TANDEM
Diabetes Care

2023

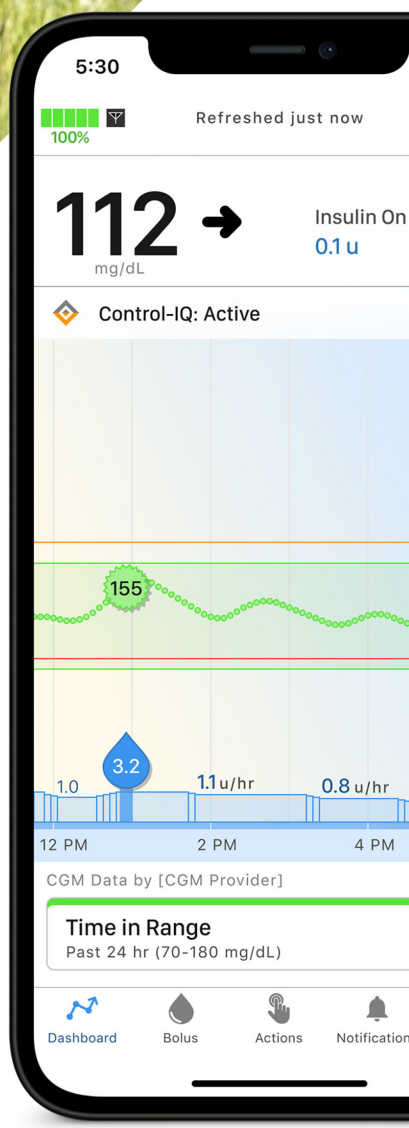
Annual Report

Do what moves you

Tandem Mobi

moves every body

Move in ways you never thought possible with Tandem Mobi, the **discreet and powerful automated insulin delivery system** designed to fit your life.



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, 2023
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.)**
12400 High Bluff Drive	**92130**
San Diego California	**(Zip Code)**
(Address of principal executive offices)	

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

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to § 240.10D-1(b). ☐
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, 2023, the aggregate market value of the registrant's common stock held by non-affiliates was approximately $1.6 billion based on the closing price for the common stock of $24.54 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 16, 2024, there were 65,631,041 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 2024 Annual Meeting of Stockholders to be filed with the Securities and Exchange Commission 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, 2023, 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 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. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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.

Risk Factor Summary

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, under the heading "Risk Factors" in Part I, Item 1A of this Annual Report, and should be carefully considered, together with other information in this Annual Report, before making investment decisions regarding our securities.

Risks Related to Our Business and Industry

- We have incurred significant operating losses since inception and cannot assure you that we will achieve sustained profitability.
- We currently rely on sales of insulin pump products to generate a significant portion of our revenue, and any factors that negatively impact sales of these products may adversely affect our business, financial condition and operating results.
- Our ability to maintain and grow our revenue depends in part on retaining a high percentage of our customer base.
- Competing products, therapeutic techniques or other technological developments and breakthroughs for the monitoring, treatment or prevention of diabetes may render our products obsolete or less desirable.
- Failure of our insulin pumps 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.
- 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.
- Any concerns regarding the safety or efficacy of our products could limit sales and cause unforeseen negative effects to our business prospects and financial results.
- 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 are 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 clinical trials and studies could prevent us from obtaining regulatory clearances, certifications, or approvals for or commercializing our products.
- 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 inability to adequately forecast customer demand, could harm our business.
- 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.

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

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.
- Public health threats, epidemics, or pandemics could have a material adverse effect on our operations, the operations of our business partners, and the global economy as a whole.
- 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 if we are unable to raise additional funds when necessary or desirable, we may not be able to achieve our strategic objectives.
- Our operating results may fluctuate significantly from quarter to quarter.

Risks Related to Privacy and Security

- If our information technology systems or those third parties upon which we rely, our data, or our software are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; harm to our reputation; loss of revenue or profits; loss of customers or sales; and other adverse consequences.
- 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.

Risks Related to Legal and Intellectual Property

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

- 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.
- 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.

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.
- New products or modifications to our existing products may require new 510(k) clearances, PMAs or certifications, or may require us to cease marketing or recall the modified products until clearances, certifications or approvals are obtained.
- 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.

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.
- 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.

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.
- 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.
- We may take actions which could limit our ability to make payments on the Notes.

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, the Netherlands, and Switzerland.

Overview

Tandem Diabetes Care, a global insulin delivery and diabetes technology company, manufactures and sells advanced automated insulin delivery systems that reduce the burden of diabetes management, while creating new possibilities for patients, their loved ones, and healthcare providers. Our pump portfolio features the Tandem Mobi system and the t:slim X2 insulin pump, both of which feature Control-IQ advanced hybrid closed-loop technology. We are based in San Diego, California.

We consider our primary addressable market to be people who live with type 1 diabetes. Through our product development efforts, we are seeking to expand our addressable market to include people living with type 2 diabetes who require intensive insulin therapy. Diabetes management can vary greatly from person to person, creating multiple market segments based on clinical needs and personal preferences. Our goal is to address the individual needs of people with insulin-dependent diabetes and their care team flexibility and choice in intelligent insulin delivery systems through an accessible portfolio of market-leading pumps, applications, and insights.

The t:slim X2 Insulin Delivery System has been our flagship technology solution. In February 2024, we expanded our pump portfolio with the U.S. launch of Tandem Mobi. Both pumps feature our Control-IQ advanced hybrid closed loop technology, with an automated insulin delivery (AID) feature designed to help increase a user's time in targeted glycemic range. Our t:slim X2 and Tandem Mobi pumps can be used with a variety of infusion sets to offer patients choice in how and where their pump is worn. In addition, they are software updatable from a personal computer and compatible with our web-based data management application.

In the four-year period ended December 31, 2023, we shipped approximately 450,000 insulin pumps, which is representative of our in-warranty global installed customer base assuming the typical four-year reimbursement cycle. Approximately 310,000 pumps were shipped to customers in the United States and 140,000 were shipped to customers outside the United States.

Diabetes and the Insulin Therapy Management Market

Diabetes is a chronic, life-threatening disease for which there is no known cure. It 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 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. The Center for Disease Control and Prevention estimates Type 2 accounts for 90-95% of diagnosed diabetes in adults in the United States.

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. In the geographies we serve, we estimate about 5 million people live with type 1 diabetes of whom, 1.9 million reside in the United States. We estimate approximately 2 million people in the United States live with type 2 diabetes and require intensive insulin therapy.

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 single-use cartridge filled with insulin by the user, and a single-use 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 1.3 million people worldwide are estimated to use an insulin pump to manage their diabetes. We estimate that approximately 800,000 people in the United States use an insulin pump, of whom approximately 90% live with type 1 diabetes. In addition, we estimate that approximately 500,000 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 continuous glucose monitoring (CGM), which is a technology 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. The American Diabetes Association Standards of Care state that diabetes devices should be offered to people with diabetes. It also states that AID systems are preferred over non-automated pumps and MDI, and should be offered for diabetes management to youth and adults with type 1 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 try 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.

Our insulin pumps are generally considered durable medical equipment and have an expected lifespan of at least four years. In addition to insulin pumps, we sell single-use 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.

We launched our flagship t:slim platform in August 2012, and its next generation, the t:slim X2, in October 2016. In February 2024, we expanded our offerings with the commercial availability of Tandem Mobi in the United States. Both pumps are fully detachable, offer Bluetooth connectivity and can be used as part of an automated insulin delivery system.

Key Features	Tandem Mobi	t:slim X2
Size	1.5” x 2.0”	2.0” x 3.1”
Control-IQ Technology	X	X
Remote Software Updates	X	X
On-body Wear	X	
Smartphone Control	X	Mobile Bolus
Insulin Capacity	200 units	300 units
Integrated Color Touchscreen		X
Pump Button for Bolus Delivery	X	X

Our t:slim X2 and Tandem Mobi pumps feature our 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 three independent pivotal studies using Control-IQ technology were published in the New England Journal of Medicine in October 2019, August 2020 and March 2023.

As part of our AID systems, we offer pump integration with multiple CGM sensors, which helps provide customizable solutions for people living with diabetes. The Dexcom G7 sensor is the fourth generation of Dexcom’s CGM that we have integrated with our pump technology since 2015. We began offering our t:slim X2 pump integrated with the Dexcom G7 sensor in the United States in December 2023 and outside the United States in January 2024. In addition, in January 2024 we announced that our t:slim X2 insulin pump with Control-IQ technology is the first AID system to integrate with the Abbott FreeStyle Libre 2 Plus sensor. Our extensive experience in CGM integration, and efforts to continue expanding the available CGM sensors integrated with our pump portfolio, represents our commitment to provide customizable solutions to help reduce burden and create new possibilities for people living with diabetes.

Tandem Device Updater

This tool allows our 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 our pumps in a manner similar to software updates on a smartphone. We have used this technology to offer our in-warranty t:slim X2 customers worldwide software updates at no cost.

Tandem Source

Our web-based data management platform 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 data that we can analyze to reveal patterns, trends, outcomes and associations that can be used to improve our products and in the analysis of clinical outcomes data. Tandem Source is designed to bring together the features of Tandem's legacy t:connect, t:connect HCP, and t:connect Portal offerings with new comprehensive data reporting in one central, scalable platform. It offers automatic data transfers from pumps using the t:connect mobile app to keep online data current and remove the need for manual pump uploads.

Sugarmate

Sugarmate is a 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 & Future Technologies

Diabetes management can vary greatly from person-to-person, creating multiple market segments based on clinical needs and personal preferences. Our goal is to address the individual needs of people with insulin-dependent diabetes and their care team flexibility and choice in intelligent insulin delivery systems, through an accessible portfolio of market-leading pumps, applications, and insights.

In support of this strategy, our portfolio of future technologies includes:

t:slim X3

Advancing our flagship t:slim platform, the t:slim X3 is planned to include enhanced technology, such as greater processing power and capacity to support our advanced algorithms, as well as increased battery life and improved durability.

Mobi: Tubeless

This offering is intended to provide an alternative tubeless infusion site option for Tandem Mobi pump users. It will allow a Tandem 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

The ergonomic, rechargeable Sigi Patch Pump is intended to reduce the burden of managing diabetes through its use of pre-filled insulin cartridges and compatibility with AID technology.

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, unique extended wear infusion set technology is expected to be part of our future portfolio.

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. In 2023, we began a pivotal study to support expanding indications to include people living with type 2 diabetes. In late 2023, our Control-IQ technology was cleared with additional features for people with type 1 diabetes age 2 and older. We are also researching the use of different insulins with our Control-IQ technology.

Markets and Distribution Methods

Our technology solutions are now available in the following 25 countries:

Australia	Denmark	Israel	Norway	Spain
Bahamas	Finland	Italy	Portugal	Sweden
Belgium	France	Luxembourg	Saudi Arabia	Switzerland
Canada	Germany	Netherlands	Slovakia	United Kingdom
Czech Republic	Ireland	New Zealand	South Africa	United States

In the United States and Canada, we employ direct sales, customer support, and clinical teams. We also partner with independent distributors for order fulfillment. Outside the United States and Canada, we contract with distributors who have substantial responsibility for sales, customer support, clinical efforts and order fulfillment.

Revenue Concentrations and Significant Customers. A small number of independent distributors in the United States and Canada are responsible for order fulfillment. We believe these distributors carry minimal inventory at any given time. Outside the United States and Canada, there may be variability in inventory levels among our distributors, particularly when they first begin product sales or surrounding the launch of new products. For the year ended December 31, 2023, two independent distributors each accounted for more than 10% of our worldwide sales.

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, single-use 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. A third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future. 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 t:slim X2 pumps, and Tandem Mobi pumps and cartridges, are currently assembled, tested, and packaged at our facilities in San Diego, California. Our t:slim X2 cartridges are manufactured by an experienced third-party contract manufacturer and packaged 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 the 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. Certain of 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 certain of our devices at various steps during the manufacturing cycle to facilitate compliance with our devices' stringent specifications.

We purchase our raw materials and select components used in the manufacturing of our products from external suppliers. We purchase some supplies from a single or limited number of sources for reasons of proprietary know-how, quality assurance, cost-effectiveness, or constraints resulting from regulatory requirements. We work closely with our suppliers to help ensure continuity of supply while maintaining high quality and reliability. However, due to required medical device manufacturing qualification requirements, we may not be able to quickly establish additional or replacement sources. In the case of sole sourced parts, we manage risk through holding inventory in-house and at the supplier to ensure continuity of supply and lower risk of disruption. We purchase many of our components and sub-assemblies from manufacturers with whom we are at least dual sourced. We work closely with all suppliers to ensure continuity of supply while maintaining high quality and reliability.

We have received certification from BSI Group, a Notified Body to the International Standards Organization (ISO), of our quality system. A Notified Body is an entity that has been designated and accredited by the national competent authority of an EU Member State in accordance with applicable EU legislation to perform third-party conformity assessment activities including calibration, testing, certification and inspection of a medical device. Certain processes used 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, certain corresponding state agencies, and Notified Bodies and foreign regulatory authorities.

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, 2023, 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 in the patent family, and in some cases may be extended. Our issued patents as of December 31, 2023 are set to expire over a range of years, from 2024 to 2042, 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.

Our patents and patent applications seek to protect aspects of key features of our pumps, cartridges, algorithms and pump systems. We believe that our patent position provides us with sufficient rights to protect our current and proposed commercial products. However, our patent applications may not result in issued patents, and any patents that have been issued or might be issued may not protect our intellectual property rights. Furthermore, we operate in an industry characterized by extensive patent litigation, and our patents may not be upheld if challenged. Any patents issued to us may be challenged by third parties as being invalid or unenforceable, and patent litigation may result in significant damage awards and injunctions that could prevent the manufacture and sale of affected products or result in significant royalty payments to continue selling the products. Third parties may also independently develop similar or competing technology that avoids our patents. The steps we have taken may not prevent the misappropriation of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States. We also face risks associated with intellectual property infringement.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information and other intellectual property by generally requiring our employees, consultants, contractors, suppliers, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements at the start of their employment or engagement. Agreements with our employees also forbid them from bringing the proprietary rights of third parties to us. We also generally require confidentiality or material transfer agreements from third parties that receive our confidential data or materials. We cannot guarantee that employees and third parties will abide by the confidentiality or assignment terms of these agreements. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary.

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 companies that manufacture insulin delivery devices, primarily Insulet, Medtronic and Ypsomed. There are also a number of other companies developing and marketing their own insulin delivery systems and/or related software applications for launch both in the U.S. market and outside the U.S., including insulin pumps and Bluetooth-enabled insulin pens to support MDI therapy. 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

Regulation of Medical Devices in the United States

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, the tslim:X2 and Tandem Mobi.

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 type 1 diabetes age 6 and older by connecting to an ACE pump and iCGM. In November 2023, our Control-IQ technology was cleared with additional features for people with type 1 diabetes age 2 and older. 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. 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 application, which 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.

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 or their immediate family member 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.

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. Our use of t:connect and Tandem Source 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 HIPAA, as amended by Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), imposes certain requirements on covered entities, which include certain healthcare providers, health plans and healthcare clearinghouses, and their business associates and covered subcontractors that receive or obtain protected health information in connection with providing a service on behalf of a covered entity relating to the privacy, security and transmission of individually identifiable health information. Although t:connect, t:connect HCP and Tandem Source 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. and United Kingdom (U.K.) General Data Protection Regulation, collectively known as GDPR, and similar E.U. member state laws. Collectively, these laws and regulations set standards that may be applicable to us regarding safeguarding the privacy and security of the personal information we collect and use from customers, healthcare providers and other individuals. These laws also require, among other things, publication of privacy notices detailing certain data collection and sharing practices and extension of certain rights to individuals, such as the right to know what data is collected about them, to obtain a copy of that data, to correct or amend that data, and to request restricted 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 to CMS pertaining to payments or other transfers of value to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other health care professionals (such as physicians assistants and nurse practitioners), and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. 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.

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.

Regulation *of Medical Devices in the European Economic Area*

On 26 May 2021, Regulation (EU) 2017/745 on Medical Devices, or the Medical Device Regulation, entered into application, repealing and replacing both Directive 93/42/EEC concerning medical devices, or MDD, and Directive 90/385/EEC concerning active implantable medical devices, or AIMD. The Medical Device Regulation and its associated guidance documents and harmonized standards govern, among other things, device design and development, preclinical and clinical or performance testing, premarket conformity assessment, registration and listing, manufacturing, labeling, storage, claims, sales and distribution, export and import and post-market surveillance, vigilance, and market surveillance. Medical devices must comply with the General Safety and Performance Requirements, or GSPRs, set out in Annex I of the Medical Device Regulation. Compliance with these requirements is a prerequisite to be able to affix the CE mark to devices, without which they cannot be marketed or sold in the European Economic Area (comprised of the 27 EU Member States, Iceland, Liechtenstein and Norway). To demonstrate compliance with the GSPRs provided in the Medical Device Regulation and obtain the right to affix the CE mark, medical devices manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Apart from low risk medical devices (Class I with no measuring function and which are not sterile), in relation to which the manufacturer may issue an EU Declaration of Conformity based on a self-assessment of the conformity of its products with the GSPRs, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization designated by a Competent Authority of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the Notified Body audits and examines the technical documentation and the quality system for the manufacture, design and final inspection of the medical devices. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the GSPRs. This Certificate and the related conformity assessment process entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EU Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the GSPRs must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and

safety of the device (e.g., product labeling and instructions for use) are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (1) clinical studies conducted on the devices being assessed, (2) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated or (3) both clinical studies and scientific literature. The conduct of clinical studies in the EEA is governed by detailed regulatory obligations. These may include the requirement of prior authorization by the Competent Authorities of the country in which the study takes place and the requirement to obtain a positive opinion from a competent Ethics Committee. This process can be expensive and time-consuming. After a device is placed on the market, it remains subject to significant regulatory requirements.

The Medical Device Regulation provides transitional provisions, amended by Regulation (EU) 2023/603. Accordingly, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD or the AIMD from 25 May 2017, and which remained valid on 26 May 2021 and have not since been withdrawn will, with certain exceptions, remain valid until 31 December 2027 for Class III and Class IIb implantable medical devices and until 31 December 2028 for other Class IIb, Class IIa and Class I devices with a measuring function or which are sterile. Class I medical devices, for which the conformity assessment procedure in accordance with the MDD or the AIMD did not require the involvement of a Notified Body but will require the involvement of a Notified Body in accordance with the Medical Device Regulation and for which an EU Declaration of Conformity was issued in accordance with the MDD or the AIMD before 26 May 2021, can continue to be placed on the EEA market until 31 December 2028. Manufacturers of medical devices may only benefit from the above extended transitional provisions deadlines if the following conditions are fulfilled: (i) the devices continue to comply with the requirements of the MDD or AIMD, (ii) there are no significant changes in the design and intended purpose, (iii) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, (iv) the manufacturer implements a quality management system by 26 May 2024 which complies with the requirements of the Medical Devices Regulation, (v) by 26 May 2024 an application is lodged with a Notified Body for conduct of the conformity assessment of the devices covered by the CE Certificate of Conformity, or the devices intended to substitute for such devices, in accordance with the Medical Device Regulation and a related written agreement is signed with the Notified Body by 26 September 2024, and (vi) from 26 May 2021, compliance with the Medical Device Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices is ensured in place of the corresponding requirements in the MDD or AIMD.

In addition, CE Certificates of Conformity issued by Notified Bodies in accordance with the MDD or the AIMD from 25 May 2017, which were valid on 26 May 2021 and have not been withdraw since but which expired before 20 March 2023, will only continue to be valid in accordance with the extended transitional deadlines above if either (i) the manufacturer signed a written agreement with a Notified Body for the conformity assessment of the device covered by the expired CE Certificate of Conformity, or the device intended to substitute that device, in accordance with the Medical Device Regulation before the date of expiry of the CE Certificate of Conformity, or (ii) a competent authority of an EEA country has granted a derogation from the application conformity assessment procedure in accordance with Article 59(1) or Article 97(1) of the Medical Device Regulation.

Class III custom-made implantable medical devices may be placed on the market until 26 May 2026 without a CE Certificate of Conformity issued by Notified Body, provided that (i) by 26 May 2024, an application is lodged with a Notified Body for the conformity assessment of the devices, in accordance with the Medical Device Regulation and a related written agreement is signed with the Notified Body by 26 September 2024.

The advertising and promotion of medical devices in the EU is subject to the national laws of the individual EEA country that implemented the MDD, the AIMD and that apply the Medical Device Regulation, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EEA countries governing the advertising and promotion of medical devices EEA countries' national legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Outside of the European Union, regulatory approval would need to be sought on a country-by-country basis 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. We may also leverage the CE Mark in certain other countries to fulfill the national applicable regulatory requirements for placing our product on national markets. In addition, we have Health Canada approval to sell the t:slim X2 in Canada.

Outside the United States, interactions between medical device companies, government officials and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. These laws include the U.K. Bribery Act and similar anti-bribery 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.

Environment, Social and Governance

Our Board of Directors and management team believe that environmental stewardship, social responsibility, and solid corporate governance are important to our business strategy and long-term value creation for our shareholders, employees, customers, and communities. The Nominating and Corporate Governance Committee of our Board oversees ESG matters across our business operations in accordance with its charter. Our management team is responsible for developing and driving strategic ESG initiatives and programs across our business and providing regular updates on progress to the Nominating and Corporate Governance Committee.

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, 2023, we had approximately 2,400 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, California, 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 2021, we began conducting employee engagement surveys through Gallup, a leading global consulting firm on employee engagement. More than 90% of our employees have participated each year, and the results demonstrated that our overall engagement levels exceed Gallup's averages worldwide and in the United States. In addition, we exceeded overall engagement in the professional, scientific and technical sector, as well as the life sciences sector. 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.

Diversity, Equity and Inclusion

Our diversity, equity and inclusion (DE&I) efforts 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 30% 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 have continued to expand since that time. 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. In 2023, our first employee resource groups were formed and focus on supporting populations within Tandem including women and gender minorities, LGBTQIA+, Pacific Islander or Asians, parents and caregivers, and in enhancing Tandem's sustainability efforts. 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 2023, approximately 400 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 teach our employees 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.

Additional Information

Our website address is *www.tandemdiabetes.com*. Copies of our filings with the SEC, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), 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 "Cautionary Note Regarding Forward-Looking Statements" at the beginning of this Annual Report and Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Annual Report.

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, 2023, we had an accumulated deficit of $951.8 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.

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, 2023 and 2022, our gross profits were $367.7 million and $413.0 million, respectively. Although we have achieved a positive overall gross margin during the years ended December 31, 2023 and 2022, we had net losses from operations of $222.6 million and $94.6 million, respectively, and we may continue to incur losses in the future.

To implement our business strategy and achieve consistent profitability, we need to, among other things, increase sales of our products and the gross profit associated with those sales, maintain an appropriate customer service, training and support infrastructure, fund ongoing research and development (R&D) activities, create additional efficiencies in our manufacturing processes while adding to our capacity, and obtain regulatory clearance, certification 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 pumps are 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 competing products by people with insulin-dependent diabetes, their caregivers and healthcare providers, the timing of regulatory clearance, certification, or approval of our products and the products of our competitors, the actual efficiencies gained in our manufacturing processes, and general economic conditions. 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. In addition, we recently launched our Tandem Mobi insulin pump. 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 Insulet, Medtronic, and Ypsomed;
- 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 clearance, certification, or approval for any such updates;
- changes in reimbursement rates or policies relating to insulin pumps or similar products or technologies by third-party payors;
- competitive pricing and attrition rates of consumers who cease using our products;
- 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 expect to rely on sales of our Tandem Mobi 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) could adversely affect our business, financial condition and operating results. 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.

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 single-use 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, including our Tandem Choice Program, aimed at our customers, their caregivers and healthcare providers, which include discounts, 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 competing 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, certification, or approvals for products or product features in a timely manner or at all, product development or commercialization delays, the impacts and disruption from health epidemics or pandemics, international conflicts, or for other reasons.

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. To continue to compete effectively, we must continue to create, invest in or acquire advanced technology, incorporate this technology into our proprietary products, obtain regulatory clearance, certification, or approvals in a timely manner, and manufacture and successfully market our products. Given these factors, we cannot guarantee that we will be able to compete effectively or continue our level of success.

Our primary competitors are major medical device companies, primarily Insulet, Medtronic, and Ypsomed. 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. Our primary competitors may 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 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 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 clearances, certifications, or 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.

Competing products, therapeutic techniques 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, therapeutic techniques, 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 competing 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 competing 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 pumps 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 pumps and related products achieving and maintaining market acceptance. For us to sell our products to people with insulin-dependent diabetes, we must demonstrate to 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 competing 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, effectiveness, ease-of-use or other perceived benefits of our products over competing 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.

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 pumps are 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.

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 are restricted in their ability to interact with healthcare professionals 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 began 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 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 in the event of general labor shortages in the United States.

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. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

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. As a result, our independent distributors may not devote a sufficient level of resources and the support required to generate awareness of our products and grow or maintain product sales at the levels we expect, which may negatively affect our sales.

For the year ended December 31, 2023, two independent distributors each accounted for more than 10% of our worldwide sales. If any of our key independent distributors were to cease to distribute our products or reduce their promotion of our products as compared to the products of our competitors, our sales could be adversely affected. In that case, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, the terms of the arrangements could result in our product margins being lower than if we directly marketed and sold our products.

If the third parties on which we increasingly rely to assist us with our current and anticipated pre-clinical development or clinical trials do not perform as expected, we may not be able to obtain regulatory clearance, certification, 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, certification, 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 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 clearances, certifications, or 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 clearances, certifications, or 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 competing 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 using 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 FDA approval and the 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. 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, certification, 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.

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 natural disasters, global conflicts, health pandemics 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 clearances, certifications, or 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.

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 clearances, certifications, or 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 inability 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 single-use 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. 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. 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 authorities, or Notified Bodies, and the failure of our suppliers to comply with regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination or interruption of distribution, operating restrictions, product seizures, delays in obtaining approval or clearance of future products, suspension or withdrawal of approvals, clearances, or certification, fines, civil penalties, or criminal prosecution. 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 clearances, certifications, or 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. 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.

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 competing 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 clearance, certification, or approval from regulatory authorities or Notified Bodies, product recalls or seizure, operating restrictions, interruption of production, fines, civil penalties and criminal prosecution 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, beyond 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. 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.

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, equity incentives, and benefits to attract and retain our personnel, which would increase our expenses. It may be difficult to continue to incentivize employees with meaningful equity incentives while limiting the use of the share reserve under our current long-term incentive plans. 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 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, liabilities, 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 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 26% of our total sales during 2023, are accompanied by certain financial and other risks related to international business markets, including:

- local product preferences and differing regulatory requirements for product clearances, certifications, or approvals;
- differing U.S. and foreign medical device import and export rules;
- more restrictive privacy and security laws relating to personal information of end-users and employees, including GDPR and other E.U. Member State national legislation;
- 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 and comparable foreign legislation;
- difficulties associated with foreign legal systems, including increased costs associated with enforcing contractual obligations in foreign jurisdictions;
- political instability and actual or anticipated military or political conflicts;
- difficulties in managing international relationships, including any relationships that we establish with foreign partners, distributors, or sales or marketing agents;
- foreign taxes, including withholding of payroll taxes;
- different reimbursement systems; 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, clearance or certification 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 begin 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.

Failure to comply with the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws could materially adversely affect our business and result in civil and/or criminal sanctions.

The FCPA, the U.K. Bribery Act, and similar anti-bribery laws enacted in other jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Because we do business in the U.K., the U.K. Bribery Act also extends to our interaction with public and private sector entities and persons outside the U.K., including in the United States. Our policies mandate compliance with these anti-bribery laws. We operate in parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. Despite our training and compliance programs, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of anti-bribery laws, or allegations of such violations, could disrupt our business and have a material adverse effect on our results of operations, financial condition, and cash flows.

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 26% of our total sales during 2023. 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.

In October 2023, Hamas initiated an attack against Israel, provoking a state of war and the risk of a larger regional conflict. While we cannot predict the broader consequences, these conflicts and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may disrupt sales through our local distributor in Israel.

Public health threats, epidemics, or pandemics could 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, 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, may be modified or delayed due to impacts of public health threats, which could 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 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. The full extent of the impact of 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, 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.

Although it is difficult to predict and adequately prepare to meet the challenges to our business posed by climate change, if new laws or regulations are more stringent than current legal or regulatory requirements, we may experience increased compliance burdens and costs to meet the regulatory obligations as well as adverse impacts on raw material sourcing, manufacturing operations and the distribution of our products.

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, 2023, we had $467.9 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, certification, 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 clearances, certifications, or 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 competing 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 clearances, certifications, 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

We may be subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we process personal data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal data privacy and security policies, and contractual requirements.

There are a number of laws in the United States governing the privacy and security of personal data, including data breach notification laws, data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws at the federal and state levels (e.g., wiretapping laws). For example, the U.S. Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), imposes specific requirements relating to the privacy of protected health information.

As another example, the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 ("CAN-SPAM”) and the Telephone Consumer Protection Act of 1991 (“TCPA”) impose specific requirements on communications with customers. For example, the TCPA imposes various consumer consent requirements and other restrictions on certain telemarketing activity and other communications with consumers by phone, fax or text message. TCPA violations can result in significant financial penalties, including penalties or criminal fines imposed by the Federal Communications Commission or fines of up to 1,500 U.S. Dollars per violation imposed through private litigation or by state authorities.

In recent years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive data privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. These state laws also allow for statutory fines for noncompliance. For example, as per the California Consumer Privacy Act of 2018 (CCPA), as amended by the California Privacy Rights Act of 2020 (CPRA) (collectively, "CCPA"), noncompliance may carry fines of up to 7,500 U.S. Dollars per violation; the CCPA also allows private litigants affected by certain data breaches to recover significant statutory damages. While these laws generally exempt some data processed in the context of clinical trials and data governed by HIPAA, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us, the third parties upon whom we rely, and our customers. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's General Data Protection Regulation ("UK GDPR") (collectively, "GDPR"), and Canada's Personal Information Protection and Electronic Documents Act ("PIPEDA") or the applicable provincial alternatives, impose strict requirements for processing personal data.

For example, under the GDPR, companies may face temporary or definitive bans on personal data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR / 17.5 million Pounds Sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, PIPEDA and various related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations.

Additionally, regulators are increasingly scrutinizing companies that process children's data. Numerous laws, regulations, and legally-binding codes, such as the Children's Online Privacy Protection Act ("COPPA"), California's Age Appropriate Design Code (effective in July 2024), the CCPA, other U.S. state comprehensive data privacy laws, the GDPR, and the UK Age Appropriate Design Code, impose various obligations on companies that process children data, including requiring certain consents to process such data and extending certain rights to children and their parents with respect to that personal data. Some of these obligations have wide ranging applications, including for services that do not intentionally target child users (defined in some circumstances as a user under the age of 18 years old). These laws may be, or in some cases have already been, subject to legal challenges and changing interpretations, which may further complicate our efforts to comply with these laws.

Our employees and personnel use Artificial Intelligence ("AI") technologies (including generative AI) to perform their work. The use and disclosure of personal data in AI technologies is subject to various data privacy laws and other data privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use AI, it could make our business less efficient and result in competitive disadvantages.

The development and use of AI/Machine Learning ("ML") technologies present various data privacy risks that may impact our business. AI/ML are subject to data privacy laws, as well as increasing regulation and scrutiny. Several jurisdictions around the globe, including the European Union and certain U.S. states, have proposed or enacted, or are considering, laws governing the development and use of AI/ML. For example, European regulators have proposed a stringent AI regulation, and we expect other jurisdictions will adopt similar laws. Additionally, certain data privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision-making, which may prove to be incompatible with our desired uses of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, require us to change our business practices and/or retrain our AI/ML, prevent or limit our use of AI/ML, or lead to regulatory fines or penalties. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated data privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

We may be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing such data (including imposing stringent requirements for consent), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from third parties through various methods, including chatbot and session replay providers, or via third-party marketing pixels. These practices may be subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring certain data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the UK have significantly restricted the transfer of personal data to the United States and other countries whose data privacy laws it deems inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant organizations based in the United States who self-certify and participate in the Framework), these mechanisms are subject to legal challenges. If these legal challenges change or invalidate these transfer mechanisms, there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful mechanism for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer obligations. Additionally, in May 2023, the Irish Data Protection Commission determined that a major social media company's use of the standard contractual clauses to transfer personal data from Europe to the United States was insufficient and levied a 1.2 billion Euro fine against the company and prohibited the company from transferring EU personal data to the United States.

Additionally, under various privacy laws and other obligations, we may be required to obtain certain consents to process personal data. For example, some of our data processing practices may be challenged under wiretapping laws, if we obtain consumer information from third parties through various methods, including chatbot and session replay providers, or via third-party marketing pixels. These practices may be subject to increased challenges by class action plaintiffs. Our inability or failure to obtain consent for these practices could result in adverse consequences, including class action litigation and mass arbitration demands.

In addition to data privacy laws, we are contractually subject to industry standards adopted by industry groups. For example, we are subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from 5,000 to 100,000 U.S. Dollars per month by credit card companies, litigation, damage to our reputation, and revenue losses. We are also bound by other contractual obligations related to data privacy, including those imposed by our payors and business partners, including obligations to comply with applicable data privacy laws. Our failure to comply with our contractual obligations may result in a loss of revenue, loss of existing and future business opportunities, and payment of financial damages to the other parties involved. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model. We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy obligations. Moreover, despite our efforts, our employees and personnel or third parties on whom we rely, may fail to comply with such obligations, which could negatively impact our business operations. In addition, a shift in consumers' data privacy expectations or other social, economic or political developments could impact the regulatory enforcement of these obligations, which could increase the cost of and complicate our compliance with applicable obligations.

If we or the third parties on whom we rely fail, or are perceived to have failed to address or comply with applicable data privacy obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing of personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become increasingly more active in bringing data privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis; if viable, these claims carry the potential for monumental statutory damages, depending on the volume of personal data and the number of violations.

Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

If our information technology systems or those third parties upon which we rely, our data, or our software are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; harm to our reputation; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of business, 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 and the third parties upon which we rely collect, receive, store, process, use, generate, disclose, make accessible, protect, secure, dispose of, share, and transmit confidential, personal, or other sensitive data, including health information, proprietary sales and marketing data, accounting and financial information, manufacturing and quality records, inventory management data, product development tasks, research and development data, customer service and technical support information. These systems and the underlying data 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, social-engineering attacks (including phishing and deep fakes, which may be increasingly more difficult to identify as fake), malicious code, denial-of-service attacks, credential harvesting, supply chain attacks, power losses, and computer system, data network failures, and other similar threats.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could significantly disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

Our systems, those of the third parties upon which we rely, and the underlying data are vulnerable to damage or interruption from a number of causes, including earthquakes, fires, floods and other natural disasters, terrorist attacks. We and the third parties upon which we rely are also subject to a variety of evolving threats, including but not limited to, social-engineering attacks (including phishing and deep fakes, which may be increasingly more difficult to identify as fake), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, supply chain attacks, personnel misconduct or error, ransomware attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, and other similar threats. Notably, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, impact our ability to provide our products or services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

In addition, our insulin pumps and other products rely on software and hardware, some of which is developed by third-party service providers, that could contain vulnerabilities. We take steps to detect and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely), but we may not be able to detect, mitigate, and remediate such vulnerabilities on a timely basis or at all, including because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Our risks may increase significantly due to the use of mobile and cloud-based applications in our medical devices. For example, while use of our Tandem Device Updater gives us the ability to quickly recover from certain risks and/or vulnerabilities, the use of mobile applications enables third parties to store their information on mobile devices that we do not control. Vulnerabilities could be exploited and result in a security incident.

Any of the previously identified or similar threats and risks could cause a security incident or other interruption that could result in the unauthorized, unlawful or accidental disclosure, access, acquisition, modification, destruction, loss, alteration, or encryption of our sensitive information or our information technology systems or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our platform/products/services.

Furthermore, many of the third parties upon whom we rely are subject to similar risks. We rely on third parties and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions and systems. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties upon whom we rely experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy- or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such an award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Moreover, remote work has become more common and has increased risks to our information technology systems and data, as more of our employees use network connections, computers and devices outside our premises or network, including working at home, while in transit, and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We may expend significant resources or modify our business activities to try to protect against security incidents. Whether or not our security measures and those of the third parties upon whom we rely 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. Certain data privacy and security obligations may require us to implement and maintain reasonable or specific security measures or industry standards to protect our information technology systems and sensitive information.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident (such as the phishing attack we experienced in 2020) or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims) and mass arbitration demands; indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause or prevent customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. Whether a cybersecurity incident is reportable to our investors may not be straightforward, may take considerable time to determine, and may be subject to change as the investigation of the incident progresses, including changes that may significantly alter any initial disclosure that we provide. Moreover, experiencing a material cybersecurity incident and any mandatory disclosures could lead to negative publicity, loss of investor, partner or customer confidence in the effectiveness of our cybersecurity measures, diversion of management's attention, governmental investigations, lawsuits, and the expenditure of significant capital and other resources.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

The failure of our or our service providers' third parties' information technology systems or our pumps' software or other mobile or cloud 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 or ability to provide our products and services. For example, we market our Tandem Device Updater as having the unique capability to deploy software updates to our pumps, which allows 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, or errors, vulnerabilities or viruses embedded within the software being transmitted, or the failure of our customers to properly use 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.

Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' (or other third parties upon whom we rely) use of generative artificial intelligence ("AI") or machine learning ("ML") technologies (collectively, "AI/ML" technologies). Any sensitive information (including confidential, competitive, proprietary, or personal data) that we input into a third-party generative AI platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI model. Additionally, where AI/ML technologies ingests personal data and makes connections using such data, those technologies may reveal other personal or sensitive information generated by the model. Moreover, AI models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI with bad inputs or logic), or if the logic of the AI is flawed (a so-called "hallucination"). We may use AI/ML outputs to make certain decisions. Due to these potential inaccuracies or flaws, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits. If such AI-based outputs are deemed to be biased, we could face adverse consequences, including exposure to reputational and competitive harm, customer loss, and legal liability.

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. On March 7, 2023, the plaintiffs filed a notice of appeal of the Court's order granting the Company's motion for summary adjudication. On August 15, 2023, the parties reached a settlement and on August 21, 2023, the Court issued an order dismissing the appeal. The risks posed by any future similar matters include civil monetary damages, attorney fees and costs, other legal penalties, reputational damage, loss of goodwill, and competitive harm.

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. While we review third party patents in advance of product launches to try to identify and avoid any infringement concerns, the large number of patents, the rapid rate of new patent issuances, and the complexity of the technology involved mean that there can be no assurance that all potentially relevant patents are identified or that our products do not infringe existing patents or patents that may be granted in the future. As such, there is a risk that third parties may assert patent infringement claims against us. Despite our efforts to avoid infringement and to resolve any claims that may arise, litigation may be necessary to defend against these claims, which could result in substantial costs and diversion of resources and may have a material adverse effect on our business, financial condition, and results of operations. 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.

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;
- try to obtain a license to intellectual property from the third parties, which may not be available on reasonable terms or at all;
- try to re-design our products around third-party intellectual property;
- incur significant royalty payments and legal expenses; or
- pay substantial damages to the party whose intellectual property rights we are allegedly infringing.

For example, in November 2023, at the Unified Patent Court (the "UPC"), we filed a revocation action and an action for a declaration of non-infringement of EP Patent No. 2 196 231 B1 (the "'231 patent") against Roche Diabetes Care GmbH. While Roche contends that Tandem's t:slim X2 pump infringes the '231 patent, we contend that our t:slim X2 pump does not practice the '231 patent. Furthermore, we contend that the claims of the '231 patent are invalid over the prior art.

In January 2024, F. Hoffman-La Roche AG and Roche Diabetes Care GmbH (collectively, "Roche"), filed an infringement action at the UPC against multiple defendants including Tandem Diabetes Care, Inc. and Tandem Diabetes Care Europe B.V. Roche alleges our t:slim X2 insulin pump, and the offering, marketing, using, importing, possessing, and supplying of such devices, infringe EP Patent No. 1 970 677 B1 (the "'677 patent"). Roche seeks, among other things, damages and other monetary relief, costs and expenses of the legal proceedings, and an order to cease and desist the allegedly infringing activities. As the UPC is a new court system that came into effect in 2023, enforcement and litigation under the UPC is new and we cannot accurately predict the outcome of such proceedings.

If any of our dosing devices is found to infringe Roche's patents and Roche's patents are also found to be valid, we could be required to redesign our technology or obtain a license from Roche to continue importing, marketing and selling our dosing devices in certain countries in Europe. However, we may not be successful in the redesign of our technology or able to obtain any such license on commercially reasonable terms or at all. We also could be forced, including by court order, to cease importing, marketing and selling certain of our products in certain countries in Europe that are found to be infringing until the patents expire. Even if we were ultimately to prevail, litigation with Roche could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. We cannot reasonably estimate the final outcome, including any potential liability or any range of potential future charges associated with litigation.

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 by governmental authorities, principally the FDA and corresponding state regulatory agencies in the United States, foreign regulatory authorities, and Notified Bodies in the EU. 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 foreign 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, packaging and storage;
- marketing, manufacturing, sales and distribution;
- import and export;
- pre-market clearance, certification, 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, certification, or approvals to market a medical device can be costly and time-consuming, which may be exacerbated if the FDA or other regulatory authorities or Notified Bodies in the EU changes their clearance, certification, and approval policies, and we may not be able to obtain these clearances, certification 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, certification, 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, certification, 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 and Notified Bodies on numerous occasions. We also regularly respond to routine inquiries from regulatory authorities and Notified Bodies. 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 or criminal penalties, injunctions, warning letters, product recalls, operating restrictions, interruption of production, delays in the introduction of products into the market, refusal of the FDA or other regulatory authorities or Notified Bodies to grant future clearances, certification, or approvals, and the suspension or withdrawal of existing clearances, certifications, or approvals by the FDA, other regulatory authorities or Notified Bodies. 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, PMAs or certifications, or may require us to cease marketing or recall the modified products until clearances, certifications or approvals 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.

For those medical devices sold in the EU and for which we have obtained a CE Certificate of Conformity by a Notified Body, we must notify our Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining variation of existing CE Certificates of Conformity or a new CE Certificate of Conformity can be a time-consuming process, and delays in obtaining required future clearances, certifications or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

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 and requirements 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 authority 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 starting 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 discontinued sales of earlier generation products in Australia and we started 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 authorities 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 authorities, 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.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products in the EU. We must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension, variation or withdrawal of CE Certificates of Conformity, product seizures, injunctions or the imposition of civil or criminal penalties that would adversely affect our business, operating results and prospects.

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, or comparable foreign legislation, 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 or their immediate family member 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, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- federal and state 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 and certain other healthcare providers, and teaching hospitals;

- 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.

Outside the United States, interactions between medical device companies and healthcare professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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 or other foreign regulatory authorities determine 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 authority 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.

The advertising and promotion of medical devices in the EU is subject to the national law of individual EU Member States implementing Directive 93/42 on medical devices, or MDD, Directive 90/385/EEC on active implantable medical devices, or AIMD, and applying Regulation 2017/745 on medical devices, or MDR, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EU Member States governing the advertising and promotion of medical devices. EU Member States' national legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national industry Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Legislative or regulatory healthcare reforms, or other regulatory 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. Further, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "IRA 2022") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA 2022 also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program.

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.

In the EU, the MDR became applicable on May 26, 2021, repealing and replacing both the MDD and Directive 90/385/EEC on active implantable medical devices. The MDR establishes transitional provisions. However, the changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, tightened and streamlined quality management system assessment procedures and additional requirements for the quality management system, additional requirements for traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfillment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the MDR.

Moreover, in the EU, some EU Member States may, after a medical device is CE marked, require the completion of additional studies that compare the cost-effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. In December 2021, Regulation No 2021/2282 on HTA, amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies and providing the basis for cooperation at EU level for joint clinical assessments in these areas. If the conclusions of these assessments are negative, or compare our products unfavorably with competing products, this may impact our pricing and reimbursement status. If we are unable to obtain or maintain favorable pricing and reimbursement status in EU Member States for our medical devices or medical devices that we may successfully develop and for which we may obtain certification, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

In addition, the exit of the UK from the EU, commonly referred to as "Brexit" could lead to regulatory divergence between the EU and the UK. On May 26, 2021, the MDR became applicable in the EU. However, the MDR is not applicable in the UK. In the UK, medical devices are governed by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) which, for the time being, retains a regulatory framework similar to the framework set out by the MDD. The government plans to introduce new legislation governing medical devices with an aim for core aspects of the future regime for medical devices to apply from July 1, 2025. New legislation has been proposed and is also anticipated for adoption in late 2023 to bring into force strengthened post-market surveillance requirements ahead of the wider future regulatory regime. These post-market surveillance requirements are expected to apply from mid-2024. Should the UK or Great Britain further diverge from the EU from a regulatory perspective, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenue or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the EU and the UK.

Governments outside the United States tend to impose strict price controls, reimbursement approval and rebate policies, which may adversely affect our ability to generate revenue.

In some countries, particularly EU countries and EFTA member states, the pricing, reimbursement and rebates of health products is subject to governmental control, and in such countries, there can be considerable pressure by governments and other stakeholders on prices, as well as reimbursement and rebates. If reimbursement of our products is unavailable or limited in scope or amount or if pricing or rebates are set at unsatisfactory levels in any such country, our prospects for generating revenue outside of the United States, if any, could be adversely affected and our business could be harmed. For example, in August 2023, a rebate agreement with the French Comité économique des produits de santé (CEPS) for sales of our t:slim X2 with Control-IQ pump in France went into effect. The rebate agreement with CEPS provides for specified reimbursements and requires specified rebates be paid, and we are currently in the process of determining the impact and allocation of such reimbursements and rebates under the agreement. While we currently cannot estimate the amount of such reimbursements and rebates that will be allocable to us, we may ultimately determine that we need to pay all or a portion of the rebates. Any such rebates that we are required to pay could adversely affect our ability to generate revenue from sales of t:slim X2 with Control-IQ in France.

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 clearance, certification, or approval of our products or the products of our competitors or collaboration partners, or the failure to obtain such clearances, certifications, or 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.

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. Given the competitiveness of the life sciences and medical device industry, the prices at which our common stock trades may fluctuate more significantly than might otherwise be typical, even with other market conditions, including general volatility, held constant. This volatility could negatively impact our ability to raise additional capital or utilize equity as consideration in any acquisition transactions we may pursue, and could make it more difficult for existing stockholders to sell their shares of the common stock at a price they consider acceptable or at all.

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.

Under current law, federal net operating losses (NOLs) incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. As of December 31, 2023, we had accumulated federal and state NOL carryforwards of approximately $168.0 million, and $262.4 million, respectively. Of the total federal NOL carryforwards, approximately $78.4 million were generated after January 1, 2018, and therefore do not expire under current law but can only be utilized to offset 80% of future taxable income. The remaining federal NOL carryforwards of $89.6 million will begin to expire in 2033, and state tax loss carryforwards continue to expire.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change in its equity ownership value over a three-year period, the corporation's ability to use its pre-change 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. We believe we experienced at least one ownership change that significantly reduced our ability to utilize our pre-2018 NOL and research credit carryforwards before they expire. Additionally, future ownership changes under Section 382 may also limit our ability to fully utilize any remaining tax benefits.

Uncertainties in the interpretation and application of existing, new and proposed tax laws and regulations could materially affect our tax obligations and effective tax rate.

The tax regimes to which we are subject or under which we operate are unsettled and may be subject to significant change. The issuance of additional guidance related to existing or future tax laws, or changes to tax laws or regulations proposed or implemented by the current or a future U.S. presidential administration, Congress, or taxing authorities in other jurisdictions, including jurisdictions outside of the United States, could materially affect our tax obligations and effective tax rate. To the extent that such changes have a negative impact on us, including as a result of related uncertainty, these changes may adversely impact our business, financial condition, results of operations, and cash flows.

The amount of taxes we pay in different jurisdictions depends on the application of the tax laws of various jurisdictions, including the United States, to our international business activities, tax rates, new or revised tax laws, or interpretations of tax laws and policies, and our ability to operate our business in a manner consistent with our corporate structure and intercompany arrangements. The taxing authorities of the jurisdictions in which we operate may challenge our methodologies for pricing intercompany transactions pursuant to our intercompany arrangements or disagree with our determinations as to the income and expenses attributable to specific jurisdictions. If such a challenge or disagreement were to occur, and our position was not sustained, we could be required to pay additional taxes, interest, and penalties, which could result in one-time tax charges, higher effective tax rates, reduced cash flows, and lower overall profitability of our operations. Our financial statements could fail to reflect adequate reserves to cover such a contingency. Similarly, a taxing authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

Effective January 1, 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Although there have been legislative proposals to repeal or defer the capitalization requirement to later years, there can be no assurance that the provision will be repealed or otherwise modified. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation.

Our tax obligations and effective tax rate in the jurisdictions in which we conduct business could increase, including as a result of the base erosion and profit shifting (BEPS) project that is being led by the Organization for Economic Co-operation and Development (OECD), and other initiatives led by the OECD or the European Commission. For example, the OECD is leading work on proposals, commonly referred to as "BEPS 2.0", which, if and to the extent implemented, would make important changes to the international tax system. These proposals are based on two "pillars", involving the reallocation of taxing rights in respect of certain multinational enterprises above a fixed profit margin to the jurisdictions in which they carry on business (subject to certain revenue threshold rules which we do not currently meet but may meet in the future) (referred to as "Pillar One") and imposing a minimum effective corporate tax rate on certain multinational enterprises (referred to as "Pillar Two"). A number of countries in which we conduct business, including through our subsidiaries, such as the Netherlands and Switzerland, have enacted with effect from January 1, 2024, or are in the process of enacting, core elements of the Pillar Two rules. Based on our current understanding of the minimum revenue thresholds contained in the Pillar Two proposal, we expect that we are likely to fall within the scope of its rules in the short-to-medium term. The OECD has issued administrative guidance providing transition and safe harbor rules in relation to the implementation of the Pillar Two proposal. We are monitoring developments and evaluating the potential impacts of these new rules, including on our effective tax rates, and considering our eligibility to qualify for these safe harbor rules.

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.

The Notes contain certain debt service requirements. Pursuant to the Notes, interest is payable in cash semi-annually at a rate of 1.50% per year.

Our failure to comply with certain obligations under the Notes, 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;

- covenants contained in 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.

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 clearance, certification, or 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.

In addition, we may from time to time seek to retire or purchase our outstanding debt, including the Notes, through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material. Further, any such purchases or exchanges may result in us acquiring and retiring a substantial amount of such indebtedness, which could impact the trading liquidity of such indebtedness.

An event of default occurred under the indenture governing the Notes.

On or about October 24, 2023, we were notified that additional interest had been accruing on the Notes since May 2021 pursuant to the terms of the indenture, as a result of our failure to timely remove the restrictive legends on the Notes and switch the Notes to an unrestricted CUSIP. This additional interest accrued at a rate of 0.50% per annum on the outstanding principal amount of the Notes. The failure to pay these overdue amounts when required constituted an event of default under the indenture. We paid all overdue amounts related to this matter in November 2023. Early repayment of the Notes due to an event of default would likely significantly impact our liquidity and financial condition, which could have a material adverse effect on our business.

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 (as defined in the indenture governing the Notes) 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 settle all or a portion of our conversion obligation through the payment of cash, which could adversely affect our liquidity. 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. A default under the indenture, or the fundamental change itself, could also lead to a default under agreements governing our existing or future indebtedness. If the repayment of the related indebtedness were to be accelerated after any applicable notice or grace periods, we may not have sufficient funds to repay the indebtedness and repurchase the notes or make cash payments upon conversions thereof.

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.

Certain provisions in the indenture governing the Notes may delay or prevent an otherwise beneficial takeover attempt.

Certain provisions in the indenture governing the Notes may make it more difficult or expensive for a third party to acquire us. For example, the terms of the Notes require us to offer to repurchase the Notes in the event of a fundamental change and, in certain circumstances, to increase the conversion rate for a holder that converts its Notes in connection with a make-whole fundamental change (as defined in the indenture governing the Notes). A takeover of the Company may trigger the requirement that we offer to repurchase the Notes and/or increase the conversion rate of the Notes for a holder that elects to convert its Notes, which could make it more costly for a potential acquirer to engage in such takeover. These and other provisions set forth in the indenture may have the effect of delaying or preventing a takeover of the Company that would otherwise be beneficial to investors.

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 before 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.

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 with a claim equal to our exposure at that time under the Capped Call Transaction with such option counterparty. Our exposure will depend on many factors but, in general, an increase in our exposure will be correlated to an increase in the market price and volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer more dilution than we currently anticipate with respect to our common stock.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and patient and customer data ("Information Systems and Data").

Our information security function is led by our Vice President, Cybersecurity (our "Information Security Team"), and is supported by our Chief Technology Officer, our Chief Legal, Privacy and Compliance Officer and legal department, our Vice President, Head of Information Technology, and our cybersecurity incident management team. Our Information Security Team is tasked with identifying, assessing and managing our cybersecurity threats and risks. It identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and our risk profile using various methods including: the use of manual and automated tools, subscribing to reports and services that identify cybersecurity threats, analyzing reports of threats and actors, conducting scans of the threat environment, evaluating our and our industry's risk profile, evaluating threats reported to us, conducting risk assessments, coordinating with law enforcement concerning threats, conducting internal and external audits and threat assessments for internal and external threats, obtaining third party threat assessments, conducting vulnerability assessments to identify vulnerabilities, and tabletop incident response exercises.

Depending on the environment and system, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including an incident response policy, vulnerability management policy, disaster recovery and business continuity plan, vendor risk management program, programs for incident detection and response, encrypting certain data, network security controls, data segregation, asset management tracking and disposal, penetration testing, employee training, access controls, physical security controls, systems monitoring, a dedicated cybersecurity officer; and cybersecurity insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the Information Security Team works with other members of management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business. Additionally, our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the Cybersecurity and Data Privacy Oversight Subcommittee (the "Privacy and Security Subcommittee") of the Nominating and Corporate Governance Committee, as well as our Board of Directors, the latter of which evaluates our overall enterprise risk.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including professional services firms, including legal counsel; cybersecurity consultants; cybersecurity software providers; managed cybersecurity service providers; penetration testing firms; and forensic investigators.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers, hosting companies, contract research organizations, contract manufacturing organizations, distributors and supply chain resources. We have a vendor management program to manage cybersecurity risks associated with our use of these providers. The program includes requiring certain vendors to complete security questionnaires, conducting risk assessments for certain vendors, reviewing security assessments, conducting security assessment calls with certain vendor security personnel, and imposing information contractual obligations on the vendor. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, see our risk factors in Part I, Item 1A of this Annual Report, including in the section titled "Risks Related to Privacy and Security."

Governance

Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The Privacy and Security Subcommittee is responsible for overseeing our cybersecurity risk management processes, including oversight and mitigation of risks from cybersecurity threats.

Our cybersecurity management processes are implemented and maintained by our Information Security Team, in consultation with members of our cybersecurity incident management team. Our cybersecurity incident management team is led by our Vice President, Cybersecurity and includes our Chief Human Resources Officer, Vice President, Privacy, senior personnel from our legal, finance, and relevant business departments (the "Incident Management Team"). Our Vice President, Cybersecurity brings extensive experience in software development, IT, and cyber security, gained in over two decades in the telecommunications, financial services, defense, and healthcare sectors. Notably, he spent the last four years at a medical device company focused on insulin delivery, where he successfully established the product security program and played a pivotal role in obtaining clearance for its flagship product line.

As the leader of our Information Security Team, our Vice President, Cybersecurity, is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our overall risk management strategy, communicating key priorities to relevant personnel, requesting and allocating budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy and security incident handling procedure are designed to escalate certain cybersecurity incidents to members of management who are part of the Incident Management Team. The Incident Management Team works to help mitigate and remediate cybersecurity incidents of which they are notified. In addition, the cybersecurity incident response policy and security incident handling procedure include escalating certain cybersecurity incidents to our disclosure committee and, if appropriate, to the Privacy and Security Subcommittee.

The Privacy and Security Subcommittee meets periodically, and receives regular reports from our Vice President, Cybersecurity and, as appropriate, other members of the Information Security Team concerning any significant cybersecurity threats and risk and the processes we have implemented to address them. The Privacy and Security Subcommittee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation, generally. The Privacy and Security Subcommittee provides regular reports to the Nominating and Corporate Governance Committee of significant matters related to the Privacy and Security Subcommittee's responsibilities, and the Nominating and Corporate Governance Committee together with the VP, Cybersecurity in turn provide regular reports to our Board of Directors on such significant matters.

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, 2023, we leased facilities with an aggregate total of approximately 358,000 square feet, as follows:

United States

- Headquarters 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 rentable square feet, began in March of 2022. Phase II of the lease, consisting of 38,099 rentable square feet, is expected to begin in the first quarter of 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. The Headquarters Lease also includes a first right of offer with respect to an additional 16,154 rentable square feet of general office space should the space become available.

- 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, which are not expected to be exercised. During the second quarter of 2023, the Company consolidated facilities by moving the administrative functions and other operations from the Vista Sorrento Lease facility to the new Headquarters Lease location, and this leased facility is currently unoccupied.

- 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. This leased facility is currently unoccupied.

- Wrigley Lease: 7,753 square feet of general administrative and research and development office space located on Wrigley Avenue in Irvine, California, which is scheduled to expire in October 2024. In January 2024, the Company extended the term of this lease through October 2025.

Outside the United States

- Switzerland Lease: 11,287 square feet of general administrative and research and development office space located in Saint-Sulpice, Switzerland, which expired in December 2023. The Company executed a new lease agreement with a lease term that begins in January 2024 and expires in December 2028.

- Canada 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 under the caption *"Commitments and Contingencies - Legal and Regulatory Matters"* in Part II, Item 8, Subsection 13 of this Annual Report, there are no material pending legal proceedings to which we or any of our subsidiaries is a party or of which any of our property is subject. See also "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" in Part I, Item 1A of this Annual Report.

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 has been trading on the Nasdaq Global Market since November 14, 2013 under the symbol "TNDM."

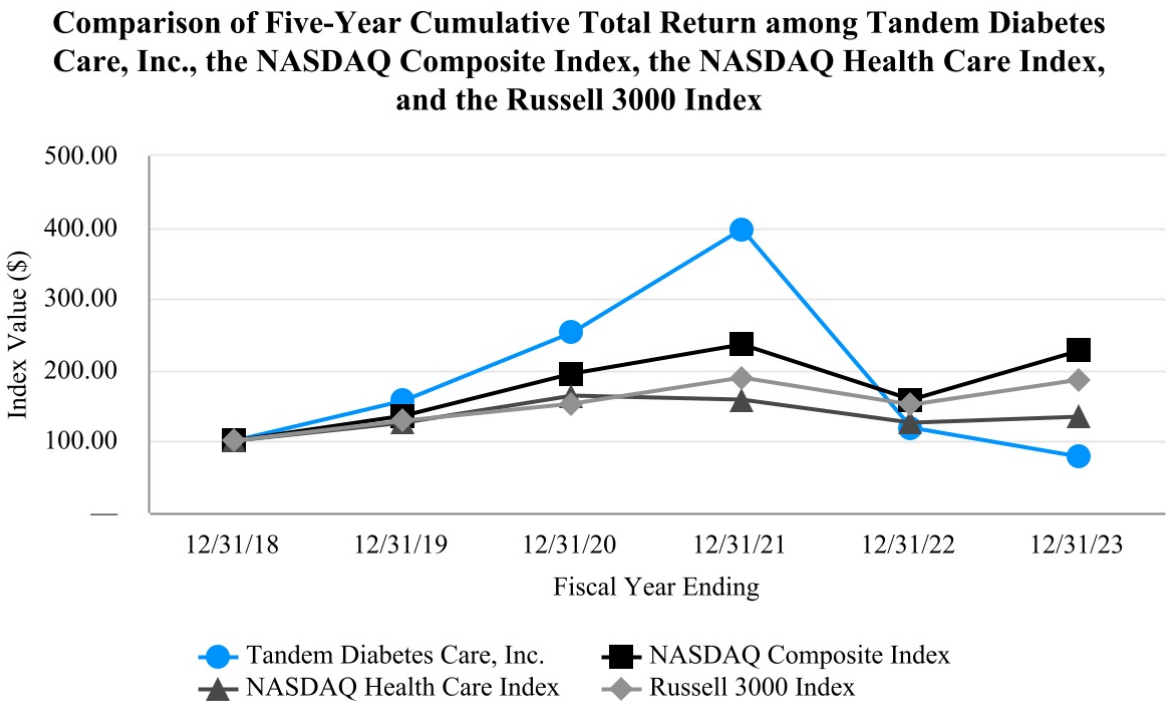
Holders of Record

As of February 16, 2024, there were approximately 45 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.

Stock Performance Graph

This performance graph shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

The following graph illustrates a comparison of the cumulative total stockholder return (change in stock price plus reinvested dividends) of our common stock with (i) The Nasdaq Composite Index, (ii) The Nasdaq Health Care Index, and (iii) the Russell 3000 Index. The graph assumes a $100 investment, on December 31, 2018, in (i) our common stock, (ii) the securities comprising the Nasdaq Composite Index, (iii) the securities comprising the Nasdaq Health Care Index, and (iv) the securities in the Russell 3000 Index.



	12/31/2018	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023
Tandem Diabetes Care, Inc.	$ 100.00	$ 156.99	$ 251.99	$ 396.42	$ 118.38	$ 77.90
NASDAQ Composite	$ 100.00	$ 135.23	$ 194.24	$ 235.78	$ 157.74	$ 226.24
NASDAQ Health Care	$ 100.00	$ 125.83	$ 163.63	$ 157.82	$ 125.58	$ 133.80
Russell 3000	$ 100.00	$ 128.54	$ 152.73	$ 189.39	$ 150.61	$ 186.68

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Unregistered Sales of Equity Securities

None.

Repurchases of Equity Securities

We did not repurchase any of our equity securities during the year ended December 31, 2023.

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. For additional information, see "Cautionary Note Regarding Forward-Looking Statements" at the beginning of this Annual Report.

A discussion of changes in our results of operations during the year ended December 31, 2022 compared with the year ended December 31, 2021 has been omitted from this Annual Report on Form 10-K but may be found in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on February 22, 2023, which discussion is incorporated herein by reference and which is available free of charge on the SEC's website at www.sec.gov.

Overview

We are a medical device company focused on the design, development and commercialization of technology solutions for people living with diabetes. We consider our primary addressable market to be people who live with type 1 diabetes. Through our product development efforts, we are seeking to expand our addressable market to include people living with type 2 diabetes who require intensive insulin therapy. Diabetes management can vary greatly from person-to-person, creating multiple market segments based on clinical needs and personal preferences. Our goal is to address the individual needs of people with insulin-dependent diabetes and their care team flexibility and choice in intelligent insulin delivery systems, through an accessible portfolio of market-leading pumps, applications, and insights.

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 in select geographies outside the United States and our technology solutions are now available in approximately 25 countries worldwide. In the four-year period ended December 31, 2023, we shipped approximately 450,000 insulin pumps, which is representative of our in-warranty global installed customer base assuming the typical four-year reimbursement cycle.

The t:slim X2 has been our flagship technology solution. In February 2024, we expanded our pump portfolio with commercial U.S. availability of the Tandem Mobi insulin pump, which is the world's smallest durable automated insulin delivery (AID) system. At approximately half the size of our t:slim X2 pump, Tandem Mobi is designed for people who seek even greater discretion and flexibility, and includes features such as expanded pump-control from our iOS mobile application, inductive charging, and an on-pump button that can be used for bolusing and other actions. In the United States, a limited release of Tandem Mobi began in the fourth quarter of 2023 and commercial availability began in February 2024.

With both the t:slim X2 and Tandem Mobi in our product portfolio, we are offering people living with diabetes a choice between the t:slim X2 and Tandem Mobi insulin pumps based on their individual needs and preferences in insulin delivery.

The majority of our customers use their insulin pump with continuous glucose monitoring (CGM) integration. This allows their insulin pump to receive CGM sensor readings, which can then be used in our 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 FDA to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar.

The t:slim X2 was the first pump on which remote software updates were made commercially available in the United States and is now also available in the countries we serve worldwide. Our Tandem Device Updater (TDU) has allowed our t:slim X2 customers to update their pump software from a personal computer. Tandem Mobi offers the same update capability with wireless, remote updates. 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. As an example, we recently launched a pump software update through TDU to allow all t:slim X2 pump users in the United States access to integration with two new CGM sensor offerings.

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 single-use 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 a data management web application that provides users, their caregivers and their healthcare providers with a fast, easy and visual way to display diabetes therapy management data from our pumps, integrated CGMs and supported blood glucose meters. Our first-generation data management application, t:connect, was commercially introduced in the United States in 2013. In the second quarter of 2023, we began a scaled global launch, starting with the United States, of our second-generation data management application, Tandem Source.

Recent Developments

Tandem Diabetes Care Launches Tandem Mobi, the World's Smallest, Durable Automated Insulin Delivery System

In February 2024, we announced the United States commercial launch of our new Tandem Mobi, the world's smallest, durable automated insulin delivery system for people living with diabetes. We have begun taking orders and shipping to eligible customers in the United States.

Integration of t:slim X2 with Abbott's FreeStyle Libre 2 Plus Sensor

In January 2024, we announced that the t:slim X2 insulin pump with Control-IQ technology became the first AID system to integrate with newly available FreeStyle Libre 2 Plus sensor, Abbott's latest CGM technology. Users in the United States are now able to experience the therapeutic benefits of a hybrid closed-loop system that helps predict and prevent high and low blood sugar. Tandem's t:slim X2 insulin pump connects wirelessly to the FreeStyle Libre 2 Plus sensor, which sends automatic glucose readings every minute to the pump.

Pump Reimbursement Cycle

Insulin pumps in the markets we serve worldwide are generally subject to a four-year reimbursement cycle, imposed by the third-party insurance carrier, government plan or healthcare system that serves as the primary payor. At the end of the typical four-year reimbursement cycle, customers may be eligible to purchase 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 take up to one year from date of warranty expiration to purchase a subsequent pump. While the majority of our insulin pump sales from initial commercialization through the current period have been generated by sales to new customers, the opportunity to make subsequent sales of renewal insulin pumps to existing customers increases each period as an escalating number of customer warranties expire. With programs dedicated to customer retention efforts, we expect such renewal purchases to represent an increasing portion of our pump shipments over time.

In the four-year period ended December 31, 2023, we shipped more than 450,000 insulin pumps worldwide, which is representative of our global in-warranty installed customer base. Our ending estimated worldwide installed customer base increased approximately 7% year over year.

Over 310,000 pumps were shipped to customers in the United States in the four-year period ended December 31, 2023, which is representative of our U.S. installed customer base.

We shipped approximately 140,000 pumps outside the United States in the four-year period ended December 31, 2023 and our products are now available in approximately 25 countries. The ordering patterns of, and levels of inventory carried by, our distributors outside the United States for pumps and supplies have historically been highly variable from period to period due to a number of factors, including summer vacations, the timing of product launches into new geographies and variability due to supply chain logistics, particularly during the global pandemic. This also influences the timing in which renewal eligibility begins for existing customers, which may not initially be consistent with trends in the U.S. market. We recently began completing a full four-year reimbursement cycle in an increasing number of our markets outside of the United States.

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 and Actions

- Sales of new products are subject to local government regulations. The requirements and timelines to receive regulatory clearance can vary substantially from country to country and delays may impact our ability to expand

our worldwide customer base and bring products to market in a competitive timeframe. These delays, or failure to receive regulatory approval could adversely impact our revenue and results of operations.

- Any adverse event involving any products that we distribute could result in future corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any action by regulatory bodies against us, and any regulatory challenges we encounter could have a negative impact on our product sales and harm our reputation.

Product - Launches and Reimbursement

- We expect our business to be impacted by the introduction of new diabetes devices and treatments by us or our competitors. The success of our products is variable and we believe it correlates to market acceptance, anticipated product launches and commercial availability. We anticipate that our Tandem Choice program, and its related financial and accounting impact, may continue to materially impact our business until the conclusion of the program.

- We have historically experienced higher net sales in our third and fourth quarters compared to the first half of the year. We believe our July 2023 announcement of FDA clearance of Tandem Mobi and its anticipated launch impacted the timing of purchasing decisions by our current and prospective customers in the second half of 2023 up through the U.S. commercial availability of Tandem Mobi in February 2024, resulting in delays that were unlike historical seasonal patterns or purchasing behaviors. Regulatory approval and/or upcoming launches of other new Tandem or competitor products could also adversely impact timing of purchasing decisions.

- In periods following new product launches, particularly with new hardware platforms, our cost of sales may increase on a per unit basis until the new products achieve manufacturing scale and operating expenses may be elevated by increased sales and marketing spend to support the product launches.

- 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, as well as changes in reimbursement structures.

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. For example, we began operations of a European distribution center beginning in the third quarter of 2022, which led to downward adjustments of inventory levels at our distributors starting in late 2022 and continuing through the first half of 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 typically 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, as well as the anticipated launch of new products.

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.

- High inflation and the effects of other macroeconomic factors and concerns have continued to disrupt our relationships with suppliers, third-party manufacturers, healthcare providers, distributors and our existing or potential customers. We are experiencing higher costs as we navigate these global macroeconomic 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 has been our flagship pump platform. Our other products include single-use insulin cartridges and infusion sets, as well as our complementary t:connect, TDU and mobile application products. Our primary customers are the end users of 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 reflect in a significant decline in pump shipments from any fourth quarter to the following first quarter. Therefore, the lowest percentage of sales is typically reported in the first quarter of each calendar year and the highest percentage is typically reported in the fourth quarter. See also "Trends and Uncertainties Impacting Financial Results—Seasonality" above.

In September 2022, we began offering the Tandem Choice program to eligible t:slim X2 customers to provide a pathway to ownership of our newest hardware platform, Tandem Mobi, for a fee when available. Tandem Choice expires on December 31, 2024. The accounting treatment for Tandem Choice is complex (see Note 2, "Summary of Significant Accounting Policies"). Initially, the program requires the deferral of some portion of sales for shipments of eligible pumps, which began 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, Tandem Mobi, we will recognize the existing deferral, incremental fees received and the associated costs of providing the new hardware, Tandem Mobi, 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 remainder of the Tandem Choice period.

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 earned on our cash equivalents and short-term investments, foreign currency transaction gains and losses, and interest expense which includes the amortization of debt issuance costs related to our 1.50% Convertible Senior Notes due May 2025 (Notes).

In October 2023, we were notified that additional interest beyond the 1.50% per annum had been accruing on the Notes since May 2021, pursuant to the terms of the indenture. The additional accrued interest of $3.3 million was fully paid in November 2023 (see Note 7, "Debt").

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

	Year Ended December 31,		
(in thousands, except percentages)	**2023**	**2022**	**2021**
Sales:			
United States	$ 554,878	$ 588,765	$ 524,907
Outside the United States	192,840	212,452	177,892
Total sales	747,718	801,217	702,799
Cost of sales	380,028	388,231	326,584
Gross profit	367,690	412,986	376,215
Gross margin	49 %	52 %	54 %
Operating expenses:			
Selling, general and administrative	352,503	335,681	261,508
Research and development	169,667	139,114	92,054
Acquired in-process research and development	78,750	31,039	—
Total operating expenses	600,920	505,834	353,562
Operating income (loss)	(233,230)	(92,848)	22,653
Other income (expense), net:			
Interest income and other, net	22,858	6,057	674
Interest expense	(9,882)	(6,208)	(6,040)
Change in fair value of common stock warrants	—	147	(1,386)
Total other income (expense), net	12,976	(4)	(6,752)
Income (loss) before income taxes	(220,254)	(92,852)	15,901
Income tax expense	2,357	1,742	335
Net income (loss)	$ (222,611)	$ (94,594)	$ 15,566

Comparison of Years Ended December 31, 2023 and 2022

Sales

For the year ended December 31, 2023, sales were $747.7 million, which included $192.8 million of sales outside the United States. For the year ended December 31, 2023, we deferred $25.1 million of pump sales as the result of our Tandem Choice program which launched in the United States in the third quarter of 2022. In addition, for the year ended December 31, 2023, we recorded a reduction to sales of $8.5 million for a new rebate structure implemented in a market outside of the United States. For the year ended December 31, 2022, sales were $801.2 million, which included $212.5 million of sales outside the United States, and we deferred $3.5 million of pump sales as a result of our Tandem Choice program.

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

	Year Ended December 31,		
	2023	2022	% Change
Pumps shipped	74,000	84,000	(12)%
Sales:			
Pump	$ 289,546	$ 329,061	(12)%
Supplies and other	290,439	263,253	10%
Deferral for Tandem Choice program	(25,107)	(3,549)	607%
Total Sales in the United States	$ 554,878	$ 588,765	(6)%

Pump sales in the United States were $289.5 million for the year ended December 31, 2023 compared to $329.1 million for the year ended December 31, 2022, as pump shipments decreased 12% compared to the year ended December 31, 2022. Throughout 2023, we faced challenging marketplace dynamics and economic conditions, with inflation and the threat of recession impacting pump purchasing decisions. Additionally, we believe the anticipation of the full release of new CGM sensor integrations with t:slim X2 and the FDA clearance of Tandem Mobi in July 2023 impacted the timing of purchasing decisions for those offerings, resulting in some customers delaying current purchases until commercial availability of these products in future periods. Sales of pump-related supplies increased primarily due to a 7% year-over-year increase in our ending estimated installed base of customers in the United States. Sales to distributors accounted for 64% and 65% of our total sales in the United States for the years ended December 31, 2023 and 2022, respectively.

Sales in the United States for the years ended December 31, 2023 and 2022 were reduced by a deferral of $25.1 million and $3.5 million, respectively, as the result of our Tandem Choice program which launched in September of 2022. The increase in the sales deferral for Tandem Choice in 2023 as compared to 2022 was primarily related to a reduction in the Tandem Choice program price. This change became effective in the third quarter of 2023, resulting in an increase to our estimate of the future customer participation rate and, therefore, a higher deferral per pump sold, coupled with the Tandem Choice program being in effect for the entire year of 2023.

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

	Year Ended December 31,		
	2023	2022	% Change
Pumps shipped	30,000	44,000	(32)%
Sales:			
Pump	$ 84,748	$ 102,846	(18)%
Pump rebate	(8,452)	—	—%
Supplies and other	116,544	109,606	6%
Total Sales Outside the United States	$ 192,840	$ 212,452	(9)%

Pump sales outside the United States were $76.3 million for the year ended December 31, 2023, compared to $102.8 million in the prior year. We began operations of a centralized European distribution center in late 2022. This resulted in a material disruption to distributor ordering patterns in the first half of 2023 as affected distributors reduced their pump and supply inventory levels to adjust for the reduced transit time. As a result, pump shipments decreased 32% compared to the year ended December 31, 2022. The year-over-year changes in pump and supply shipments were not directly correlated with actual customer demand. The decrease in pump sales was partially offset by an increase in average selling prices due primarily to geographical mix. Pump sales outside the United States also included a reduction to sales of $8.5 million for a new rebate structure implemented in a single market. Sales to distributors accounted for 99% and 96% of our total sales outside the United States for the years ended December 31, 2023 and 2022, respectively.

Cost of Sales and Gross Profit

Our cost of sales for the year ended December 31, 2023 was $380.0 million, resulting in gross profit of $367.7 million, compared to cost of sales of $388.2 million and gross profit of $413.0 million for the year ended December 31, 2022. The gross margin for 2023 was 49%, compared to 52% in 2022.

The decrease in our gross profit for the year ended December 31, 2023 was primarily the result of the $53.5 million decrease in total sales, driven by lower pump shipments and an increase in sales deferral related to the Tandem Choice Program. Amounts deferred were $25.1 million and $3.5 million for the years ended December 31, 2023 and 2022, respectively. This deferral reduced gross margin by approximately two percentage points in 2023, but had negligible impact in 2022. The impact on gross margin from our Tandem Choice program will fluctuate through the expiration of the program based on the timing of availability of Tandem Mobi and the number of eligible customers who ultimately elect to participate. In addition, the sales rebate of $8.5 million also negatively impacted gross margin by nearly one percentage point.

Gross margin benefited from progress in underlying fundamentals, including lower material cost, an increase in average selling prices and manufacturing efficiencies, as well as leverage of fixed overhead. These benefits were offset by the impact of product and geographical mix. Pump sales, which have the highest gross margin, were 46% of total worldwide sales, excluding the impact of Tandem Choice in 2023, compared to 53% in 2022.

Operating Expenses

Our operating expenses for the year ended December 31, 2023 were $600.9 million, compared to $505.8 million for the year ended December 31, 2022. A significant portion of the increase was driven by certain unique or non-recurring transactions. In 2023, we incurred $78.8 million of acquired in-process research and development expenses in connection with our acquisition of AMF Medical, compared to $31.0 million of acquired IPR&D expenses in connection with our acquisition of Capillary Biomedical in 2022 (see Note 12, “Acquisitions”). Additionally, personnel and discretionary spending attributable to these acquisitions, in both SG&A and R&D, was $22.4 million in 2023 and $3.3 million in 2022. As a part of continued operating efficiency measures in 2023 and 2022, we incurred non-recurring operating lease impairment charges in SG&A of $14.1 million and $12.4 million, respectively, from a facilities consolidation (see Note 6, “Leases”). In 2023, we also incurred employee severance costs of $2.7 million.

Selling, General and Administrative Expenses. SG&A expenses increased 5% to $352.5 million for the year ended December 31, 2023, from $335.7 million for the same period in 2022. Employee-related expenses for our SG&A functions comprise the majority of SG&A expenses. Excluding the severance costs described above, the remaining increase of $11.9 million in salaries, incentive compensation, and other employee benefits was primarily the result of continued support services for our growing installed customer base. We also experienced a $2.8 million increase in other non-employee discretionary spending, primarily attributable to outside consulting, outside services, and travel, in addition to the impact of facilities consolidation charges described above.

Research and Development Expenses. R&D expenses increased 22% to $169.7 million for the year ended December 31, 2023, from $139.1 million for the same period in 2022. The increase in R&D expenses was primarily the result of a $23.0 million increase in salaries and related benefits due to our acquisitions, as well as an increase in personnel to support our product development efforts. We also experienced a $7.5 million increase in other non-employee discretionary spending, including equipment and supplies costs, clinical trial expenses, and information technology costs attributable to R&D.

Acquired In-Process Research and Development Expenses. Acquired IPR&D expenses of $78.8 million for the year ended December 31, 2023 represented the value of assets acquired, and acquisition-related expenses, in connection with our acquisition of AMF Medical (see Note 12, “Acquisitions”). Acquired IPR&D expenses of $31.0 million for the year ended December 31, 2022 represented the value of assets acquired, and acquisition-related expenses in connection with our acquisition of Capillary Biomedical.

Other Income (Expense), Net

Total other income, net for the year ended December 31, 2023 was $13.0 million, compared to expense of $4,000 in 2022. Other income, net for 2023 primarily consisted of $21.2 million of interest income earned on our cash equivalents and short-term investments, and $1.5 million in foreign currency transaction gains, partially offset by $9.9 million of interest expense which included $3.3 million of additional interest as discussed above and the amortization of debt issuance costs related to our Convertible Senior Notes. Other expense, net for 2022 consisted primarily of $6.2 million of interest expense related to our Convertible Senior Notes, offset by $6.1 million of interest income earned on our cash equivalents and short-term investments. Interest income increased in 2023 primarily due to the higher interest rate environment as compared to 2022.

Income Tax Expense

We recognized income tax expense of $2.4 million on a pre-tax loss of $220.3 million for the year ended December 31, 2023, compared to income tax expense of $1.7 million on a pre-tax loss of $92.9 million for the year ended December 31, 2022. Income tax expense for the years ended December 31, 2023 and 2022 was primarily attributable to federal, state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

Liquidity and Capital Resources

At December 31, 2023, we had $467.9 million in cash and cash equivalents and short-term investments. We believe that our cash and cash equivalents, short-term investments, and future cash flows from operations will be sufficient to fund our ongoing core business activities for at least the next 12 months.

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.

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. We expect to rely on these sources of cash, primarily from product sales, to fund our material cash requirements in both the short and long term.

The following table shows a summary of our cash flows for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Net cash provided by (used in):			
Operating activities	$ (31,810)	$ 50,464	$ 111,359
Investing activities	(85,740)	33,168	(186,876)
Financing activities	4,113	16,877	51,932
Effect of foreign exchange rate changes on cash	(212)	827	153
Net increase (decrease) in cash and cash equivalents	$ (113,649)	$ 101,336	$ (23,432)

Operating activities. Net cash used in operating activities was $31.8 million for the year ended December 31, 2023, compared to cash provided by operating activities of $50.5 million and $111.4 million, respectively, for the years ended December 31, 2022 and 2021. The reduction in net cash provided by operating activities for 2023 compared to 2022 was primarily a result of the $128.0 million increase in net loss, offset by increase of $58.8 million net non-cash adjustments. Net non-cash adjustments were primarily related to acquired in-process research and development expenses, operating lease termination and impairment charges and stock-based compensation expense. In addition, a net decrease of $17.7 million in changes of working capital balances. Changes of working capital balances primarily consisted of increases in inventories, prepaid and other current assets, and deferred revenue. Inventories increased to $157.9 million at December 31, 2023 from $111.1 million at December 31, 2022, primarily due to a return to target stocking levels post-pandemic as supply chain constraints subsided, as well as the scaling up of inventory to meet anticipated demand for Tandem Mobi.

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.

Investing activities. Net cash used in investing activities was $85.7 million for the year ended December 31, 2023, which primarily consisted of $69.5 million cash paid for the acquisition of AMF Medical, including transaction costs (see Note 12, "Acquisitions"), $26.8 million in purchases of property and equipment of which $8.7 million was associated with improvements to the now completed new Headquarters lease facility (see Note 6, "Leases"), and $24.8 million cash paid for purchases of intangible assets and strategic investments, offset by $35.4 million provided by short-term investments activity as proceeds from maturities and redemptions exceeded purchases. Net cash provided by investing activities was $33.2 million for the year ended December 31, 2022, which primarily consisted of $101.8 million provided by short-term investments activity as proceeds from maturities and redemptions exceeded purchases, offset by $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 primarily consisted of $163.4 million used by short-term investments activity as purchases exceeded maturities and redemptions, $14.2 million in purchases of property and equipment, and $9.3 million cash paid for purchases of intangible assets and strategic investments.

Financing activities. Net cash provided by financing activities was $4.1 million for the year ended December 31, 2023, which primarily consisted of proceeds from the issuance of common stock under our stock plans, net of payments for related tax withholdings. Net cash provided by financing activities was $16.9 million and $51.9 million, respectively, for the years ended December 31, 2022 and 2021, which primarily consisted of proceeds from the issuance of common stock under our stock plans, net of payments for related tax withholdings. The reduction in proceeds from the issuance of common stock under our stock plans was primarily due to the decrease in the market price of our common stock and fewer employee stock options exercised.

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;
- contractual debt obligations, including periodic interest payments;
- 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, including contingent earnout payments that become payable upon the achievement of certain milestones;
- 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;
- payments under licensing, development and commercialization agreements; and

- integration costs related to acquisitions 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 on May 1 and November 1 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 before the maturity date.

Cash payments due by calendar year for our Convertible Senior Notes at December 31, 2023, are as follows (in thousands):

	Total	2024	2025
Principal amount of convertible senior notes[(1)]	$ 287,500	$ —	$ 287,500
Contractual interest	6,469	4,313	2,156
Total	$ 293,969	$ 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.

We may from time to time seek to retire or purchase our outstanding debt, including the Notes, through cash purchases and/or exchanges for equity securities, in open market purchases, privately negotiated transactions or otherwise. Such repurchases or exchanges, if any, will depend on prevailing market conditions, our liquidity requirements, contractual restrictions, and other factors. The amounts involved in any such transactions, individually or in the aggregate, may be material.

Promissory Note Payable

In connection with our acquisition of Capillary Biomedical, Inc. (see Note 12, "Acquisitions"), we assumed a $4.7 million promissory note payable. The promissory note accrues interest at the rate of 5% per year, and becomes due and payable upon the first sale or license of the commercialized product. At December 31, 2023, $4.7 million was included as a component of other long-term liabilities on the consolidated balance sheet.

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, single-use 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 and rebates. 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, Tandem Source 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 or pump platform 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, 2022 to determine whether our net operating losses and credits are likely to be limited by Section 382. Based on this study, 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.

Critical Accounting Policies

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 of America (U.S. GAAP). The preparation of these consolidated financial statements requires management to make estimates and judgments, which present a significant level of estimation uncertainty and that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements and accompanying notes as of the date of the 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 from these estimates and have a material impact on our financial condition and results of operations.

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, 2023, 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, 2023, 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 12, “Acquisitions” 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 two years following the acquisition, 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, 2023, we are party to a standby letter of credit arrangement in support of certain operating lease obligations (See Note 13 "Commitments and Contingencies" to the consolidated financial statements in Part II, Item 8 of this Annual Report).

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 investment portfolio. We review our 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, 2023 were primarily due to an increase in market interest rates after certain debt securities were purchased. Based on the credit quality of the available-for-sale debt securities 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 a significant impact on the realized value of our investment portfolio. A hypothetical 100 basis-point (one percentage point) increase or decrease in interest rates compared to actual rates at December 31, 2023, would have affected the estimated fair value of our investments portfolio by approximately $3.6 million.

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 related to 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, a distribution center in the Netherlands and, beginning in 2023, a research and development facility in Switzerland associated with the acquisition of AMF Medical. Our sales to customers in the United States are made in U.S. dollars. Sales from our distribution center in the Netherlands are made to independent distributors under agreements denominated in Euros, and our sales in Canada are denominated in Canadian dollars. Approximately 20% of our revenue was denominated in foreign currencies for the year ended December 31, 2023. In addition, we purchase certain inventory from a third-party contract manufacturer located in Mexico. We believe our exposure to foreign currency rate fluctuations is primarily related to our operations in Europe and Canada, and acquisition related contingent earnout payments (see Note 12, "Acquisitions"), where fluctuations in the rate of exchange between the U.S. dollar and the local currency could adversely affect our financial results, including income and losses as well as assets and liabilities.

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 have foreign currency exchange risk related to existing assets and liabilities, certain inventory purchase agreements, other 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, 2023 and 2022 and for each of the three years in the period ended December 31, 2023, 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, 2023 and 2022, 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, 2023 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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, 2023, 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 21, 2024 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 Expected Replacement Rates

Description of the Matter	As discussed in Note 2 to the consolidated financial statements, the Company has a warranty reserve of $37.2 million. The Company accrues for costs related to the warranty reserve liability at the time of shipment. Warranty costs are estimated primarily based on the expected replacement rates utilizing historical experience. Auditing management's expected replacement rates on pumps was complex as it required a significant level of effort due to the amount of data utilized in determining the expected replacement rates. Management's estimate considers historical claims experience and the assumption of historical data predictive of future activity and events, in particular, the number of historical periods used and the weighing of historical data. It is possible that the future replacement rates may not be reflective of historical product replacement rates and changes in this assumption could have a material impact on the Company's estimated 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 process. Specifically, we tested controls over management's review and calculation of the expected replacement rates, including controls over the accuracy and completeness of data used. To test the Company's expected replacement rates we performed audit procedures that included, among others, testing the completeness and accuracy of the underlying data used in the calculation. We involved our data science professionals to evaluate the methodologies and assumptions and test the calculations used by the Company. We recalculated the warranty expected replacement rates using historical data. We performed sensitivity analyses of the expected replacement rates assumption to evaluate the impact of changes in the warranty reserve.

/s/ Ernst & Young LLP

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

San Diego, California
February 21, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 58,868	$ 172,517
Short-term investments	409,044	444,384
Accounts receivable, net	105,555	114,717
Inventories	157,937	111,117
Prepaid and other current assets	16,585	7,241
Total current assets	747,989	849,976
Property and equipment, net	76,542	68,552
Operating lease right-of-use assets	87,791	110,626
Other long-term assets	40,336	23,631
Total assets	$ 952,658	$ 1,052,785
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 49,586	$ 55,730
Accrued expenses	12,726	9,595
Employee-related liabilities	43,430	38,682
Operating lease liabilities	17,060	13,121
Deferred revenue	43,994	18,837
Other current liabilities	28,462	29,325
Total current liabilities	195,258	165,290
Convertible senior notes, net - long-term	285,035	283,232
Operating lease liabilities - long-term	113,572	123,524
Deferred revenue - long-term	13,331	16,874
Other long-term liabilities	31,830	23,918
Total liabilities	639,026	612,838
Commitments and contingencies (Note 13)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 65,552 and 64,513 shares issued and outstanding at December 31, 2023 and 2022, respectively.	66	65
Additional paid-in capital	1,263,997	1,170,888
Accumulated other comprehensive income (loss)	1,369	(1,817)
Accumulated deficit	(951,800)	(729,189)
Total stockholders' equity	313,632	439,947
Total liabilities and stockholders' equity	$ 952,658	$ 1,052,785

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,		
	2023	**2022**	**2021**
Sales	$ 747,718	$ 801,217	$ 702,799
Cost of sales	380,028	388,231	326,584
Gross profit	367,690	412,986	376,215
Operating expenses:			
Selling, general and administrative	352,503	335,681	261,508
Research and development	169,667	139,114	92,054
Acquired in-process research and development expenses	78,750	31,039	—
Total operating expenses	600,920	505,834	353,562
Operating income (loss)	(233,230)	(92,848)	22,653
Other income (expense), net:			
Interest income and other, net	22,858	6,057	674
Interest expense	(9,882)	(6,208)	(6,040)
Change in fair value of common stock warrants	—	147	(1,386)
Total other income (expense), net	12,976	(4)	(6,752)
Income (loss) before income taxes	(220,254)	(92,852)	15,901
Income tax expense	2,357	1,742	335
Net income (loss)	$ (222,611)	$ (94,594)	$ 15,566
Other comprehensive income (loss):			
Unrealized gain (loss) on short-term investments	$ 3,606	$ (2,233)	$ (693)
Foreign currency translation gains (losses)	(420)	1,032	(143)
Comprehensive income (loss)	$ (219,425)	$ (95,795)	$ 14,730
Net income (loss) per share - basic	$ (3.43)	$ (1.47)	$ 0.25
Net income (loss) per share - diluted	$ (3.43)	$ (1.47)	$ 0.24
Weighted average shares used to compute basic net income (loss) per share	64,969	64,146	63,000
Weighted average shares used to compute diluted net income (loss) per share	64,969	64,146	64,349

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

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

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 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
Exercise of stock options	73	—	1,295	—	—	1,295
Vesting of restricted stock units, net of shares withheld for taxes	467	—	(7,790)	—	—	(7,790)
Issuance of common stock under Employee Stock Purchase Plan	499	1	10,678	—	—	10,679
Stock-based compensation expense	—	—	88,926	—	—	88,926
Unrealized gain on short-term investments	—	—	—	3,606	—	3,606
Foreign currency translation losses	—	—	—	(420)	—	(420)
Net loss	—	—	—	—	(222,611)	(222,611)
Balance at December 31, 2023	65,552	$ 66	$ 1,263,997	$ 1,369	$ (951,800)	$ 313,632

(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,		
	2023	**2022**	**2021**
Operating Activities			
Net income (loss)	$ (222,611)	$ (94,594)	$ 15,566
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization expense	15,715	14,330	13,845
Amortization of debt issuance costs	2,204	1,896	1,727
Provision for expected credit losses	5,540	4,782	2,333
Operating lease termination and impairment charges	14,099	7,567	—
Amortization of premium on short-term investments	3,587	4,187	365
Stock-based compensation expense	88,076	84,918	60,752
Acquired in-process research and development expenses	78,750	31,039	—
Other	515	988	2,399
Changes in operating assets and liabilities:			
Accounts receivable, net	4,277	(7,830)	(30,980)
Inventories	(46,053)	(42,452)	(4,954)
Prepaid and other current assets	(9,139)	(58)	(1,570)
Other long-term assets	(3,187)	(1,207)	1,313
Accounts payable	(4,864)	24,493	10,275
Accrued expenses	2,537	(461)	4,640
Employee-related liabilities	5,167	(12,869)	17,399
Deferred revenue	21,525	8,358	10,611
Operating leases and other current liabilities	4,302	25,445	6,217
Other long-term liabilities	7,750	1,932	1,421
Net cash provided by (used in) operating activities	(31,810)	50,464	111,359
Investing Activities			
Purchases of short-term investments	(510,859)	(467,652)	(733,388)
Proceeds from maturities and redemptions of short-term investments	546,218	569,492	570,023
Purchases of property and equipment	(26,804)	(34,097)	(14,180)
Acquisitions, including in-process research and development, net of cash acquired	(69,496)	(25,720)	—
Purchases of intangible assets and strategic investments	(24,799)	(8,855)	(9,331)
Net cash used in investing activities	(85,740)	33,168	(186,876)
Financing Activities			
Proceeds from issuance of common stock under Company stock plans, net	4,184	17,469	51,340
Proceeds from exercise of common stock warrants	—	83	592
Other financing activities	(71)	(675)	—
Net cash provided by financing activities	4,113	16,877	51,932
Effect of foreign exchange rate changes on cash	(212)	827	153
Net increase (decrease) in cash and cash equivalents	(113,649)	101,336	(23,432)
Cash and cash equivalents at beginning of period	172,517	71,181	94,613
Cash and cash equivalents at end of period	$ 58,868	$ 172,517	$ 71,181
Supplemental disclosures of cash flow information			
Interest paid	$ 7,565	$ 4,313	$ 4,313
Income taxes paid	$ 1,923	$ 411	$ 260
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
Purchases of property and equipment included in accounts payable	$ 2,946	$ 4,237	$ 1,034
Intangible costs in accounts payable	$ —	$ 515	$ 1,029

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.

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 have been principally focused on the t:slim X2 Insulin Delivery System (t:slim X2), which has been the Company's flagship pump platform and 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. In February 2024, the Company expanded its pump portfolio with the U.S. launch of Tandem Mobi. The Company's insulin pump products are compatible with other complementary digital health offerings, such as the mobile application, cloud-based diabetes management applications and the Tandem Device Updater, a Mac- and PC-compatible tool that 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 single-use 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, Netherlands, and Switzerland. 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

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, 2023, except for adding the accounting policy for sales rebates, which is 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.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and employee-related liabilities are reasonable estimates of their fair values because of the short-term nature of these assets and liabilities. Short-term investments are carried at fair value.

The Company'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 $271.7 million and $260.5 million at December 31, 2023 and 2022, respectively, based on Level 2 quoted market prices as of those dates.

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, 2023, 2022 and 2021.

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 customer-related risks, review of outstanding invoices, forecasts about the future, and various other assumptions and estimates that are believed to be reasonable under the circumstances, including changes to credit risks as a result of 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,	
	2023	2022	2021	2023	2022
Distributor B	12.2 %	11.6 %	11.9 %	10.0 %	12.8 %
Distributor C	*	*	*	10.5 %	*
Distributor D	*	*	*	10.6 %	10.4 %
Distributor E	10.8 %	14.4 %	14.0 %	11.5 %	16.2 %

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

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 (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 are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recognized over their estimated useful lives on a straight-line basis. The Company did not recognize any intangible asset impairment losses during the years ended December 31, 2023, 2022 and 2021.

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 and related leasehold improvements and furniture and fixtures recognized in 2023 and 2022 (see Note 6, "Leases"), there were no impairments of long-lived assets, including acquired intangible assets, during the years ended December 31, 2023, 2022 and 2021.

Strategic Investments

The Company held equity investments totaling $10.1 million and $16.4 million in two separate private companies at December 31, 2023 and 2022, respectively, each of which represented less than 5% of the outstanding equity of the respective company as of the date of investment. The investments are carried at cost minus impairment, if any, adjusted for changes in observable prices. The Company monitors these investments 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. The investments were included as a component of other long-term assets on the consolidated balance sheets at December 31, 2023 and 2022.

In November 2023, the Company made an additional investment of approximately $22.3 million in subordinated convertible notes of one of its private investee companies. The subordinated notes are convertible into equity of the private company upon certain qualifying events, including at their final maturity in 2024. The subordinated convertible notes are non-interest bearing, and are only repayable before conversion into equity upon a change in control of the private company. At December 31, 2023, the $22.3 million subordinated convertible notes investment was included as a component of other long-term assets on the consolidated balance sheet.

Revenue Recognition

Revenue is generated primarily from sales of insulin pumps, single-use 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 rebates and returns.

Revenue Recognition for Arrangements with Multiple Performance Obligations

The Company considers the individual deliverables in its product offering to be 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, Tandem Source 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.

Revenue Recognition for Tandem Choice Program

In September 2022, the Company launched a new technology access program referred to as Tandem Choice, that provides eligible, in-warranty t:slim X2 customers in the United States with the flexibility to obtain the newest hardware platform, Tandem Mobi, when it becomes commercially available. Participating customers have the right to purchase the alternative Tandem pump for a fee, referred to as Choice Right. Tandem Choice expires on December 31, 2024. The program was determined to create a material right for which a portion of each t:slim X2 pump transaction price was allocated and deferred.

During the third and fourth quarters of 2023, the Company reduced the fee for the Tandem Choice program. The change in the program resulted in an increase to the amount of the transaction price allocated to the material right as the Company expects more customers to exercise the right as compared to the prior existing program price.

For purposes of evaluating 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 contemplated the likelihood that the respective option will be exercised. At December 31, 2023 and 2022, $30.6 million and $6.8 million, respectively, were allocated to the material right provided to customers and recorded in current deferred revenue on the consolidated balance sheets.

Sales Rebates

The Company is subject to certain rebates on pricing programs with managed care organizations, such as governmental and third-party commercial payors. The Company estimates provisions for rebates based on contractual arrangements, estimates of products sold subject to rebate, known events or trends and channel inventory data. At December 31, 2023, estimated sales rebates of $8.5 million were recorded on the consolidated balance sheet, of which $8.0 million was included in other long-term liabilities as the estimated payment due date was beyond twelve months from the balance sheet date. Accordingly, actual rebates paid may differ from estimated amounts recorded in the accompanying consolidated financial statements. The Company did not provide sales rebates before the fourth quarter of 2023.

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 $0.4 million and $0.5 million at December 31, 2023 and 2022, 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 single-use 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 using historical experience. Insulin pumps returned to the Company may be refurbished and redeployed. Experience has shown that initial data for any given pump version or pump platform 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 December 31, 2023, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Balance at beginning of the period	$ 36,537	$ 30,401	$ 22,075
Provision for warranties issued during the period	35,690	32,699	27,604
Settlements made during the period	(32,617)	(25,447)	(18,768)
Decreases in warranty estimates	(2,437)	(1,116)	(510)
Balance at end of the period	$ 37,173	$ 36,537	$ 30,401

As of December 31, 2023 and 2022, total product warranty reserves were included in the following consolidated balance sheet accounts (in thousands):

	December 31, 2023	December 31, 2022
Other current liabilities	$ 18,135	$ 17,280
Other long-term liabilities	19,038	19,257
Total warranty reserve	$ 37,173	$ 36,537

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 stock incentive plans, and the fair value of the employees' purchase rights under the Company's Employee Stock Purchase Plan (ESPP), using the Black-Scholes option pricing model on the date of grant. The Black-Scholes option pricing model requires the use of assumptions about a number of variables, including stock price volatility, expected term, dividend yield and risk-free interest rate (see Note 8, "Stockholders' Equity"). The fair value of restricted stock unit (RSU) awards issued under the Company's stock incentive plans 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 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 generally 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 incentive 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, 2023, 2022 and 2021, the numerator and denominator of the diluted net income (loss) per share computation were calculated as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Net income (loss) - basic and diluted	$ (222,611)	$ (94,594)	$ 15,566
Weighted average shares outstanding - basic	64,969	64,146	63,000
Dilutive common share equivalents:			
Options to purchase common stock	—	—	1,129
Unvested restricted stock units	—	—	62
Warrants to purchase common stock	—	—	157
Awards to be granted under the ESPP	—	—	1
Weighted average shares outstanding - diluted	64,969	64,146	64,349

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

	Year Ended December 31,		
	2023	2022	2021
Options to purchase common stock	135	1,138	3,124
Unvested restricted stock units	2,089	1,118	—
Warrants to purchase common stock	194	194	1
Awards granted under the ESPP	14	8	—
Convertible senior notes (if-converted)	2,554	2,554	2,554
	4,986	5,012	5,679

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, 2023 and 2022 (in thousands):

At December 31, 2023	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
U.S. Government-sponsored enterprises	$ 181,851	$ 518	$ (215)	$ 182,154
U.S. Treasury securities	114,714	318	(28)	115,004
Commercial paper	72,505	33	(27)	72,511
Corporate debt securities	39,225	156	(6)	39,375
Total	$ 408,295	$ 1,025	$ (276)	$ 409,044

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

The contractual maturities of available-for-sale debt securities as of December 31, 2023, were as follows (in thousands):

	Years to Maturity			
At December 31, 2023	Within One Year	One to Two Years	Two to Three Years	Estimated Fair Value
U.S. Government-sponsored enterprises	$ 86,875	$ 56,647	$ 38,632	$ 182,154
U.S. Treasury securities	74,214	40,790	—	115,004
Commercial paper	72,511	—	—	72,511
Corporate debt securities	12,620	26,755	—	39,375
Total	$ 246,220	$ 124,192	$ 38,632	$ 409,044

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, 2023 were primarily due to an increase in market interest rates after certain debt securities were purchased. 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, 2023 and 2022.

4. Composition of Certain Financial Statement Items

Accounts Receivable

Accounts receivable, net consisted of the following at December 31, 2023 and 2022 (in thousands):

	December 31, 2023	December 31, 2022
Accounts receivable	$ 110,453	$ 119,044
Less: allowance for credit losses	(4,898)	(4,327)
Accounts receivable, net	$ 105,555	$ 114,717

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, 2023, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Balance at beginning of the period	$ 4,327	$ 4,249	$ 3,857
Provision for expected credit losses	5,540	4,782	2,333
Write-offs and adjustments, net of recoveries	(4,969)	(4,704)	(1,941)
Balance at end of the period	$ 4,898	$ 4,327	$ 4,249

Inventories

Inventories consisted of the following at December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Raw materials	$ 42,783	$ 39,207
Work-in-process	44,026	18,571
Finished goods	71,128	53,339
Total inventories	$ 157,937	$ 111,117

Property and Equipment

Property and equipment, net consisted of the following at December 31, 2023 and 2022 (in thousands):

	December 31,	
	2023	2022
Leasehold improvements	$ 37,565	$ 35,828
Office furniture and equipment	11,842	13,772
Computer equipment and software	10,340	12,330
Manufacturing and scientific equipment	69,589	62,797
Total cost	129,336	124,727
Less: accumulated depreciation and amortization	(52,794)	(56,175)
Total property and equipment, net	$ 76,542	$ 68,552

Depreciation and amortization expense related to property and equipment was $13.8 million, $12.3 million, and $11.7 million for the years ended December 31, 2023, 2022 and 2021, 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, 2023 and 2022, which were included in other long-term assets on the consolidated balance sheets, were as follows (in thousands):

	December 31,	
	2023	2022
Intangible assets, gross amount	$ 12,502	$ 12,502
Accumulated amortization	(9,726)	(7,875)
Intangible assets, net	$ 2,776	$ 4,627
Weighted average remaining amortization period (in months)	18	30

Amortization expense related to intangible assets subject to amortization amounted to $1.9 million, $2.0 million and $2.2 million for the years ended December 31, 2023, 2022 and 2021, 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 future amortization expense is $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, 2023 and 2022, 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, 2023			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[(1)]	$ 48,033	$ 48,033	$ —	$ —
U.S. Government-sponsored enterprises	182,154	—	182,154	—
U.S. Treasury securities	115,004	115,004	—	—
Commercial paper	72,511	—	72,511	—
Corporate debt securities	39,375	—	39,375	—
Total assets	$ 457,077	$ 163,037	$ 294,040	$ —

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

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

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

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 and lease liabilities 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 (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.

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.

Headquarters Lease

In September 2021, the Company entered into a lease agreement for 181,949 square feet of general administrative, laboratory, and research and development office space (the Premises) located on High Bluff Drive in San Diego, California (Headquarters Lease). Possession of the Premises will 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 Headquarters Lease also includes a first right of offer with respect to an additional 16,154 rentable square feet of general office space at December 31, 2023, should the space become available.

The 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 (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 (Phase II Rent Commencement Date). The Headquarters 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 Headquarters Lease term was determined assuming the renewal options would not be exercised.

The initial base rent for the Headquarters 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.

In December 2023, the Company entered into an agreement to sublease the Phase II portion of the Premises under its Headquarters Lease from January 2025 through March 2029. Future minimum payments for base rent due under Phase II of the Headquarters Lease, net of sublease rent, are estimated to be $2.2 million in total for 2025 through 2028, and $23.2 million in total for 2029 through 2035.

Operating Lease Termination and Impairment Charges

In the second quarter of 2023, the Company began using Phase I of the Headquarters Lease for operations that previously occupied 77,458 square feet of leased space located on Roselle Street (Roselle leases) in San Diego, California. The Roselle leases expired in May 2023. Also in the second quarter of 2023, the Company relocated operations that occupied 73,929 square feet of leased space on Vista Sorrento Parkway in San Diego, California (Vista Sorrento Lease) to the new Headquarters Lease location.

During the second quarter of 2023, in connection with permanently ceasing use of the Vista Sorrento facility, the Company recorded a $14.1 million impairment charge as the carrying amount of the assets related to the Vista Sorrento Lease exceeded its fair value based on the Company's estimate of future discounted cash flows related to the leased facility. Estimates used to determine the present value of future cash flows over the remaining lease term included projected sublease income and a discount rate. The $14.1 million charge was comprised of an $11.2 million impairment of operating lease right-of-use assets and a $2.9 million write-off of fixed assets consisting primarily of leasehold improvements, and was recorded as a component of selling, general and administrative expenses in the consolidated statement of operations.

During the fourth quarter of 2022, the Company recorded $12.4 million of lease termination and impairment charges primarily related to its 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 was recorded as a component of selling, general and administrative expenses in the consolidated statement of operations.

Lease Costs

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

	Year Ended December 31,		
	2023	**2022**	**2021**
Operating lease cost	$ 15,971	$ 18,432	$ 8,627
Short-term lease cost	108	142	90
Loss on lease termination and right-of-use asset impairment charges	11,224	5,699	—
Total lease cost	$ 27,303	$ 24,273	$ 8,717

Lease Liabilities

Maturities of operating lease liabilities at December 31, 2023 were as follows (in thousands):

Years Ending December 31,	
2024	$ 17,065
2025	17,023
2026	17,068
2027	17,333
2028	13,840
Thereafter	90,004
Total undiscounted lease payments	172,333
Less: amount representing interest	(41,701)
Present value of operating lease liabilities	130,632
Less: current portion of operating lease liabilities	(17,060)
Operating lease liabilities - long-term	$ 113,572

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

	December 31, 2023	**December 31, 2022**
Weighted-average remaining lease term (in years)	10.2	10.8
Weighted-average discount rate used to determine operating lease liabilities	5.4 %	5.3 %

Lease Payments

Cash paid for amounts included in the measurement of lease liabilities, representing operating cash flows, were as follows (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Operating lease payments	$ 13,864	$ 11,960	$ 9,462
Operating lease termination payments	—	4,769	—
Total cash payments	$ 13,864	$ 16,729	$ 9,462

Leases For Which Accounting Has Not Yet Commenced

As of December 31, 2023, the Phase II Commencement Date for the Headquarters Lease had not yet occurred. Accordingly, the consolidated balance sheet at December 31, 2023 does not include operating lease right-of-use assets and operating lease liabilities, and the consolidated statements of operations for the years ended December 31, 2023, 2022 and 2021 do not include any lease costs, related to Phase II of the Headquarters Lease. In addition, the above disclosures of the Company's lease costs, maturities of operating lease liabilities, weighted-average remaining lease term, and weighted-average discount rate do not include any amounts related to Phase II of the Headquarters Lease. Because the incremental borrowing rate will not be available until the Phase II Commencement Date, which is currently estimated to occur in the first quarter of 2025, 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 completed an offering of $287.5 million aggregate principal amount of unsecured Convertible Senior Notes with a stated interest rate of 1.50% and a maturity date of May 1, 2025 (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 (Capped Call Transactions) discussed below.

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 before 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 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 before 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. Beginning January 1, 2021, the Notes have been 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, 2023	December 31, 2022
Principal amount	$ 287,500	$ 287,500
Unamortized debt issuance costs	(2,465)	(4,268)
Net carrying amount	$ 285,035	$ 283,232

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, 2023 and 2022, the if-converted value of the Notes did not exceed the principal amount.

As of December 31, 2023, the unamortized debt issuance costs of $2.5 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 1.3 years.

In October 2023, the Company was notified that additional interest beyond the 1.50% per annum had been accruing on the Notes since May 2021, pursuant to the terms of the indenture. This additional interest continued to accrue at a rate of 0.50% per annum on the outstanding principal amount of the Notes until November 2, 2023. The overdue unpaid interest itself accrued interest at a rate of 2.50% per annum. The Company paid all overdue amounts related to this matter in November 2023.

The following table details interest expense related to the Notes recognized for the years ended December 31, 2023, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Contractual interest expense[(1)]	$ 7,565	$ 4,313	$ 4,313
Amortization of debt issuance costs	1,803	1,896	1,727
Total interest expense	$ 9,368	$ 6,209	$ 6,040

(1) Contractual interest expense for the year ended December 31, 2023 includes $3.3 million of additional interest as discussed above.

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

In the second quarter of 2022, the Company entered into a three-year Revolving Line of Credit Agreement that provided the Company with a maximum principal borrowing amount of $100.0 million (Line of Credit), reduced by any letters of credit issued and outstanding under a $15.0 million letter of credit sub-limit. On August 2, 2023, the Revolving Line of Credit Agreement was amended to reduce the maximum principal borrowing amount to $50.0 million for the remainder of the term, limited to a percentage of eligible accounts receivable during the third quarter of 2023.

The Company terminated the Revolving Line of Credit Agreement in January 2024, with no borrowings made thereunder.

Promissory Note Payable

In connection with the acquisition of Capillary Biomedical, Inc. (see Note 12, "Acquisitions"), the Company assumed a $4.7 million promissory note payable. The promissory note accrues interest at the rate of 5.0% per year, and becomes due and payable upon the first sale or license of the commercialized product. At December 31, 2023 and 2022, the loan balance of $4.7 million was included as a component of other long-term liabilities on the consolidated balance sheets.

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, 2023 (in thousands):

Shares reserved for issuance upon conversion of Convertible Senior Notes	2,554
Shares underlying outstanding warrants	194
Shares underlying outstanding stock options	3,896
Shares underlying unvested restricted stock units	3,176
Shares authorized for issuance pursuant to awards granted under the ESPP	454
Shares authorized for future equity award grants	702
Total	10,976

Common Stock Warrants

Warrants outstanding to purchase shares of the Company's common stock as of December 31, 2023 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 common stock at the per share exercise price of the warrant.

Stock Incentive Plans

In May 2023, the Company's stockholders approved the 2023 Long-Term Incentive Plan (2023 Plan), under which 2,602,184 shares of common stock were initially reserved for issuance. Under the 2023 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. The 2023 Plan replaced the Company's Amended and Restated 2013 Stock Incentive Plan (2013 Plan), and no further equity awards will be granted under the 2013 Plan.

Stock Options

The maximum term of stock options granted under the Company's active plans is ten years. 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 under the Company's stock incentive plans:

	Total Stock Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
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
Granted	—	$ —		
Exercised	(72,536)	$ 17.86		$ 1,400
Canceled/forfeited/expired	(473,773)	$ 90.14		$ 95
Outstanding at December 31, 2023	3,896,004	$ 54.79	5.30	$ 11,703
Vested and expected to vest at December 31, 2023	3,890,496	$ 54.75	5.30	$ 11,703
Exercisable at December 31, 2023	3,675,678	$ 53.11	5.19	$ 11,703

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 continuous 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 continuous 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 110,074, 53,662 and 25,674 performance-based RSUs during the years ended December 31, 2023, 2022 and 2021, respectively. The Company estimated the fair value of performance-based RSUs at the date of grant using the intrinsic value method and the probability that the specified performance metrics will be met. These awards vest upon the Company's actual performance relative to predefined performance metrics and subject to the awardee's continuous service through the respective December 31, 2024 and 2025 measurement dates as defined in the award agreements. For certain performance-based RSUs with market-based criteria, the Company used a Monte Carlo methodology to estimate the fair value at the date of grant.

The following table summarizes RSU activities, which includes performance-based RSUs, for the Company's stock incentive plans:

	Total RSUs	Weighted-Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
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
Granted	2,359,907	$ 28.13	
Vested	(735,155)	$ 73.17	
Canceled/forfeited	(282,425)	$ 59.17	
Unvested awards outstanding at December 31, 2023	3,176,159	$ 40.61	$ 93,951
Awards expected to vest at December 31, 2023	3,088,745	$ 40.50	$ 91,365

The aggregate fair value of RSUs that vested during the years ended December 31, 2023, 2022 and 2021 was $21.2 million, $12.7 million, and $5.1 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

The Company's Employee Stock Purchase Plan (ESPP) was approved by the Board in October 2013. The ESPP 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, offerings under the ESPP consist of a two-year offering period with four six-month purchase periods which begin in May and November of each year.

During the years ended December 31, 2023, 2022 and 2021, 499,431, 262,936 and 172,694 shares of our common stock, respectively, were purchased under the ESPP for proceeds of $10.7 million, $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,		
	2023	2022	2021
Cost of sales	$ 6,212	$ 7,685	$ 6,434
Selling, general and administrative	56,304	57,196	43,567
Research and development	25,561	20,037	10,751
Total stock-based compensation expense	$ 88,077	$ 84,918	$ 60,752

The total stock-based compensation expense capitalized as part of the cost of the Company's inventories was $2.0 million at December 31, 2023, and $1.1 million at December 31, 2022.

At December 31, 2023, the total unamortized stock-based compensation expense of approximately $116.7 million will be recognized over the remaining weighted average vesting term of approximately 1.9 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,		
	2023	2022	2021
Weighted average grant date fair value (per share)	N/A	$ 42.16	$ 56.89
Risk-free interest rate	N/A	2.7 %	1.0 %
Dividend yield	N/A	0.0 %	0.0 %
Expected volatility	N/A	72.0 %	75.1 %
Expected term (in years)	N/A	5.8	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,		
	2023	2022	2021
Weighted average grant date fair value (per share)	$ 10.35	$ 21.89	$ 38.19
Risk-free interest rate	4.9 %	3.4 %	0.2 %
Dividend yield	0.0 %	0.0 %	0.0 %
Expected volatility	63.9 %	56.9 %	44.2 %
Expected term (in years)	1.3	1.3	1.3

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

Expected Dividend Yield. The 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 cost recognized by the Company for the 401(k) plan was $4.2 million and $4.2 million, respectively, for the years ended December 31, 2023 and 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,		
	2023	2022	2021
United States	$ (135,411)	$ (94,033)	$ 15,211
Foreign	(84,843)	1,181	690
Income (loss) before provision for income taxes	$ (220,254)	$ (92,852)	$ 15,901

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

	Year Ended December 31,		
	2023	2022	2021
Current:			
Federal	$ 308	$ 216	$ —
State	345	1,228	174
Foreign	1,704	298	161
Total current tax expense	2,357	1,742	335
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred income tax benefit	—	—	—
Income tax expense	$ 2,357	$ 1,742	$ 335

The expense 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,		
	2023	2022	2021
Income tax expense (benefit) at federal statutory rate [1]	$ (46,253)	$ (19,499)	$ 3,339
State income tax, net of federal benefit	(1,313)	(926)	(254)
Warrants revaluation	—	(31)	356
Research and development credits	(6,283)	(6,263)	(5,703)
Section 382 limitation	(5)	—	(97)
Stock-based compensation	14,904	2,282	(7,609)
Officers' compensation	1,547	2,931	4,024
Recognition of acquired deferred tax assets	(5,048)	—	—
Acquired IPR&D expenses	14,938	6,518	—
Other	1,074	962	124
Change in valuation allowance	28,796	15,768	6,155
Income tax expense	$ 2,357	$ 1,742	$ 335

(1) For the years ended December 31, 2023, 2022 and 2021, the federal statutory tax rate was 21%.

Significant components of the Company's net deferred income tax assets at December 31, 2023 and 2022 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, 2023. 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 $190.7 million and $162.7 million at December 31, 2023 and 2022, 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,	
	2023	2022
Deferred tax assets:		
Net operating loss (NOL) carryforwards	$ 54,802	$ 54,598
Research and development tax credits carryforwards	27,516	22,400
Capitalized research and development expenses	52,875	29,760
Accrued compensation	32,097	34,378
Lease liabilities	31,037	32,738
Other	20,778	20,927
Total deferred tax assets	219,105	194,801
Deferred tax liabilities:		
Operating lease right-of-use assets	(20,869)	(26,505)
Fixed assets	(6,916)	(4,467)
Other	(656)	(1,103)
Total deferred tax liabilities	(28,441)	(32,075)
Less valuation allowance	(190,664)	(162,726)
Net deferred tax assets	$ —	$ —

As of December 31, 2023, the Company had accumulated federal and state NOL carryforwards of approximately $168.0 million, and $262.4 million, respectively. Of the total federal net operating loss carryforwards, approximately $78.4 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 $89.6 million will begin to expire in 2033, and state tax loss carryforwards continue to expire in 2024, unless previously utilized. The remaining California NOL carryforwards of $177.6 million will begin expiring in 2031. The Company had approximately $19.9 million of foreign tax loss carryforwards as of December 31, 2023. The foreign tax loss carryforwards begin to expire in 2024, unless previously utilized.

The Company also has federal and California research credit carryforwards of approximately $24.2 million and $24.2 million, respectively, as of December 31, 2023. The federal research credit carryforwards will begin expiring in 2039, 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, 2022 to determine whether its net operating losses and credits are likely to be limited by Section 382. Based on this study, 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.

In 2022, as part of the Capillary Biomedical, Inc. transaction, the Company acquired deferred tax assets consisting of federal and state net operation loss carryovers, research tax credit carryovers, and other tax attributes of approximately $7.8 million. These deferred tax assets are subject to limitations on future use under Section 382 and some of the attributes may expire unused. The Company completed an analysis under Section 382. As a result, the Company recognized deferred tax assets, net of contra reserve, of approximately $5.0 million in 2023. The Company included these deferred tax assets in its components of deferred tax assets in the table above, to the extent that such deferred tax assets are available for future utilization, and the balances are fully offset by valuation allowance as of December 31, 2023.

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, 2023, 2022 and 2021 (in thousands):

	Year Ended December 31,		
	2023	2022	2021
Gross unrecognized tax benefits at the beginning of the year	$ 16,986	$ 13,589	$ 10,107
Increases related to current year positions	3,961	3,403	3,482
Increases (decreases) related to prior year positions	580	(6)	—
Gross unrecognized tax benefits at the end of the year	$ 21,527	$ 16,986	$ 13,589

As of December 31, 2023 and December 31, 2022, the Company had $19.2 million and $15.0 million of unrecognized tax benefits, respectively, 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, 2023, 2022 and 2021. 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. Before 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, single-use 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, 2023, 2022 and 2021, 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,		
	2023	2022	2021
United States	$ 554,878	$ 588,765	$ 524,907
Outside the United States	192,840	212,452	177,892
Total Sales	$ 747,718	$ 801,217	$ 702,799

Sales to distributors accounted for 64%, 65%, and 67% of the Company's total United States sales for the years ended December 31, 2023, 2022 and 2021, respectively. Sales to distributors accounted for 99%, 96%, and 95% of the Company's total sales outside the United States for the years ended December 31, 2023, 2022 and 2021, respectively.

12. Acquisitions

AMF Medical Acquisition

On December 10, 2022, the Company entered into a Share Purchase Agreement (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 (Transaction). AMF Medical is the developer of the Sigi Patch Pump, which is designed to be an ergonomic, rechargeable patch pump that reduces the burden of managing diabetes through its use of pre-filled insulin cartridges. The Sigi Patch Pump is under development and not commercially available.

On January 19, 2023, the Company completed the acquisition of AMF Medical under 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 made in the third quarter of 2022, a cash payment of CHF 62.4 million paid at the closing of the Transaction, and additional contingent earnout payments of up to CHF 129.6 million. The contingent earnout payments 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 two years following the closing date of the Transaction, and a payment of up to CHF 91.2 million upon obtaining regulatory clearance from the United States Food and Drug Administration of an automated controller enabled (ACE) pump. The contingent consideration will be recognized as each contingency is resolved and the respective consideration is paid or becomes payable. As of December 31, 2023, the contingencies related to the earnout milestones were not yet resolved and, therefore, the related amounts were not included in the fair value of the asset acquired and were not recognized as a liability on the consolidated balance sheet at December 31, 2023. The Company funded the initial closing payment using existing cash balances. As of December 31, 2022, the previous strategic investment was included as a component of other long-term assets on the consolidated balance sheet (see Note 2, "Summary of Significant Accounting Policies").

The transaction was accounted for as an asset acquisition as substantially all the value of the gross assets was concentrated in a single asset. The Company recorded a $78.8 million charge in 2023 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, 2023 included the operating results of AMF Medical since the date of acquisition.

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 (see Note 7, "Debt"). 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 was concentrated in a single asset. The Company recorded a $31.0 million charge in 2022 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.

13. Commitments and Contingencies

Legal and Regulatory Matters

On September 8, 2023, a purported stockholder of the Company filed a putative securities class action complaint (captioned *Lowe v. Tandem Diabetes Care, Inc., et al,* Case No. 23-cv-1657) in the United States District Court for the Southern District of California against the Company and certain of the Company's current executive officers. The complaint generally alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, by failing to properly account for and disclose the full impact that COVID-19, inflation, and the sales of competitors' products were having on the Company's sales and revenue. The complaint seeks unspecified monetary damages and other relief. Although the Company intends to vigorously defend against this claim, there is no guarantee that the Company will prevail. Accordingly, the Company is unable to determine the ultimate outcome of this lawsuit or determine the amount or range of potential losses associated with the lawsuit.

From time to time, the Company is involved in various other legal proceedings, regulatory matters, and other disputes or claims arising from or related to claims incident to the normal course of the Company's 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, as of December 31, 2023 the Company believes it is not currently a party to any 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 merit of the claims raised or the outcome, legal proceedings may have an adverse impact on the Company as a result of defense and settlement costs, diversion of management time and resources, and other factors.

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, 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, 2023, obligations under our purchase agreements totaled approximately $189.2 million, of which approximately $181.5 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, 2023 and 2022 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, 2023	December 31, 2022
Sales	$ 196,796	$ 220,502
Gross profit	$ 93,295	$ 115,523
Operating expenses	$ 128,355	$ 133,300
Operating loss	$ (35,060)	$ (17,777)
Net loss	$ (30,002)	$ (15,852)
Net loss per share, basic and diluted	$ (0.46)	$ (0.25)
Weighted average shares used to compute basic and diluted net loss per share	65,369	64,384

For the three months ended December 31, 2023 and 2022, there was no difference in the weighted average number of shares used to calculate basic and diluted net loss per share due to the Company's net loss position for each of the periods presented.

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, 2023, 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, 2023.

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, 2023, 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, 2023, 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, 2023 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, 2023 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, 2023, 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, 2023, 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, 2023 and 2022, 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, 2023, and the related notes and our report dated February 21, 2024 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 21, 2024

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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 paragraph (b) of Item 406 of Regulation S-K. We will promptly disclose on our website (i) any amendment to or any waiver (including an implicit waiver) of, our Code of Ethics (Senior Financial Officers) that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, and that relates to any element of the code of ethics definition enumerated in paragraph (b) of Item 406 of Regulation S-K, and (ii) the nature of any such amendment or waiver.

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 set forth above will be set forth in our definitive proxy statement for our 2024 annual meeting of stockholders (the "Proxy Statement"), to be filed with the SEC not later than 120 days after the end of the fiscal year ended December 31, 2023, under the headings "Election of Directors," "Executive Officers," "Certain Relationships and Related-Party Transactions," "Corporate Governance-Director Independence, Agreements and Relationships," "Legal Proceedings with Directors," "Corporate Governance," "Compensation Governance," "Delinquent Section 16(a) Reports" and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in the Proxy Statement under the headings "Compensation Discussion and Analysis," "Executive Compensation Tables," "Director Compensation," "Compensation Committee Interlocks and Insider Participation," and "Compensation Committee 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 the Proxy Statement under the headings "Compensation Governance—Stock Incentive Plans" and "Stock Ownership," 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 the Proxy Statement under the heading "Corporate Governance—Director Independence, Agreements and Relationships," and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be set forth in the Proxy Statement under the heading "Appointment of Independent Registered Public Accounting Firm," 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 1, 2023 and currently in effect).	10-Q	001-36189	3-Aug-23	3.1	
3.2	Amended and Restated Bylaws (as amended through August 1, 2023 and currently in effect).	10-K	001-36189	3-Aug-23	3.2	
4.1	Reference is made to Exhibits 3.1 and 3.2.					
4.2	Description of Capital Stock.					X
4.3	Form of Common Stock Certificate.	S-1/A	333-191601	1-Nov-13	4.1	
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	
4.6	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	4.1	
10.1*	Tandem Diabetes Care, Inc. Amended and Restated 2013 Stock Incentive Plan.	DEF 14A	001-36189	26-Apr-18	Appendix B	
10.2*	Tandem Diabetes Care, Inc. Amended and Restated 2013 Stock Incentive Plan.	10-Q	001-36189	30-Jul-2020	10.2	
10.3*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2013 Stock Incentive Plan.	10-Q	001-36189	30-Jul-2020	10.1	

10.4*	Form of Stock Option Agreement under the Amended and Restated 2013 Stock Incentive Plan.	S-1/A	333-191601	1-Nov-13	10.7
10.5*	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
10.6*	Tandem Diabetes Care, Inc. Amended and Restated 2013 Employee Stock Purchase Plan.	DEF 14A	001-36189	26-Apr-18	Appendix C
10.7*	Tandem Diabetes Care, Inc. 2023 Sr. Management Cash Bonus Plan.	10-Q	001-36189	3-May-2023	10.1
10.8	Tandem Diabetes Care, Inc. 2023 Long-Term Incentive Plan.	10-Q	001-36189	3-Aug-2023	10.1
10.9	Form of Restricted Stock Units Agreement under the 2023 Long-Term Incentive Plan.	10-Q	001-36189	3-Aug-2023	10.2
10.10*	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
10.11*	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
10.12*	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
10.13*	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
10.14*	Separation Agreement, dated August 18, 2023, by and between Tandem Diabetes Care, Inc. and Brian Hansen.	8-K	001-36189	18-Aug-23	10.1
10.15*	Transition and Consulting Agreement, dated December 1, 2023, by and between the Company and David B. Berger.	8-K	001-36189	11-Dec-23	10.1
10.16*	Form of Indemnification Agreement for Directors and Officers	S-1	333-191601	7-Oct-13	10.11
10.17	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
10.18**	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

10.19†	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	
10.20†	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	
10.21†	License Agreement, dated July 14, 2016, by and between Tandem Diabetes Care, Inc. and TypeZero Technologies, LLC (acquired by DexCom, Inc.).	10-Q	001-36189	30-Apr-2020	10.1	
10.22†	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	
10.23	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	
10.24†	Share Purchase Agreement by and Between Tandem Diabetes Care, Inc., and AMF Medical.	10-K	001-36189	22-Feb-2023	10.33	
10.25	Employee Offer Letter, dated October 31, 2023, by and between Tandem Diabetes Care, Inc. and Mark Novara.					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
97	Tandem Diabetes Care, Inc. Clawback Policy.					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) is of the type of information that the Company customarily and actually treats as private or confidential.

* 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 21, 2024

POWER OF ATTORNEY

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

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

Signature	Title	Date
/s/ JOHN F. SHERIDAN John F. Sheridan	President, Chief Executive Officer and Director (Principal Executive Officer)	February 21, 2024
/s/ LEIGH A. VOSSELLER Leigh A. Vosseller	Executive Vice President, Chief Financial Officer and Treasurer (Principal Financial and Accounting Officer)	February 21, 2024
/s/ DICK P. ALLEN Dick P. Allen	Director	February 21, 2024
/s/ KIM D. BLICKENSTAFF Kim D. Blickenstaff	Director	February 21, 2024
/s/ MYOUNGIL CHA Myoungil Cha	Director	February 21, 2024
/s/ PEYTON R. HOWELL Peyton R. Howell	Director	February 21, 2024
/s/ JOAO PAULO FALCAO MALAGUEIRA Joao Paulo Falcao Malagueira	Director	February 21, 2024
/s/ KATHLEEN MCGRODDY-GOETZ Kathleen McGroddy-Goetz	Director	February 21, 2024
/s/ REBECCA B. ROBERTSON Rebecca B. Robertson	Chair of the Board	February 21, 2024
/s/ RAJWANT S. SODHI Rajwant S. Sodhi	Director	February 21, 2024
/s/ CHRISTOPHER J. TWOMEY Christopher J. Twomey	Director	February 21, 2024

Board of Directors

Rebecca Robertson
Chair

Dick Allen
Director

Kim Blickenstaff
Director

Myoungil Cha
Director

Peyton Howell
Director

Joao Malagueira
Director

Kathleen McGroddy-Goetz, Ph.D.
Director

John Sheridan
Director

Rajwant Sodhi
Director

Christopher Twomey
Director

Executive Team

John Sheridan
President & Chief Executive Officer

Elizabeth Gasser
Executive VP, Chief Strategy & Product Officer

Mark Novara
Executive VP & Chief Commercial Officer

Susan Morrison
Executive VP & Chief Administrative Officer

Leigh Vosseller
Executive VP & Chief Financial Officer

Shannon Hansen
Executive VP, Chief Legal,
Privacy & Compliance Officer

Rick Carpenter
Chief Technical Officer

Tom Fox
Chief Human Resources Officer

Learn more about the People Behind the Pump

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