of the Day-Count Convention). If the applicable Compounded SARON is less than zero, the applicable Compounded SARON shall be deemed zero.

6.4 Exchange Rate

All amounts to be paid hereunder in currencies other than CHF, such as the Sellers' Advisor Closing Fees Amount to SVB Securities LLC, shall be converted to CHF using the exchange rates as quoted on the website of the Swiss National Bank (www.snb.ch/en/iabout/stat/statpub/zidea/id/current_interest_exchange_rates/3) (bid rates Zurich 11:00 a.m. Swiss time) one (1) Business Day before such payment is effectuated in order to determine any remainder payment due hereunder (or, for purposes of any estimated amounts, one (1) Business Day before the relevant estimate needs to be delivered). For example, the Sellers' Advisor Closing Fee Amount due in USD shall be expressed in CHF based on the aforementioned exchange rate, such CHF amount to be considered for purposes of the determination of the Net Debt, the Net Working Capital, the Pre-Closing Taxes, and the Company Transaction Expenses.

7. Representations

7.1 Fundamental Representations of the Sellers

Subject to the limitations set forth in Section 8.2, Section 9 and Section 11.8, each Seller hereby severally (but not jointly or jointly and severally) represents to the Buyer within the meaning of article 197 CO, in respect of himself, herself or itself only, that the following statements (such statements together, the **Fundamental Representations**) are true and correct in all respects both as of the date of this Agreement and as of the Closing Date, except that those representations and warranties which are explicitly made as of a specific date shall be true and correct only as of such date.

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7.1.1 Capacity and Authority / Validity of Agreement

(a) Each Seller has the full capacity and authority to enter into this Agreement and any transactions contemplated hereunder and to perform his, her or its respective obligations under this Agreement. The Sellers 1, 8, 9, 10, 11, 13 and 14 are duly organized and validly existing under the Laws of their respective place of incorporation. The execution and performance of this Agreement by such Sellers was duly authorized by all requisite corporate actions.

(b) This Agreement constitutes valid and binding obligations of each Seller, enforceable against each Seller in accordance with its terms, except to the extent that the enforceability may be limited by applicable bankruptcy, reorganization, insolvency, moratorium or other Laws affecting the enforcement of creditors' rights generally. There exist no limitations under applicable Law, the constituting or governing documents of the Sellers 1, 8, 9, 10, 11, 13 and 14 or any contracts by which a Seller is bound that would prevent such Seller from entering into or performing its obligations under this Agreement.

(c) None of the Sellers is insolvent or bankrupt under the Laws of his or her place of residence or, with respect to Sellers 1, 8, 9, 10, 11, 13 and 14, its jurisdiction of incorporation, is unable to pay its debts as they fall due or has not proposed and is liable to any arrangement (whether by court process or otherwise) under which his, her or its creditors (or any group of them) would receive less than the amounts due to them where any such insolvency, bankruptcy, inability to pay debts or arrangement would affect his, her, or its ability to enter into or perform its obligations under this Agreement and/or any documents which are to be entered into by him, her or it pursuant to or otherwise in connection with this Agreement.

(d) There are no proceedings in relation to any compromise or arrangement with creditors or any winding up, bankruptcy or insolvency proceedings concerning a Seller and no events have occurred which would justify such proceedings where any such proceedings or events would affect his, her or its ability to enter into or perform its obligations under this Agreement and/or any documents which are to be entered into by him, her or it pursuant to or otherwise in connection with this Agreement.

(e) The execution and performance by each Seller of this Agreement and the consummation of the transactions contemplated hereunder does and will not breach, violate or conflict with any agreement or any applicable Law to which such Seller is a party or subject, or constitute a default or an event under any such agreement which would give rise to any right of any Person or to any obligation of such Seller which would be materially inconsistent with such Seller's obligations under this Agreement or the transactions contemplated hereunder and materially negatively prejudice this Agreement and the transactions contemplated hereunder.

(f) There are no Actions pending or threatened against any of the Sellers challenging the validity of this Agreement or any transaction contemplated in this Agreement, or which would operate to hinder or substantially impair the consummation of the transactions contemplated by this Agreement.

7.1.2 Organization of the Company; No Conflicts

(a) The Company is duly incorporated and organized and validly existing under the Laws of Switzerland and has the full corporate capacity, power and authority to own or use its assets and properties and to carry on its business as currently conducted.

(b) The execution and performance by the Sellers of this Agreement and the consummation of the transactions contemplated under this Agreement does and will not (i) violate or conflict in any respect with any provision of the Articles of Association or organizational regulations or (ii) materially breach or violate any agreement to which the Company is a party or constitute a default or an event under any Material Contract that would give rise to any right of the counterparty to terminate such Material Contract.

(c) Except as specifically set forth in this Agreement, no notification, registration or filing is required to be made by the Company with, and no permit, license, certification, consent, authorization, approval or exemption is required to be obtained by the Company from, any Governmental Authority in connection with the execution of this Agreement or the consummation of the transactions contemplated hereunder, which if not obtained is likely to materially adversely affect the Company.

(d) No insolvency, bankruptcy, moratorium or similar proceedings have been opened or applied for by the Company and the Company is not required to file for any such proceedings under the Laws applicable to it. The Company is not illiquid (*zahlungsunfähig*), over-indebted (*✔berschuldet*) or subject to a loss of capital (*Kapitalverlust*).

7.1.3 Shares

(a) The share capital of the Company is structured as set forth in Recital A. No decision has been taken to amend the share capital structure other than disclosed herein. All decisions regarding the conditional and/or authorized capital increases set out in the Articles of Association have been taken in accordance with applicable Laws.

(b) Each Seller is, or upon issuance of the Option Shares will be, the sole legal and beneficial owner of the Shares as set forth next to his, her or its name in Annex B, free and clear of any Liens. All

the transfers of the Issued Shares which have occurred until the Closing Date have been approved by the board of directors of the Company.

(c) The Issued Shares have been validly issued and fully paid, and as of the Closing Date, the Option Shares to be issued upon exercise of the Options will have been validly issued and fully paid. Except for the Convertible Loan Agreement, as of the date of this Agreement, the Issued Shares and the Options constitute, and as of the Closing Date, the Shares will constitute, all of the shares and other securities in the Company.

(d) Other than the Options and the Convertible Loan Agreement, there are no outstanding options, warrants, calls, conversion rights or other agreements, commitments or rights of any kind relating to the sale, issuance, voting, transfer or other disposal or the acquisition of any of the Shares or any other securities of the Company. Following the Exercise Date, other than the Convertible Loan Agreement, there will be no outstanding options, warrants, calls, conversion rights or other agreements, commitments or rights of any kind relating to the sale, issuance, voting, transfer or other disposal or the acquisition of any of the Shares or any other securities of the Company.

(e) The Company owns no shares or securities and has no other equity interest in any other Person. The Company has not undertaken to acquire any shares or securities or other equity interest or to make any other or further investment, whether directly or indirectly, in any other Person. The Company has no foreign branch office or other permanent establishment in a foreign country.

(f) All previous share certificates issued in the past by the Company have been duly cancelled and, as of the Closing Date, no share certificates will have been issued representing any Share.

7.1.4 Intellectual Property Rights

(a) The Company owns the Owned Intellectual Property Rights listed in Annex 7.1.4, free and clear from any Liens (the **Fundamental Intellectual Property Rights**). The Fundamental Intellectual Property Rights constitute all registered Intellectual Property Rights owned by the Company that (i) pertain to the Sigi Patch Pump and (ii) are necessary for the research, development, manufacture, use, or commercialization of the Sigi Patch Pump on a worldwide basis as specified in Annex 7.1.4 as currently conducted and as currently proposed to be conducted after the Closing Date.

(b) The Fundamental Intellectual Property Rights owned by the Company are registered solely in the name of the Company or in the Company's former corporate name "Advanced Microfluids SA". All registration fees for the Fundamental Intellectual Property Rights that are or will become due and payable until the Closing Date are fully paid or will be fully paid when becoming due and payable until the Closing Date.

(c) In relation to the Fundamental Intellectual Property Rights, and except for any licenses contained in the Data Room Documents, the Company has not previously outlicensed, assigned, transferred, or otherwise conveyed any right, title or interest thereto to any third party (including the Sellers).

(d) As of the date of this Agreement, the Company has not received any claim in writing alleging any infringement by the Sigi Patch Pump of any third party's Intellectual Property Rights.

(e) The Company has, to the Sellers' Best Knowledge, not misappropriated any Intellectual Property Rights of a third party in the design or the development of the Sigi Patch Pump.

(f) No third party claims disputing the Company's ownership or the validity of any Fundamental Intellectual Property Rights have been notified to the Company in writing.

(g) Except as stated in Annex 7.1.4, no Fundamental Intellectual Property Right is the subject of any outstanding order, judgment, injunction, decree, legal or governmental proceeding (other than pending applications for registration or renewals of registrations or the recording of any assignment(s) of any Fundamental Intellectual Property Rights) restricting or affecting in any material manner the ownership or use of the Fundamental Intellectual Property Rights.

7.2 Business Representations of the Sellers

Subject to the limitations set forth in Section 8.2, Section 9 and Section 11.8, each Seller hereby severally (but not jointly or jointly and severally) represents to the Buyer within the meaning of article 197 CO, in respect of himself, herself or itself only, that the statements set forth in this Section 7.2 following this paragraph (such statements together, the **Business Representations**) are true and correct as of the date of this Agreement and as of the Closing Date, except that those representations and warranties which are explicitly made as of a specific date shall be materially true and correct only as of such date.

7.2.1 Financial Statements

(a) The Financial Statements have been prepared in accordance with the Swiss Code of Obligations and the accounting principles as applied throughout the last three financial years. The Financial Statements are true, correct, free of any omission and complete in all material respects and are not misleading, and reflect the state of affairs, the financial condition and the results of the operations of the Company as at the respective accounts date and for the financial period then ending in accordance with the applicable accounting principles.

(b) To the extent that contingent Liabilities were not required to be included in the Liabilities reflected on the balance sheet included in the Financial Statements, such Liabilities have been reflected as below-the-line items on such balance sheet as required by the Swiss Code of Obligations or otherwise disclosed in the notes to the respective Financial Statements.

(c) The Company does not have any Liabilities, other than Liabilities (i) set forth in the balance sheet included in the Interim Financial Statements, and not discharged subsequent to such date, or (ii) incurred by the Company subsequent to the date of the balance sheet included in the Interim Financial Statements, in the ordinary course of business and not discharged since such date.

(d) To the Sellers' Best Knowledge, and except as included in the Interim Financial Statements, the Company does not have any Liability that relates to or has arisen out of a breach of contract, breach of warranty, tort or infringement by or against the Company.

(e) All of the Accounts Receivable included in the Financial Statements have arisen from bona fide transactions in the ordinary course of business consistent with past practice and, to the extent not previously collected, are fully collectible, net of the allowance for doubtful accounts, in the ordinary course of business in accordance with their terms and assuming that the methods of collection practices and procedures used in the collection of the Accounts Receivable are consistent with those historically used by the Company.

(f) The Company has no commitments to purchase inventory, other than in the ordinary course of business.

(g) The Company has not guaranteed or otherwise provided security for any third party obligation (including the Sellers).

7.2.2 Taxes

(a) The Company has timely filed all Tax Returns required to be filed. All such Tax Returns (i) have been prepared in the manner required by applicable Law, (ii) are true, correct, complete and not misleading in all respects, and (iii) accurately reflect the facts they are required to reflect by applicable Laws.

(b) The Company is not a party to any Action by any Tax Authority and no written notice of any such Action has been received by the Company during the twelve (12) months before the date of this Agreement.

(c) All material accounts, books, financial records and supporting documents of the Company are up to date and have been accurately kept, in accordance with the Laws pertaining to Tax.

(d) All Taxes for which the Company is liable have been duly withheld, deducted and/or paid to the competent Tax Authority or, if not due, fully provided for in the Financial Statements. Except for the payment of source Taxes (*Quellensteuer*) and related default interests due and payable on the compensation paid to the independent member of the board of directors of the Company, the Company is not in default (*Zahlungsverzug*) with the payment of any Taxes.

(e) Other than ordinary course audits or investigations (including the VAT audit by the Swiss Federal Tax Administration scheduled for December 12 to December 13, 2022), the Company has not been the subject of any audit or investigation by any Governmental Authority.

(f) No claim has been made by any Governmental Authority before the date hereof in the past three (3) years in a jurisdiction where the Company does not file Tax Returns that the Company is or may be subject to Taxation by that jurisdiction. The Company has no permanent establishment outside Switzerland that could subject it to Liabilities for Taxes outside Switzerland.

(g) The Data Room Documents contain all Tax Rulings issued to the Company. The Company fully complies with the terms and conditions of the Tax Rulings and the Tax Rulings are in full force and effect and not subject to any threat of termination.

(h) All transactions and agreements between the Company and its shareholders or its shareholders' Affiliates have been concluded on arm's length terms.

7.2.3 Assets

The Company has good and valid title to, or a valid right secured by contract (including lease, rental or other leasing agreement) or otherwise to use, all of the assets used by the Company in the conduct of its business and all of the assets included in the balance sheet contained in the Financial Statements, in each case free and clear of all Liens. The assets owned by or validly licensed, leased or rented to the Company include all of the assets that are used in its operations as currently conducted, are adequate to conduct the business as currently conducted, and will be adequate to enable the Buyer to continue to conduct its business as currently conducted. The assets of the Company are in good operating condition and repair, normal wear and tear excepted, are in their current condition safe to operate and suitable for the uses intended therefor, are free from any latent defects and have been maintained in accordance with normal industry practice. The Company has not delayed or postponed any maintenance expenses of buildings, plants, machinery, vehicles, structures or equipment, compared to the ordinary course of business consistent with past practice and normal industry practice.

7.2.4 Intellectual Property Rights

(a) To the Sellers' Best Knowledge, all Intellectual Property Rights necessary in connection with the operations of the Company as currently conducted and as currently proposed to be conducted after the Closing are (i) owned by the Company (the **Owned Intellectual Property Rights**), or (ii)

otherwise lawfully used by the Company (the **Licensed Intellectual Property Rights**). As of the date of this Agreement, Annex 7.2.4 includes all registered Owned Intellectual Property Rights as well as a schedule of known due dates for office actions, payments and other actions required to be handled within one year from the Closing Date for the prosecution and maintenance of registered Owned Intellectual Property Rights and further identifies for each right the name of the law firm handling its prosecution and maintenance.

(b) The Data Room Documents contain a list of Patents, Trademarks and Domain Names registered to or applied to for by the Company. All necessary renewal applications have been filed and all payments have been made when due and payable to maintain such Trademarks and Domain Names.

(c) No claims, disputes, opposition or nullity proceedings (including for opposition, cancellation, revocation or rectification) are pending or threatened in writing challenging the ownership, use or validity of the Owned Intellectual Property Rights.

(d) To the Sellers' Best Knowledge, no third party is infringing on, or making unauthorized use of, the Owned Intellectual Property Rights.

(e) To the Sellers' Best Knowledge, the Company does not infringe on any Intellectual Property Rights of any third party. The Company has not been, since December 31, 2020, threatened in writing in connection with any infringement of any Intellectual Property Rights of any third party.

(f) To the Sellers' Best Knowledge, the Owned Intellectual Property Rights and the Licensed Intellectual Property Rights include all Intellectual Property Rights necessary for the conduct of the Company's business as currently conducted and as currently proposed to be conducted after the Closing, and none of the Owned Intellectual Property Rights and Licensed Intellectual Property Rights are the subject of any Action or covenant restricting the ownership or materially restricting the use of the respective Intellectual Property Rights as intended to be used in the Company's business as currently conducted and as currently proposed to be conducted after the Closing. To the Sellers' Best Knowledge, none of the Owned Intellectual Property Rights or Licensed Intellectual Property Rights are owned or possessed by any of the Sellers or any director, officer or employee of the Company.

(g) The Company has entered into non-disclosure agreements to protect the Company's trade secrets, confidential information, customer lists, software, technical information, data, process technology, plans, drawings, and blue prints, as the case may be, that relate to the Company's business and which are disclosed to third parties in the ordinary course of the Company's business.

(h) The Company has fulfilled all of its obligations concerning employees', consultants' and other persons' inventions and designs, and the exclusive right to all Intellectual Property Rights (including but not limited to Copyrights and inventions) created by any such persons in fulfilling their contractual obligations towards the Company, has been validly assigned to the Company except for moral rights and other personality rights, which may not be assigned pursuant to mandatory applicable Law.

(i) The Company has taken reasonable steps to protect its trade secrets, confidential information, and processes to prevent any unauthorized third party to access and use such trade secrets, confidential information, and processes with regard to the Intellectual Property Rights owned or licensed by the Company.

7.2.5 Information Technology Assets

(a) The computer systems, communication systems, software and hardware used by the Company (the **Information Technology Assets**) are in good working condition and sufficient to perform all computing, information technology and data processing operations necessary for the operation of the Company's business as currently conducted and, to the Sellers' Best Knowledge, as currently intended to be conducted after the Closing. To the Sellers' Best Knowledge, the Company has taken reasonable steps and implemented reasonable safeguards to protect its Information Technology Assets, including without limitation against any unauthorized use or access, to ensure business continuity.

(b) The Information Technology Assets are adequate and sufficient for the current requirements of the Company in terms of functionality and performance and for the size and scope of the business as currently being conducted by the Company. In the twelve (12) months prior to the date of this Agreement, the Company has not suffered any failure, virus or bug in or breakdown of any part of the Information Technology Assets which has caused any material disruption or interruption to its use by the Company.

(c) The Company has reasonable procedures in place to ensure the security of the Information Technology Assets and data stored on them, including, without limitation, an effective firewall, properly administered and run password protection, virus checking software and procedures for taking and storing back-up copies of the software and stored data and appropriate disaster recovery provisions.

(d) All records, data and information of the Company are recorded, stored, maintained or operated or otherwise held by the Company and the use of or access to such records and systems is not wholly or partly dependent on any facilities (except for telecommunication transmission facilities) which are not under the ownership or control (for the avoidance of doubt, control shall include use of or access to such records and systems by means of an agreement with cloud or other service providers) of the Company.

7.2.6 Product Software

(a) All software forming part of the Sigi Patch Pump as of the date of this Agreement (the **Product Software**) is owned by or validly licensed to the Company, and the Company has the right to use it as currently used and as currently intended to be used.

(b) To the Sellers' Best Knowledge, all licenses granted to the Company of third party software forming part of Product Software are in full force and effect without default by any party thereto, the Company has paid any and all royalties due thereunder, and no such license may be terminated by the third party as a result of the transaction contemplated by this Agreement. Furthermore, to the Sellers' Best Knowledge, the Company is in compliance with the terms of use of any and all licenses which govern the use of Product Software.

(c) The Company is not obligated or under any liability to make any recurring payments by way of royalties, fees or otherwise to any owner or licensor of any Product Software other than commercially available, standard software (including, without limitation, any former and current employee and consultants) with respect to the use thereof.

(d) The Company is aware of, and in all material respects in compliance with, the terms of use of the licenses which govern the use of Public Software incorporated into the Product Software. To the Sellers' Best Knowledge, no Public Software has been incorporated with any Product Software owned by the Company in a manner that, under the applicable license, as of the date of this Agreement requires the Company to (i) disclose or distribute source code of any Product Software owned by the Company, (ii) to license any Product Software owned by the Company

under a Public Software license, or (iii) to license any Product Software owned by the Company for the purpose of making derivative works.

7.2.7 Licenses; Regulatory Matters

(a) The Company possesses all Licenses that are required in order for the Company to conduct the Company's business as currently conducted or currently intended to be conducted after the Closing Date. The Data Room Documents contain true, correct and complete copies of each of these Licenses. All of these Licenses are valid and in full force and effect.

(b) The Licenses do not unexpectedly or otherwise unduly restrict the business or operations of the Company.

(c) The Company has complied with, is in compliance with, and has at all times operated the Company's business and maintained its assets in compliance with, all terms and requirements of each of these Licenses and all Laws in all material respects.

(d) Neither the execution of this Agreement, nor the consummation of the transactions contemplated hereby, will cause any termination, revocation, non-renewal, suspension or modification of any License.

(e) The Company has not received any notification from any Governmental Authority or other Person alleging any violation of any License by the Company. To the Sellers' Best Knowledge, no event has occurred or circumstance exists that (with or without notice or lapse of time) may contravene, conflict with or result in a violation or breach of, or give any Person the right to cancel, terminate, revoke or modify any of these Licenses. There are no proceedings pending or, to the Sellers' Best Knowledge, threatened against the Company to cancel, terminate, revoke or modify any License.

7.2.8 Real Property

(a) The Company does not own any real property. The Data Room Documents include, list or refer to all documents and information pertaining to all real property leased by the Company (the **Real Property Leases**).

(b) No party to any Real Property Lease has given written notice of termination or made a claim or given notice in writing with respect to any material breach or material default under such lease, and all such written leases are valid, binding and in full force and effect. None of the Real Property Leases can be terminated, modified or subject to any other adverse consequences which are triggered, upon or due to the transaction contemplated by this Agreement.

(c) All interior fittings conducted by the Company of the real property leased have been approved by the landlord.

(d) The cash deposit made by the Company with the Banque Cantonale Vaudoise (BCV) as a rent guarantee covers the entire guarantee amount due under the Real Property Leases and the Company is not obligated to make any further payment in this regard.

7.2.9 Employment

(a) The Data Room Documents contain a complete and accurate list of all employees of the Company as of the date of this Agreement (the **Employees**).

(b) All employment agreements with Employees have been entered into on terms and conditions substantially in accordance with the standard agreements made available as part of the Data

Room Documents, except to the extent specific executed employment agreements have been made available as part of the Data Room Documents. No Employee has a notice period longer than six (6) months, nor is there any termination compensation payable for termination on due notice that would exceed the equivalent of six (6) months' salary (except for compensation during the notice period or as required by Law).

(c) As of the date hereof, none of the Key Persons has given notice to terminate his or her employment agreement, nor has notice to terminate been given by the Company. The employment agreements with the Key Persons have been disclosed to the Buyer.

(d) To the Sellers' Best Knowledge, the Company is in compliance with all material contractual and legal obligations relating to employees. The Company is not, or has not been since December 31, 2020 subject to pending or threatened in writing any disputes with Governmental Authorities, works councils or other employee representatives.

(e) Except for the Transaction Bonus, no material salary increases has been resolved or announced, there are no employment or benefit agreements, plans or arrangements entitling any Employee to severance or other payments upon a change of Control of the Company and there are no outstanding loans between the Company and any of its Employees.

(f) No mass dismissals, in particular those which would give rise to any notification to a Governmental Authority, have been announced in the past or are being planned.

(g) Other than the staff lending by bNovate Technologies AG to the Company disclosed in the Data Room Document, bNovate Technologies AG has not lent any other staff to any third party during 2022.

7.2.10 Material Contracts

(a) The Data Room Documents contain complete and correct copies of all contracts in effect as of the date hereof to which the Company or the Sellers are a party (the **Material Contracts**), and which:

(i) grant rights to any party thereto, if such right would have a material negative impact on the Company's business as currently conducted;

(ii) contain any provision that refers to a change of Control of the Company;

(iii) restrict the Company from engaging in or competing in any line of business as currently conducted or currently intended to be conducted by the Company;

(iv) constitute a partnership, joint-venture, cooperation, consortium, profit sharing or similar material contract;

(v) constitute a contract relating to Licensed Intellectual Property Rights;

(vi) contain any guarantee, indemnity or similar undertaking in respect of a third party obligation in excess of CHF 100,000 or the equivalent thereof in any other currency calculated on the date hereof;

(vii) are supply or research and development agreements that are material to the business of the Company;

(viii) relate to the acquisition or disposal by the Company during the previous three (3) years of a company, business or real property for a consideration of CHF 100,000 or more;

(ix) contain any off-balance sheet borrowing arrangement (including factoring arrangements);

(x) are contracts of employment with any director, officer, manager or employee of the Company, or any consultancy or agency contracts;

(xi) contracts with or that require the retention of or payment to, an investment bank, broker, financial advisor, accountant, attorney or other advisor;

(xii) have been entered into (i) by the Company, on one hand, and any of the Sellers, any Affiliate of any of the Sellers, any Person related to any of the Sellers or in which any of the Sellers or any Affiliate of any of the Sellers has any interest in (whether directly or indirectly), on the other hand, or (ii) otherwise than at arm's length or in the ordinary course of business;

(xiii) have been entered into for a term of more than two years, are or are likely to be of an unprofitable or loss making nature or contain material obligations or restrictions of an exceptional or unusual nature;

(xiv) are contracts or agreements with the top ten (10) suppliers by amount of purchases by Company (excluding any non-material purchase orders), together with a list setting out the absolute amount purchased and as percentage of total purchases;

(xv) are lease agreements regarding premises;

(xvi) contemplate a notice period for termination of more than six (6) months;

(xvii) have, or is likely to have, a material adverse effect on the financial or trading position or prospects of Company; and

(xviii) are grants allocated by third parties to the Company.

(b) All Material Contracts are in full force and effect and are valid and enforceable by the Company in accordance with their terms. In the past three (3) years until the date of this Agreement, the Company has not received any written notice of any material default under any Material Contract. As of the date of this Agreement, the Company is not and, to the Sellers' Best Knowledge, no other party thereto is in material default or material breach under any such Material Contract (and, to the Sellers' Best Knowledge, no event has occurred, with or without notice, that would result in a material default or material breach thereunder), and the Company has not delivered, as of the date hereof, any claim or written notice of default or breach under any such Material Contract.

(c) To the Sellers' Best Knowledge, the Company and each counterparty have at all times properly performed and complied with all of their obligations arising out of any Material Contract, and none of the Company or any of the Sellers has received written notice according to which the Company is, or is alleged to be, in default under any Material Contract.

(d) None of the contracts, agreements, arrangements or understandings which are material for the Company or for the business of the Company, taken as a whole, can be terminated, modified or subject to any other adverse consequences which are triggered upon or due to the transaction contemplated by this Agreement, unless disclosed in the Data Room Documents.

7.2.11 Insurance

(a) The Company maintains insurance as required by Law for companies engaged in the business conducted by the Company (such insurance hereinafter the **Target Insurance Policies**).

(b) No act, omission, misrepresentation or non-disclosure has occurred which makes any of the Target Insurance Policies voidable, nor have any circumstances arisen which would render any of these policies void or unenforceable for illegality or otherwise, nor has there been any breach of the terms, conditions and warranties of any of the policies that would entitle insurers to decline to pay all or any part of any claim made under the Target Insurance Policies.

(c) All premiums due on or before the Closing Date by the Company in respect of the Target Insurance Policies have been paid or provisioned for in the Financial Statements, and all such Target Insurance Policies are in full force and effect.

(d) As of the date of this Agreement, no written notice of cancellation, termination or revocation or other written notice of premium increase, material alteration of coverage, or that any such Target Insurance Policies are no longer in full force or effect or that the issuer of any such Target Insurance Policies is not willing or able to perform its obligations thereunder has been received by the Company with respect to any such Target Insurance Policies.

(e) There have not been any claims made under the Target Insurance Policies by the Company during the past three (3) years until the date of this Agreement and during the same period there has not been any denial of coverage by an insurer with respect to any claim made by the Company in relation to such Target Insurance Policies.

(f) All incidents that occurred and became known to the Company before the Closing Date and that could result in a claim under any Target Insurance Policy have been timely notified to the relevant insurers in due form.

7.2.12 Litigation

As of the date of this Agreement, there are no written Actions pending or threatened in writing against the Company or involving the Company before any Governmental Authority. There are no outstanding settlement agreements or similar written agreements with any Governmental Authority or other Person and no outstanding orders, judgments, injunctions or awards issued by any Governmental Authority against the Company.

7.2.13 Absence of Material Adverse Effect

From the balance sheet date of the Interim Financial Statements until the date hereof, no Material Adverse Effect has occurred.

7.2.14 Fair Disclosure

All information included in the Data Room Documents is true, complete and not misleading and provides a fair and accurate picture of the business and financial situation of the Company. There is no material fact, which a reasonable buyer would use for the assessment of the transactions under this Agreement, which has not been disclosed in the Data Room Documents.

7.2.15 Compliance

(a) To the Sellers' Best Knowledge, the Company:

(i) complies with the Laws applicable to it (it being understood and agreed that with respect to compliance with employment Laws and data protection Laws, Sections 7.2.9(d) and 7.2.15(d), respectively, shall exclusively apply); and

(ii) has obtained all material permits or authorizations required under applicable Law to operate its business as currently conducted and all such permits and authorizations are in full force and effect.

(b) No investigations, enquiries or proceedings are pending or have been threatened in writing which are reasonably likely to result in the suspension or revocation of any permits or authorizations necessary to operate the Company's business as currently conducted.

(c) To the Sellers' Best Knowledge, during the past three (3) years before the date hereof, the Company (including any of its directors, officers or employees) has not made, offered or authorized use of any corporate funds or provided anything of value (i) for unlawful payments, contributions, gifts, entertainment or other unlawful expenses relating to political activity, (ii) to domestic or foreign government officials or employees of third parties or other Persons in violation of anti-corruption or anti-bribery Laws applicable to the Company, or (iii) for a bribe, rebate, payoff, influence payment, kickback or other similar payment in violation of any Law applicable to the Company.

(d) To the Sellers' Best Knowledge, the Company has been in material compliance with all data protection Laws applicable to it with respect to the collection, storage, use, and other processing of personal data as defined by such Laws.

7.2.16 Environment

(a) There are no contaminated sites (Altlasten) at any property operated or otherwise used by the Company that could give rise to Liability of the Company.

(b) No activities of the Company, no property, no assets and no facilities used or owned by the Company are or have been the source of any pollution or damage to human health or the environment.

(c) No dangerous or toxic wastes or substances are or have been used, produced, generated, stored or treated on land currently owned, used or leased, or which has been owned, used or leased in the past, by the Company, and the Company has not shipped or caused the shipment of any dangerous or toxic wastes or substances nor disposed or caused the disposal of wastes on sites other than those specifically designed for their storage, treatment or destruction and other than in compliance with applicable Laws and regulations.

7.2.17 Social Security, Pensions and Benefit Plans

The Company is and has been in compliance with all applicable social security and pension laws applicable to the Employees in all material respects.

7.2.18 Books and Records; Bank Accounts

(a) The stock books, stock transfer records and other shareholder records for the Company (i) are complete and correct in all material respects, (ii) have been maintained in accordance with good business practices and the applicable Laws, and (iii) set out and disclose all main business and financial transactions of the Company. At the Closing Date, all stock books, stock transfer records and other shareholder records will be in the possession of the Company.

(b) Annex 7.2.18 contains a true, correct and complete list of the bank accounts held by Company as of the date of this Agreement, including the name of each bank or financial institution as well as the account details, and the names of all persons authorized to draw thereon or to have access to these accounts.

(c) The Data Room Documents contain copies of minutes and/or written resolutions, respectively, of the shareholders' meetings and the board of directors of the Company since January 1, 2020. All such minutes and/or written resolutions, respectively, of the shareholders' meetings and the board of directors of the Company have been duly executed and are in full force and effect and in compliance with the Laws. No claim has been made or threatened in writing by any Person in relation to such written resolutions of the board of directors of the Company.

7.2.19 Broker's Fees

Expect for the fee arrangement with SVB Securities LLC, the Company does not have any obligation to pay, secure or guarantee any broker's, finder's or transaction or similar fee or commission in connection with the execution or consummation of this Agreement.

7.3 Representations of the Buyer

The Buyer hereby represents to the Sellers within the meaning of article 197 CO that the following statements (the **Buyer Representations**) are true and correct in all respects both as of the date of this Agreement and as of the Closing Date:

(a) The Buyer is a corporation duly incorporated and organized and validly existing under the Laws of its place of incorporation, is in good standing and has the full corporate capacity, power and authority to own or use its assets and properties and to conduct its business as the same is presently being conducted.

(b) The Buyer has the full power and authority to enter into this Agreement and any transactions contemplated hereunder and to perform its respective obligations. This Agreement constitutes the legal, valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms, except to the extent that the enforceability may be limited by applicable bankruptcy, reorganization, insolvency, moratorium or other Laws affecting the enforcement of creditors' rights generally. There exist no limitations under applicable Law, the constituting or governing documents of the Buyer or any contracts by which the Buyer is bound that would prevent the Buyer from entering into or performing its obligations under this Agreement.

(c) The Buyer is not insolvent or bankrupt under the Laws of its jurisdiction of incorporation, is not unable to pay its debts as they fall due or has not proposed and is not liable to any arrangement (whether by court process or otherwise) under which its creditors (or any group of them) would receive less than the amounts due to them where any such insolvency, bankruptcy, inability to pay debts or arrangement would affect its ability to enter into or perform its obligations under this Agreement and/or any documents which are to be entered into by it pursuant to or otherwise in connection with this Agreement.

(d) There are no proceedings in relation to any compromise or arrangement with creditors or any winding up, bankruptcy or insolvency proceedings concerning the Buyer and no events have occurred which would justify such proceedings where any such proceedings or events would affect its ability to enter into or perform its obligations under this Agreement and/or any documents which are to be entered into by it pursuant to or otherwise in connection with this Agreement.

(e) There are no Actions pending or threatened against the Buyer or any of its Affiliates challenging the validity of this Agreement or any transaction contemplated in this Agreement, or which would operate to hinder or substantially impair the consummation of the transactions contemplated by this Agreement.

(f) The Buyer is, after its Due Diligence Review and in particular the review and analysis of the Disclosure Documents, not aware of any breach by any of the Sellers of any Fundamental Representations or any Business Representations.

(g) The Buyer has procured that on the Closing Date it will have the necessary funds at its disposal to finance the transactions contemplated by this Agreement.

7.4 Exclusive Representations

(a) The Buyer acknowledges that, other than as expressly provided in this Agreement, the Sellers have not made and do not make, and the Buyer has not relied and does not rely on, any representation or warranty, express or implied, pertaining to the subject matter of this Agreement. In particular, the Buyer acknowledges that:

(i) the Sellers are not making any representations as to budgets, business plans, forward-looking statements, statements of intent or opinion and other projections of a financial, technical or business nature relating to the business of the Company, and

(ii) nothing in any of the information documents made available to the Buyer prior to the date hereof shall be deemed to constitute a representation or warranty, except as expressly set forth in this Agreement.

(b) The Sellers acknowledge that, other than as expressly provided in this Agreement or any other Transaction Document, the Buyer has not made and do not make, and the Sellers have not relied and do not rely on, any representation or warranty, express or implied, pertaining to the subject matter of this Agreement.

8. Remedies

8.1 Partial Liquidation

(a) The Buyer shall (i) during a period of five (5) years following the Closing Date refrain from any actions, and procure that the Company refrains from any actions, that could lead to an indirect partial liquidation (*indirekte Teilliquidation*) as defined in article 20a of the Swiss Federal Act on Direct Federal Taxation (*Bundesgesetz ✔ber die direkte Bundessteuer*) and the corresponding cantonal Tax provisions and thus to a reclassification of the relevant Sellers' private capital gain to taxable income from investment and (ii), irrespective of any fault or knowledge and without being subject to any limitations under this Agreement or under the CO, indemnify and hold harmless the Sellers (except the Sellers 1, 8, 9, 10, 11, 13 and 14) from and against all Taxes, damages and any reasonable professional or other out-of-pocket fees, expenses or other costs incurred in or in connection with or in connection with the reclassification of the Sellers' income as described in this Section 8.1.

(b) In the event any of the Sellers receive from the Tax Authorities the notification and/or assessment concerning the reclassification of the relevant Sellers' private capital gain to taxable income from investment, such Seller shall give the Buyer notice as soon as reasonably practicable, but at the latest five (5) Business Days after receipt of the notification. The Buyer shall have the right to instruct the respective Seller, and the respective Seller in such case shall be obliged, to appeal

(*Einsprache*) against such notification and thereafter initiate legal proceedings. Any and all such legal proceedings shall be at the costs and expenses of the Buyer. However, the Buyer shall not indemnify the respective Seller for own (legal or tax) advisors. In case the respective Seller engages its own (legal or tax) advisors, the costs of such own (legal or tax) advisors shall be borne by the respective Seller and such own (legal or tax) advisors shall not have the right to file the appeal (*Einsprache*), which is to be prepared by the Buyer (it being agreed that the Buyer shall provide the draft appeal reasonably in advance prior to filing to such Seller or his or her own (legal or tax) advisors and shall take into account any reasonable comments). If a Seller breaches his or her obligations set out in this Section 8.1(b), such Seller's rights to be indemnified under this Section 8.1 shall be precluded and forfeited (*verwirkt*).

(c) The Buyer undertakes to impose its obligations under this Section 8.1 to any subsequent acquirer of any or all of the Shares, whereby the Buyer shall remain jointly and severally liable with any such acquirer for any and all claims of the Sellers arising out of or in connection with the indemnity set forth in this Section 8.1.

8.2 General Remedies

(a) The relevant Seller shall be liable to the Buyer, subject to the further provisions set forth in this Section 8.2, Section 9 and Section 11.8, for any Damage incurred or sustained by the Buyer as result of, or arising from or based upon, any breach of:

(i) from and after the Closing (A) any of the Fundamental Representations or (B) any of the Business Representations made by a Seller, irrespective of any fault on the part of the relevant Seller; or

(ii) any covenant, undertaking or agreement of any Seller contained in this Agreement;

provided that except in the case of fraud (*Betrug*), intentional deceit (*absichtliche Täuschung*, within the meaning of article 28 CO, article 192(3) CO and article 199 CO), a breach of the Fundamental Representations referred to in Sections 7.1.1 to 7.1.3, a breach of any covenant, undertaking or agreement of any Seller contained in this Agreement referred to in paragraph (ii) above (including a breach of an indemnification obligation pursuant to Section 10 and Annex 10), the Buyer's sole remedy and recourse against the Sellers for such breaches shall be the rights to (i), upon notification made in good faith of a claim for compensation pursuant to Section 9.1, withhold from, and (ii), once the relevant Damage has been finally determined in accordance with this Agreement, declare set-off against, any amounts due and payable by the Buyer to the relevant Seller under this Agreement after the Closing Date (including any Earnout Payments, but excluding for the avoidance of doubt the Preliminary Closing Consideration) an amount equal to such Seller's Liability Percentage with respect to the relevant Damage.

(b) The Buyer shall be liable to any of the Sellers, subject to the further provisions set forth in this Section 8.2 and Section 9 (to the extent applicable pursuant to the terms of this Agreement), for any Damage incurred or sustained by any of the Sellers as result of, or arising from or based upon, any breach of:

(i) from and after the Closing, any of the Buyer Representations, irrespective of any fault on the part of the Buyer; or

(ii) any covenant, undertaking or agreement of the Buyer contained in this Agreement (other than the specific indemnification obligations set forth in Section 8.1).

9. Remedies Procedure

9.1 Notification / Third Party Claims

(a) In the event of a claim for compensation under Section 8.2, the Compensated Party shall deliver to the Compensating Party a written notice describing in reasonable detail the nature of the matter, circumstance or Third Party Claim (as defined below), the underlying facts and the amount of the reasonably anticipated Damage subject to compensation under Section 8.2, and the basis for his, her or its claim for compensation under Section 8.2, in each case to the extent then known (such notice the **Notice of Breach**) within the earlier of:

(i) twenty (20) Business Days after the Compensated Party has obtained knowledge of a matter or circumstance that could give rise to a claim for compensation under Section 8.2; or

(ii) twenty (20) Business Days after receipt by the Compensated Party of a notice from a third party of any pending or threatened Action against the Compensated Party or a submission to, or a decision or order by, any Governmental Authority that has given or could give rise to a claim for compensation under Section 8.2 (a **Third Party Claim**).

(b) Failure to give Notice of Breach in accordance with Section 9.1(a) shall not affect the liability provided hereunder except to the extent that the relevant Damage has been caused or aggravated by virtue of the Compensated Party's failure duly and timely to give Notice of Breach in accordance with Section 9.1(a), in which case the Compensating Party shall have no liability for the Damage, or part of the Damage, so caused or aggravated by the Compensated Party.

(c) In case any Third Party Claim is brought or threatened by a third party (including any Governmental Authority) against the Buyer or, after the Closing, the Company, the Buyer shall use Commercially Reasonable Efforts to oppose or cause the Company to use reasonable best efforts to oppose such Third Party Claim.

(d) The Compensated Party shall give the Compensating Party reasonable opportunity and time to comment or discuss with the Compensated Party any measures which the Compensating Party proposed to take or omit to take in connection with the Third Party Claim. The Compensating Party may engage his, her or its own separate counsel, but the fees and expenses of such counsel shall be borne by the Compensating Party. The Compensating Party may elect not to exercise, or to waive, at any time the right to be consulted by the Compensated Party and/or (if the Buyer is the Compensated Party) the Company with respect to any particular Third Party Claim and the conduct of the proceedings thereof. Upon the Compensated Party's request to the Compensating Party, the Compensating Party shall use Commercially Reasonable Efforts to assist the Compensated Party and/or (if the Buyer is the Compensated Party) the Company in the defense of a Third Party Claim at the Compensated Party's and/or (if the Buyer is the Compensated Party) the Company's sole cost and expense. The Compensated Party shall not, and (if the Buyer is the Compensated Party) shall procure that the Company will not, settle any Third Party Claim without the prior written consent of the Compensating Party (in the case of the Sellers, the Sellers' Representative), which shall not be unreasonably withheld.

(e) Where relevant the provisions of this Section 9.1 shall be in lieu of, and not in addition to, the Compensated Party's duty to immediately inspect and notify the Compensating Party in accordance with article 201 CO.

9.2 Time Limitations

9.2.1 Statute of Limitations (*Verwirkung*) of Claims for Liability under Section 8.2

(a) Any claim for compensation under Section 8.2(a)(i) or Section 8.2(b)(i) must be notified on or before:

(i) with respect to a breach of the Fundamental Representations or any breach of the Buyer Representations, the date that is ten (10) years after the Closing Date;

(ii) with respect to a breach of Section 7.2.4 (Intellectual Property Rights), the date that is five (5) years after the Closing Date;

(iii) with respect to a breach of Section 7.2.2 (Taxes), the earlier of (A) the date that is six (6) months after the assessment for the relevant Taxes has been determined and become legally binding without the possibility to reopen the Tax assessment (*rechtskräftig festgesetzt ohne Möglichkeit der Wiedereröffnung im Rahmen eines Nachsteuerverfahrens*) and (B) the date that is 90 (ninety) calendar days after the expiration of the relevant statute of limitations (or extensions or waivers thereof) applicable to the relevant Taxes; and

(iv) with respect to a breach of any of the Business Representations, other than those referred to in Section 9.2.1(a)(ii) and (iii), the date that is eighteen (18) months after the Closing Date.

(b) Any claim for compensation subject to the remedy under Section 8.2(a)(ii) or Section 8.2(b)(ii) must be notified on or before the date that is ten (10) years after the Closing Date.

(c) After the relevant date specified in Section 9.2.1(a) or Section 9.2.1(b), any claim for compensation under Section 8.2 shall be considered precluded and forfeited (*verwirkt*), if it has not been notified on or before such date; it being understood that any such claim that has been notified by giving a Notice of Breach on or before such date shall not be considered precluded and forfeited (*nicht verwirkt*), if the Compensated Party initiates formal proceedings in accordance with Section 12.2 with respect to such claim by the date that is six (6) months after the date of the relevant Notice of Breach.

9.2.2 Term of Claims under Section 8.1

(a) In the sense of a condition subsequent (*resolutive Bedingung*), any claim for losses subject to indemnification under Section 8.1 must be notified on or before, and, if not notified in accordance with Section 8.1(b) on or before, shall be considered expired (*erloschen und verwirkt*) after the sixth (6th) anniversary of the Closing Date.

(b) Any claim notified on or before the relevant date specified in this Section 9.2.2 may be pursued after such date and shall lapse (*verjähren*) in accordance with the general statute of limitations applicable to such claim pursuant to article 127 et seq. CO.

9.2.3 Waiver of Statute of Limitations under Article 210 CO

Any limitation period specified in this Agreement to apply to a claim shall be in lieu of and replace the statute of limitations pursuant to article 210 CO, if and to the extent such statute of limitations pursuant to article 210 CO would otherwise apply to such claim, and the Parties explicitly agree that any statute of limitations pursuant to article 210 CO shall be deemed waived and not apply to this Agreement.

9.3 Liability Limitations

(a) All facts and circumstances which have been Fairly Disclosed in:

(i) this Agreement; or

(ii) the Data Room Documents (an index of which is attached hereto as Annex 9.3(a)(ii) (the **Data Room Index**), including any information provided by the Sellers or the Company and their Representatives (including in the form of e-mail) in response to questions or information requests by the Buyer or its advisors;

(all documents and information referred to in this Section 9.3(a), including all matters, facts or circumstances summarized or referred to therein, collectively the **Disclosure Documents**) shall operate as an exclusion of, or, depending on the relevant disclosure, as a limitation to, the Business Representations, and, accordingly, the Sellers shall be under no liability to the Buyer and the Buyer shall not be entitled to seek compensation from the Sellers pursuant to Section 8.2(a)(i) if such liability is based on any matters, facts or circumstances that have been Fairly Disclosed in the Disclosure Documents.

(b) The Compensating Party's obligation to compensate the Compensated Party for any claim subject to compensation under Section 8.2 shall be reduced if and to the extent that:

(i) the Compensated Party has failed to mitigate, or, in the case of the Buyer, failed to cause the Company to mitigate, the Damage in respect thereof, as required under Swiss Law;

(ii) the Compensated Party has recovered or by applying Commercially Reasonable Efforts could recover or could have recovered, or, in the case of the Buyer, failed to cause the Company to recover, from any third Person, including, but not limited to, an insurer, any sum in respect of any matter to which a claim made relates, after deduction of all duly documented costs and expenses incurred in making such recovery (including reasonable attorneys' fees);

(iii) an accrual, a provision, reserve or valuation allowance has been made or included in the Final Closing Accounts, if and to the extent such provision, reserve or valuation allowance was taken into account in the adjustments pursuant to Section 2.3;

(iv) such liability is attributable to any act, omission, transaction or arrangement (A) after the Closing, of the Compensated Party or any of his, her or its Affiliates (including the Company in the case of the Buyer) (or his, her or its respective directors, employees, agents or successors in title) or to which the Compensated Party has given his, her or its prior written consent, in each case outside the ordinary course of business of the Company as at the Closing, (B) before the Closing, by any Seller, any Affiliate of any Seller or the Company acting in accordance with the written direction or written request of the Buyer or any of its Affiliate, or (C) pursuant to and in compliance with this Agreement or any other Transaction Document;

(v) the Compensated Party or any of his, her or its Affiliates or any of his, her or its Representatives is actually aware at the date of this Agreement of the Damage or Tax which is the subject matter of the claim for liability pursuant to Section 8.2;

(vi) such compensation obligation arises or is increased as a result of changes in assessment methods and accounting or Tax practices, which have been introduced by the Buyer or the Company after the Closing Date;

(vii) the Compensated Party or, following the Closing, in the case of the Buyer, the Company, any successor to the Compensated Party or, in the case of the Buyer, all or part of the Company's business or any Affiliate or direct or indirect shareholder of the Compensated Party receives, or through Commercially Reasonable Efforts, could receive or could have

received, any benefits by repayments, set-off or reduction of Taxes which it would not have received or could not receive but for the circumstances giving rise to a claim, including any tax benefit resulting from a reduction of the Tax base or the increase of the Tax loss (*e.g.,* because of the lengthening or depreciation periods or higher depreciation allowances) after the Closing whereby the tax benefit from such reversal effect shall be calculated by applying the then applicable corporate income Tax rate on the aggregate amount by which the Tax base is reduced or the Tax loss is increased because of the reversal effect; or

(viii) such claim arises or is increased solely as a result of administrative practice (including, but not limited to, practice of any Governmental Authority) or rule of Law not in force at the Closing Date or the withdrawal after the Closing Date of any concession previously made by any relevant Governmental Authority or as a result of any change made or introduced on or after the Closing Date in any administrative practice (including, but not limited to, practice of any Governmental Authority) or rule of Law, whether or not such change or withdrawal purports to be effective retrospectively in whole or part, or any change in the rates of Taxes in force at the Closing Date or any imposition of any Taxes or any withdrawal of Relief, in each case not in effect at the Closing.

(c) If a Compensating Party has paid (whether in cash or by set-off, as applicable) an amount in discharge of liability under Section 8.2, and the Compensated Party, any of his, her or its Affiliates or, in the case of the Buyer, the Company receives (whether by insurance, payment, discount, credit, Relief or otherwise) from any Person a sum that indemnifies or compensates the Compensated Party, any of his, her or its Affiliates or, in the case of the Buyer, the Company (in whole or in part) for the losses which are the subject matter of such Compensating Party's liability under Section 8.2, then the Compensated Party shall:

(i) promptly notify the relevant Compensating Party of the fact and provide such information as the relevant Compensating Party may reasonably request;

(ii) take all commercially reasonable steps or proceedings as the relevant Compensating Party may request to enforce such right, at the expense of the relevant Compensating Party; and

(iii) pay to the relevant Compensating Party as soon as practicable after receipt an amount equal to the amount recovered from the third party or, if less, the amount previously paid by the Compensating Party to the Compensated Party in respect of the relevant claim, in each case net of Tax payable thereon and less any reasonable and documented third party costs of recovery.

(d) The Compensating Party shall not have any liability to the Compensated Party under Section 8.2, unless (i) the amount of the claim or series of related claims made by the Compensated Party for indemnification thereunder exceeds CHF 200,000 (Swiss Francs two hundred thousand) (such claim or series of related claims, a **Qualifying Claim**), and (ii) the amount of the Compensating Party's obligation to indemnify the Compensated Party in respect of the relevant Qualifying Claim exceeds, or when aggregated with the amount of the total indemnification obligation of the Compensating Party in respect of all other Qualifying Claims will exceed, CHF 2,000,000 (Swiss Francs two million) (the **Threshold Amount**). If the Threshold Amount has been exceeded, the Compensating Party shall be liable to the Compensated Party for any Qualifying Claim of the Compensated Party, and not just the Damage in excess of the Threshold Amount. This Section 9.3(d) shall not apply to (i) any liability of the Sellers on the basis of a breach of any of the Fundamental Representations or any breach pursuant to Section 8.2(a)(ii), or (ii) any liability of the Buyer on the basis of a breach of any of the Buyer Representations.

(e) The maximum aggregate liability of any of the Sellers under or in connection with:

(i) any breach of the Business Representations shall be limited to and not exceed an amount equal to such Seller's Liability Percentage of the Cap;

(ii) any breach of the Fundamental Representations or any breach pursuant to Section 8.2(a)(ii) shall be limited to, and not exceed, an amount equal to the amount of proceeds actually received by such Seller (including any amount set-off pursuant to Section 8.2(a)).

(f) Notwithstanding anything in this Agreement to the contrary, no limitations on liability hereunder, including without limitation under this Section 9.3 (except for Section 9.3(b)) shall apply:

(i) in case of fraud (*Betrug*) or intentional deceit (*absichtliche Täuschung*, within the meaning of article 28 CO, article 192(3) CO and article 199 CO) by the Compensating Party;

(ii) to the compensation obligations of the Buyer under Section 8.1 and Section 8.2(b)(ii)**.**

(g) The limitations on the Compensating Party's liability pursuant to this Section 9.3 shall apply cumulatively.

(h) The remedies under Section 8.2(a)(i) shall be in lieu of, and not in addition to, the remedies provided for under statutory Law or case Law. All remedies provided for under statutory Law or case Law, including the right to rescind this Agreement following the Closing, shall not apply to, and are hereby expressly excluded and waived by each Party with respect to, any such breach, to the extent permissible. In particular, and without limiting the generality of the foregoing, each Party explicitly waives his, her or its right of partial or entire contract rescission under article 24 and article 205 CO.

10. Indemnities by the Sellers

The Indemnities by the Sellers shall be governed by Annex 10.

11. General Provisions

11.1 Effect on Third Parties

No Person other than the Parties shall have any rights or benefits under this Agreement, and nothing in this Agreement is intended to confer on any Person other than the Parties any rights, benefits or remedies, except that each Released Person shall have a direct claim against the Buyer under this Agreement for any right or benefit granted to it by Section 5.3.

11.2 Notices

(a) All notices or other communications to be given or made under or in connection with this Agreement shall be given or made in writing and delivered by hand or sent (postage prepaid) by registered, certified or express post (return receipt requested), courier or by electronic transmission in .pdf format or similar format to the following addresses:

if to the Sellers:	[***]

	[***]
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with a copy (which shall not constitute notice) to:	[***]
if to [***]:	[***]
with a copy (which shall not constitute notice) to:	[***]
if to the Buyer:	[***]
with a copy (which shall not constitute notice) to:	[***]
	[***]

(b) Notices delivered by hand shall be deemed delivered when actually delivered. Notices given by post or courier shall be deemed delivered when received. Notices given by electronic transmission shall be deemed to be delivered at the time such notices are sent to the relevant addresses above, if no delivery failure or error messages are received by the sender.

(c) Irrespective of the delivery or receipt of a notice, any notice given hereunder shall be deemed to have been timely given, if dispatched or sent prior to the expiry of a term or deadline set forth in this Agreement (if any), but the recipient shall be under no obligation to perform any act under this Agreement before it, he or she has received such notice.

11.3 Entire Agreement

This Agreement, including the Annexes and any other documents referred to herein, constitutes the entire agreement and understanding among the Parties with respect to the subject matter hereof, and supersedes all prior oral or written agreements and understandings of the Parties relating to such subject matter, including the Term Sheet.

11.4 Amendments and Waivers

(a) This Agreement may only be modified or amended by a written document signed by the Parties.

(b) Any waiver of any term or condition of this Agreement, waiver of any breach of any term or condition of this Agreement, or waiver of, or election whether or not to enforce, any right or remedy arising under this Agreement or at Law, must be in writing and signed by or on behalf of the Person granting the waiver, and no waiver or election shall be inferred from a Party's conduct.

(c) Any waiver of a breach of any term or condition of this Agreement shall not be, or be deemed to be, a waiver of any subsequent breach.

11.5 No Assignment

The Parties shall not assign, hold on trust, transfer, charge or otherwise deal with this Agreement or any rights or obligations hereunder, including, but not limited to, by way of a business transfer (*Vermögens✔bertragung*) or demerger (*Abspaltung*), to any third party nor grant, declare, create or dispose of any right or interest in it, without the prior written consent of the Sellers (if the assignment is proposed to be undertaken by the Buyer) or the Buyer (if the assignment is proposed to be undertaken by any of the Sellers); provided, however, that the Buyer and, following the Closing, any of the Sellers may assign this Agreement or any of its respective rights and obligations hereunder to any of its Affiliates as long as the assignor remains jointly and severally liable with the assignee for any obligations under this Agreement, and provided further that the Buyer may assign this Agreement or any of its respective rights and obligations hereunder in connection with (a) a transfer, sale, license, conveyance or disposition of the Sigi Patch Pump to any third party, (b) a spinoff, sale or other transfer of all or substantially all of the assets of any product line, business unit or operating segment to which the Sigi Patch Pump belongs or (c) the acquisition (whether by merger, consolidation, sale or otherwise) of the Buyer, as long as, in each case (1) the Buyer provides written notice to the Sellers of such assignment, (2) such assignee agrees to be or is, by operation of law or otherwise, bound by the terms and conditions of this Agreement, and (3) such assignee and its Affiliates are of comparable financial standing as the Buyer.

11.6 No Set-Off

Except for any claim of the Buyer against the relevant Seller pursuant to this Agreement, the Buyer shall not be entitled to set off any of its claims it may have against any of the Sellers against, or otherwise withhold the proper payment of, any amount payable by the Buyer to any Seller under or pursuant to this Agreement.

11.7 Severability

Should any part or provision of this Agreement be held to be invalid or unenforceable by any competent arbitral tribunal, court, governmental or administrative authority having jurisdiction, the other provisions of this Agreement shall nonetheless remain valid. In this case, the Parties shall endeavor to negotiate a substitute provision that best reflects the economic intentions of the Parties without being unenforceable, and shall execute all agreements and documents required in this connection.

11.8 Relationship between the Sellers and the Buyer

No Seller shall be jointly and severally liable with any of the other Sellers for any of the obligations undertaken by any of the Sellers pursuant to this Agreement, including, without limitation, in connection with the adjustment pursuant to Section 2.3 or based on the indemnification obligations pursuant to Section 8. Each Seller's liability under this Agreement, including based on the indemnification obligations pursuant to Section 8, or otherwise shall be several (*teilschuldnerisch*), determined by reference to the Liability Percentage.

11.9 Counterparts; Delivery by Electronic Transmission

This Agreement may be executed and delivered by each Party in separate counterparts, each of which when so executed and delivered shall be deemed an original and all of which taken together shall constitute one and the same Agreement. This Agreement and any other Transaction Document, and any amendments hereto or thereto, to the extent signed and delivered by means of electronic signature or e-signature (irrespective of whether the relevant electronic signature or e-signature has been issued by a provider recognized or accredited under applicable Law or not) or other electronic transmission (*e.g.*, e-mail delivery in .pdf format or similar format), shall be treated in all manner and respects as an original contract and shall be considered to have the same binding legal effects as if it were the original signed version thereof delivered in person.

12. Governing Law and Dispute Resolution

12.1 Governing Law

This Agreement and any claim, controversy or dispute arising out of or related to this Agreement, any of the transactions contemplated hereby, the relationship of the Parties hereunder, or the interpretation and enforcement of the rights and duties of the Parties, whether arising in contract, tort or otherwise, shall be governed by and construed in accordance with the substantive Laws of Switzerland, excluding the UN Convention on Contracts for the International Sale of Goods, without giving effect to any choice of law or conflict of law provision or rule that would cause the application of the Laws of any jurisdiction other than Switzerland.

12.2 Dispute Resolution

Any dispute, controversy or claim arising out of, or in relation to, this Agreement, including the validity, invalidity, breach, or termination thereof, shall be resolved by arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Arbitration Centre in force on the date on which the notice of arbitration is submitted in accordance with those rules. The number of arbitrators shall be three. The seat of the arbitration shall be Zurich. The arbitration proceedings shall be conducted in English.

[Signatures on next page]

Executed as of the date written on the cover page to this Agreement.

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Annex B - Individual Holdings of Sellers

[***]

Annex 1 - Definitions

[***]

Annex 2.5 - Earn-out

[***]

Schedule 2.5(a) - Development List

[***]

Annex 2.5.2(a) - Form of Quarterly Reports

[***]

Annex 3.4 - Form of Closing Memorandum

[***]

Annex 4.2.2(d) - Form of Employment Agreement with Key Persons

[***]

Annex 7.1.4 - Fundamental Intellectual Property Rights

[***]

Annex 7.2.4 - Owned Intellectual Property Rights

[***]

Annex 7.2.18 - Bank Accounts

[***]

Annex 9.3(a)(ii) - Index of Data Room Documents

[***]

Annex 10 - Indemnities by the Sellers

[***]

SUBSIDIARIES OF THE REGISTRANT

Name of Entity	State/Country of Organization
AMF Medical SA	Switzerland
Capillary Biomedical, LLC	United States
Sugarmate, LLC	United States
Tandem Diabetes Care Canada, Inc.	Canada
Tandem Diabetes Care Europe B.V.	Netherlands

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-3 No. 333-222143) of Tandem Diabetes Care, Inc.,

(2) Registration Statement (Form S-8 No. 333-232944) pertaining to the 2013 Stock Incentive Plan of Tandem Diabetes Care Inc.,

(3) Registration Statement (Form S-8 No. 333-226915) pertaining to the 2013 Stock Incentive Plan, and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care Inc.,

(4) Registration Statement (Form S-8 No. 333-192406) pertaining to the 2006 Stock Incentive Plan, 2013 Stock Incentive Plan, and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care Inc.,

(5) Registration Statement (Form S-8 No. 333-202254) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc.,

(6) Registration Statement (Form S-8 No. 333-209685) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc.,

(7) Registration Statement (Form S-8 No. 333-223377) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc., and

(8) Registration Statement (Form S-8 No. 333-216529) pertaining to the 2013 Stock Incentive Plan and 2013 Employee Stock Purchase Plan of Tandem Diabetes Care, Inc;

of our reports dated February 22, 2023, with respect to the consolidated financial statements of Tandem Diabetes Care, Inc. and the effectiveness of internal control over financial reporting of Tandem Diabetes Care, Inc., included in this Annual Report (Form 10-K) of Tandem Diabetes Care, Inc. for the year ended December 31, 2022.

/s/Ernst & Young LLP

San Diego, California
February 22, 2023

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John F. Sheridan, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tandem Diabetes Care, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Tandem Diabetes Care, Inc.

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

Dated: February 22, 2023

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Leigh A. Vosseller, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tandem Diabetes Care, Inc.

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Tandem Diabetes Care, Inc.
By: /s/ Leigh A. Vosseller
Leigh A. Vosseller
Executive Vice President, Chief Financial Officer and Treasurer

Dated: February 22, 2023

Exhibit 32.1

CERTIFICATION
Pursuant to U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Tandem Diabetes Care, Inc. (the "Company") for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John F. Sheridan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: February 22, 2023

/s/ John F. Sheridan
John F. Sheridan
President, Chief Executive Officer and Director

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
Pursuant to U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Annual Report on Form 10-K of Tandem Diabetes Care, Inc. (the "Company") for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leigh A. Vosseller, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: February 22, 2023

/s/ Leigh A. Vosseller
Leigh A. Vosseller
Executive Vice President, Chief Financial Officer and Treasurer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.