UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2022

OR

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

For the Transition Period from to

Commission File Number 001-36189

Tandem Diabetes Care, Inc.
(Exact name of registrant as specified in its charter)

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

(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 Exchange on Which Registered
Common Stock, par value $0.001 per share	**TNDM**	**Nasdaq Global Market**

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 x 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 an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of April 29, 2022, there were 63,962,732 shares of the registrant's Common Stock outstanding.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2022	December 31, 2021
Assets	(Unaudited)	(Note 1)
Current assets:		
Cash and cash equivalents	$ 93,681	$ 71,181
Short-term investments	541,710	552,630
Accounts receivable, net	94,133	110,725
Inventories	79,987	68,551
Prepaid and other current assets	8,953	8,433
Total current assets	818,464	811,520
Property and equipment, net	49,987	50,386
Operating lease right-of-use assets	131,058	27,503
Other long-term assets	15,768	15,728
Total assets	$ 1,015,277	$ 905,137
Liabilities and Stockholders’ Equity		
Current liabilities:		
Accounts payable	$ 45,341	$ 28,032
Accrued expenses	6,362	9,419
Employee-related liabilities	38,258	51,556
Operating lease liabilities	8,080	9,279
Deferred revenue	10,881	10,182
Other current liabilities	22,893	23,388
Total current liabilities	131,815	131,856
Convertible senior notes, net - long-term	281,905	281,467
Operating lease liabilities - long-term	129,195	23,922
Deferred revenue - long-term	17,531	16,940
Other long-term liabilities	17,449	17,840
Total liabilities	577,895	472,025
Commitments and contingencies (Note 12)	—	—
Stockholders’ equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 63,941 and 63,833 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively.	64	64
Additional paid-in capital	1,089,689	1,068,259
Accumulated other comprehensive loss	(3,061)	(616)
Accumulated deficit	(649,310)	(634,595)
Total stockholders’ equity	437,382	433,112
Total liabilities and stockholders’ equity	$ 1,015,277	$ 905,137

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	**2021**
Sales	$ 175,907	$ 141,037
Cost of sales	84,814	67,750
Gross profit	91,093	73,287
Operating expenses:		
Selling, general and administrative	73,271	58,563
Research and development	33,160	17,961
Total operating expenses	106,431	76,524
Operating loss	(15,338)	(3,237)
Other income (expense), net:		
Interest income and other, net	381	272
Interest expense	(1,516)	(1,506)
Change in fair value of common stock warrants	34	(690)
Total other expense, net	(1,101)	(1,924)
Loss before income taxes	(16,439)	(5,161)
Income tax benefit	(1,724)	(117)
Net loss	$ (14,715)	$ (5,044)
Other comprehensive loss:		
Unrealized loss on short-term investments	$ (2,517)	$ (38)
Foreign currency translation gain (loss)	72	(76)
Comprehensive loss	$ (17,160)	$ (5,158)
Net loss per share, basic and diluted	$ (0.23)	$ (0.08)
Weighted average shares used to compute basic and diluted net loss per share	63,880	62,448

See accompanying notes to unaudited condensed consolidated financial statements.

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

Three Months Ended March 31, 2022

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	63,833	$ 64	$ 1,068,259	$ (616)	$ (634,595)	$ 433,112
Exercise of stock options	101	—	3,782	—	—	3,782
Vesting of restricted stock units, net of shares withheld for taxes	5	—	(299)	—	—	(299)
Exercise of common stock warrants	2	—	16	—	—	16
Stock-based compensation expense	—	—	17,931	—	—	17,931
Unrealized loss on short-term investments	—	—	—	(2,517)	—	(2,517)
Foreign currency translation adjustments	—	—	—	72	—	72
Net loss	—	—	—	—	(14,715)	(14,715)
Balance at March 31, 2022	63,941	$ 64	$ 1,089,689	$ (3,061)	$ (649,310)	$ 437,382

Three Months Ended March 31, 2021

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
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	111	1	3,135	—	—	3,136
Exercise of common stock warrants	125	—	437	—	—	437
Fair value of common stock warrants at time of exercise	—	—	12,434	—	—	12,434
Stock-based compensation expense	—	—	13,014	—	—	13,014
Unrealized loss on short-term investments	—	—	—	(38)	—	(38)
Foreign currency translation adjustments	—	—	—	(76)	—	(76)
Net loss	—	—	—	—	(5,044)	(5,044)
Balance at March 31, 2021	62,571	$ 63	$ 968,450	$ 106	$ (655,205)	$ 313,414

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

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2022	**2021**
Operating Activities		
Net loss	$ (14,715)	$ (5,044)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization expense	3,628	3,485
Amortization of debt issuance costs	438	428
Provision for expected credit losses	846	143
Provision for inventory obsolescence	346	64
Change in fair value of common stock warrants	(34)	690
Amortization of premium on short-term investments	562	209
Stock-based compensation expense	18,110	12,947
Other	468	(73)
Changes in operating assets and liabilities:		
Accounts receivable, net	15,729	8,389
Inventories	(11,963)	(3,084)
Prepaid and other current assets	741	(1,412)
Other long-term assets	(582)	(17)
Accounts payable & accrued expenses	13,732	10,815
Employee-related liabilities	(13,299)	(1,448)
Deferred revenue	1,290	1,871
Operating leases and other current liabilities	(1,106)	1,094
Other long-term liabilities	(391)	(372)
Net cash provided by operating activities	13,800	28,685
Investing Activities		
Purchases of short-term investments	(110,719)	(154,300)
Proceeds from maturities of short-term investments	111,559	140,200
Proceeds from sales of short-term investments	7,000	11,530
Purchases of property and equipment	(2,643)	(3,524)
Net cash provided by (used in) investing activities	5,197	(6,094)
Financing Activities		
Proceeds from issuance of common stock under Company stock plans, net	3,484	3,135
Proceeds from exercise of common stock warrants	16	438
Net cash provided by financing activities	3,500	3,573
Effect of foreign exchange rate changes on cash	3	14
Net increase in cash and cash equivalents	22,500	26,178
Cash and cash equivalents at beginning of period	71,181	94,613
Cash and cash equivalents at end of period	$ 93,681	$ 120,791
Supplemental disclosures of cash flow information		
Income taxes paid	$ 170	$ 197
Supplemental schedule of non-cash investing and financing activities		
Right-of-use assets obtained in exchange for operating lease obligations	$ 107,478	$ 15,087
Purchase of property and equipment included in accounts payable	$ 1,553	$ 924
Intangible costs in accounts payable and other long-term liabilities	$ 1,029	$ 2,244

See accompanying notes to unaudited condensed consolidated financial statements.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

Tandem Diabetes Care, Inc. is a medical device company focused on the design, development and commercialization of technology solutions for people living with diabetes. Tandem Diabetes Care, Inc. is incorporated in the state of Delaware. Unless the context requires otherwise, the terms the “Company” or “Tandem” refer to Tandem Diabetes Care, Inc., together with its wholly-owned subsidiaries in the U.S., Canada and the Netherlands.

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

Basis of Presentation and Principles of Consolidation

The Company has prepared the accompanying unaudited condensed consolidated financial statements in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, all adjustments which are of a normal and recurring nature, considered necessary for a fair presentation of the financial information contained herein, have been included.

Interim financial results are not necessarily indicative of results anticipated for the full year or any other period(s). These unaudited condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and accompanying notes included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2021 (Annual Report), from which the balance sheet information herein was derived. The condensed consolidated financial statements include the accounts of Tandem Diabetes Care, Inc. and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

The functional currency of the Company’s foreign subsidiary is the local currency. The Company translates the financial statements of its foreign subsidiary into U.S. dollars using period-end exchange rates for assets and liabilities and average exchange rates for each period for revenue, costs and expenses. Translation related adjustments are included in other comprehensive loss, and in accumulated other comprehensive income in the stockholders’ equity section of the Company’s condensed 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 condensed consolidated statements of operations.

Reclassifications

Starting with the first quarter of 2022, the Company included the liability related to common stock warrants (see Note 5, “Fair Value Measurements”) as a component of other current liabilities on the Company’s condensed consolidated balance sheet. In addition, deferred revenue long-term, which was previously reported as a component of other long-term liabilities, is now separately reported on the condensed consolidated balance sheet. The corresponding balances at December 31, 2021, 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 three months ended March 31, 2022, as compared to those disclosed in the Company's 2021 Annual Report.

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.

Accounts Receivable

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

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable, accrued expenses, and employee-related liabilities are reasonable estimates of their fair values because of the short-term nature of these assets and liabilities. Short-term investments are carried at fair value. The carrying value and estimated fair value of certain of the Company's common stock warrants was determined using the Black-Scholes pricing model as of March 31, 2022 and December 31, 2021 (see Note 5, "Fair Value Measurements").

The Company's convertible senior notes are carried at amortized cost on the condensed consolidated balance sheets (see Note 7, "Debt"). The Company determined the fair value of its convertible senior notes to be $363.3 million and $430.0 million at March 31, 2022 and December 31, 2021, respectively, based on Level 2 quoted market prices as of those dates.

Operating Lease Right-of-Use Assets and Liabilities

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

Cost Basis Equity Investment

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

Intangible Assets Subject to Amortization

Finite-lived intangible assets are recorded at cost, net of accumulated amortization and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recognized over their estimated useful lives on a straight-line basis. The Company reviews its finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company did not recognize any impairment losses during the three months ended March 31, 2022 and 2021.

In 2020, the Company acquired Sugarmate, Inc. (Sugarmate), the developer of a mobile app designed to help people visualize diabetes therapy data in innovative ways. The Sugarmate acquisition was accounted for as an acquisition of assets. Substantially all of the fair value was concentrated in a single identifiable asset, a technology-based intangible asset. The purchased intangible asset is amortized on a straight-line basis over an estimated useful life of five years.

Revenue Recognition

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

Revenue Recognition for Arrangements with Multiple Performance Obligations

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

Warranty Reserve

The Company generally provides a four-year warranty on its insulin pumps to end user customers and may replace any pumps that do not function as intended in accordance with the product specifications within the warranty period. Additionally, the Company offers a six-month warranty on disposable insulin cartridges and infusion sets. Estimated warranty costs are recorded at the time of shipment, and the Company reevaluates the estimate of the warranty reserve obligation at each reporting period. Warranty costs are estimated primarily based on the current expected product replacement cost and expected replacement rates utilizing historical experience. Insulin pumps returned to the Company may be refurbished and redeployed. Experience has shown that initial data for any given pump version may be insufficient; therefore, the Company's process relies on long-term historical averages until sufficient data are available. As actual experience becomes available, the Company uses the data to update the historical averages. The Company may make further adjustments to the warranty reserve when deemed appropriate, giving additional consideration to the length of time each pump version has been in the field and revised future expectations of performance based on new features and capabilities that may become available through Tandem Device Updater.

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

	Three Months Ended March 31,	
	2022	2021
Balance at beginning of the period	$ 30,401	$ 22,075
Provision for warranties issued during the period	7,201	5,896
Settlements made during the period	(6,021)	(4,256)
Decrease in warranty estimates	(1,137)	(546)
Balance at end of the period	$ 30,444	$ 23,169

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

	March 31, 2022	December 31, 2021
Other current liabilities	$ 13,509	$ 13,076
Other long-term liabilities	16,935	17,325
Total warranty reserve	$ 30,444	$ 30,401

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the estimated fair value of the award, and the portion that is ultimately expected to vest is recognized as compensation expense over the requisite service period on a straight-line basis. The Company estimates the fair value of stock options issued under the Company's Amended and Restated 2013 Stock Incentive Plan (2013 Plan) and the fair value of the employees' purchase rights under the Company's 2013 Employee Stock Purchase Plan (ESPP) using the Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model requires the use of assumptions about a number of variables, including stock price volatility, expected term, dividend yield and risk-free interest rate (see Note 8, "Stockholders' Equity"). The fair value of restricted stock unit (RSU) awards issued under the Company's 2013 Plan that vest solely based on service is estimated based on the fair market value of the underlying stock on the date of grant. The fair value of RSU awards issued under the 2013 Plan that vest based upon the Company's actual performance relative to predefined performance metrics is estimated based on the fair market value of the underlying stock on the date of grant and the probability that the specified performance criteria will be met, subject to the awardee's continuing service through the measurement date. At each reporting period, 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.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share reflects the potential dilution that would occur if securities exercisable for or convertible into common stock were exercised for or converted into common stock. Dilutive common share equivalents are comprised of stock options and unvested RSUs outstanding under the Company's stock plans, potential awards to be granted pursuant to the ESPP, and common stock warrants, each calculated using the treasury stock method; and shares issuable upon conversion of the convertible senior notes calculated using the if-converted method. For common stock warrants that are recorded as a liability in the accompanying condensed consolidated balance sheets, the calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of the warrants is dilutive to loss per share for the period, an adjustment is made to net loss used in the calculation to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method.

For the three months ended March 31, 2022 and 2021, 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.

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):

	Three Months Ended March 31,	
	2022	2021
Options to purchase common stock	4,424	5,068
Unvested restricted stock units	630	133
Warrants to purchase common stock	211	379
Awards granted under the ESPP	78	78
Convertible senior notes (if-converted)	2,554	2,554
	7,897	8,212

Recent Accounting Pronouncements

In June 2020, the FASB issued ASU No. 2020-06, *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, which is intended to simplify the accounting for convertible instruments. This new guidance eliminated certain models that require separate accounting for embedded conversion features, and eliminated certain of the conditions for equity classification for contracts in an entity's own equity. Accordingly, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance could be adopted through either a modified retrospective method of transition or a fully retrospective method of transition. ASU 2020-06 is effective for public business entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company elected to early adopt the new standard on January 1, 2021 using the modified retrospective method and, accordingly, recorded a net reduction to accumulated deficit of $9.0 million, a decrease to additional paid-in capital of $85.8 million, and an increase to convertible senior notes, net - long-term of $76.8 million to reflect the impact of the accounting change (see Note 7, "Debt").

3. Short-Term Investments

The Company invests in marketable securities primarily consisting of debt instruments of the U.S. Government, U.S. Government-sponsored enterprises, and financial institutions and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments at March 31, 2022 and December 31, 2021 (in thousands):

At March 31, 2022	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:				
U.S. Treasury securities	$ 296,072	$ 1	$ (2,388)	$ 293,685
Commercial paper	156,913	—	(202)	156,711
Corporate debt securities	51,649	6	(196)	51,459
U.S. Government-sponsored enterprises	37,217	—	(362)	36,855
Supranational bonds	3,000	—	—	3,000
Total	$ 544,851	$ 7	$ (3,148)	$ 541,710

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

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

	Years to Maturity		
At March 31, 2022	Within One Year	One to Two Years	Estimated Fair Value
U.S. Treasury securities	$ 223,643	$ 70,042	$ 293,685
Commercial paper	156,711	—	156,711
Corporate debt securities	43,906	7,553	51,459
U.S. Government-sponsored enterprises	23,612	13,243	36,855
Supranational bonds	3,000	—	3,000
Total	$ 450,872	$ 90,838	$ 541,710

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 March 31, 2022 were primarily due to the recent increase in market interest rates. The Company does not intend to sell the available-for-sale debt securities that are in an unrealized loss position, and it is not more likely than not that the Company will be required to sell these debt securities before recovery of their amortized cost bases, which may be at maturity. Based on the credit quality of the available-for-sale debt securities in an unrealized loss position, and the Company's estimates of future cash flows to be collected from those securities, the Company believes the unrealized losses are not credit losses. Accordingly, the Company did not recognize any impairment losses related to its available-for-sale debt securities at March 31, 2022.

4. Composition of Certain Financial Statement Items

Accounts Receivable

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

	March 31, 2022	December 31, 2021
Accounts receivable	$ 98,477	$ 114,974
Less: allowance for credit losses	(4,344)	(4,249)
Accounts receivable, net	$ 94,133	$ 110,725

Allowance for Credit Losses

The following table provides a reconciliation of the changes in the allowance for estimated accounts receivable credit losses for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	**2021**
Balance at beginning of the period	$ 4,249	$ 3,857
Provision for expected credit losses	846	143
Write-offs and adjustments, net of recoveries	(751)	(441)
Balance at end of the period	$ 4,344	$ 3,559

Inventories

Inventories consisted of the following at (in thousands):

	March 31, 2022	**December 31, 2021**
Raw materials	$ 28,223	$ 26,911
Work-in-process	18,520	16,612
Finished goods	33,244	25,028
Total inventories	$ 79,987	$ 68,551

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

	Fair Value Measurements at March 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[1]	$ 44,905	$ 44,905	$ —	$ —
U.S. Treasury securities	293,685	293,685	—	—
Commercial paper	156,711	—	156,711	—
Corporate debt securities	51,459	—	51,459	—
U.S. Government-sponsored enterprises	36,855	—	36,855	—
Supranational bonds	3,000	—	3,000	—
Total assets	$ 586,615	$ 338,590	$ 248,025	$ —
Liabilities				
Common stock warrants[2]	$ 113	$ —	$ —	$ 113
Total liabilities	$ 113	$ —	$ —	$ 113

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets				
Cash equivalents[1]	$ 48,286	$ 48,286	$ —	$ —
U.S. Treasury securities	221,724	221,724	—	—
Commercial paper	218,381	—	218,381	—
Corporate debt securities	58,836	—	58,836	—
U.S. Government-sponsored enterprises	50,686	—	50,686	—
Supranational bonds	3,003	—	3,003	—
Total assets	$ 600,916	$ 270,010	$ 330,906	$ —
Liabilities				
Common stock warrants[2]	$ 147	$ —	$ —	$ 147
Total liabilities	$ 147	$ —	$ —	$ 147

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

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

The Company's Level 3 liabilities at March 31, 2022 and December 31, 2021 included the remaining Series A warrants issued by the Company in connection with the public offering of common stock in October 2017. The Series A warrants, which expire in October 2022, provide holders the right to purchase shares of the Company’s common stock at an exercise price of $3.50 per share. As of March 31, 2022 and December 31, 2021, there were Series A warrants outstanding to purchase 1,000 shares of the Company’s common stock (see Note 8, “Stockholders’ Equity”).

The Company reassesses the fair value of the outstanding Series A warrants at each reporting date utilizing a Black-Scholes pricing model. Variables used in the pricing model include the closing market price of the Company’s common stock at the balance sheet date, as well as estimated stock price volatility, dividend yield, remaining warrant term and risk-free interest rate. A significant increase (decrease) in any of these inputs in isolation, particularly the market price of the Company’s common stock, would have resulted in a significantly higher (lower) fair value measurement. The assumptions used to estimate the fair values of the outstanding Series A warrants at March 31, 2022 and December 31, 2021 are presented below:

	Series A Warrants	
	March 31, 2022	**December 31, 2021**
Risk-free interest rate	1.1 %	0.3 %
Expected dividend yield	0.0%	0.0%
Expected volatility	44.4 %	39.1 %
Expected term (in years)	0.6	0.8

The following table presents a summary of changes in the fair value of the Company’s Level 3 financial liabilities for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	**2021**
Balance at beginning of period	$ 147	$ 14,261
(Gain) loss recognized from the change in fair value of common stock warrants	(34)	690
Common stock warrants exercised during the period	—	(12,434)
Balance at end of period	$ 113	$ 2,517

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 assets on the Company’s condensed consolidated balance sheets. The Company is required to recognize operating lease right-of-use assets and liabilities, and begin recording lease expense when the Company takes possession of the leased property (the Commencement Date). The Company recognizes lease expense for these leases on a straight-line basis over the lease term. Because the Company’s leases do not provide an implicit interest rate, the Company uses its incremental borrowing rate based on the information available at the lease Commencement Date to determine the operating lease right-of-use assets and liabilities based on the present value of future lease payments over the lease term. The Company used the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date.

Certain leases include an option to renew, with renewal terms that can extend the lease term for additional periods. The exercise of lease renewal options is at the Company’s sole discretion. For renewal options that are reasonably certain at the lease Commencement Date of being exercised, the Company includes the renewal option period in the lease term.

Vista Sorrento Lease

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

Tech Center Lease

In September 2021, the Company entered into a lease agreement for 181,949 square feet of additional general administrative, laboratory, and research and development office space (the Premises) located on High Bluff Drive in San Diego, California (Tech Center Lease). Possession of the Premises is expected to be tendered to the Company by the landlord in two phases, with Phase I consisting of 143,850 rentable square feet, and Phase II consisting of 38,099 rentable square feet. The Company intends to use Phase I of the Tech Center Lease for operations currently occupying 77,458 square feet of leased space, located on Roselle Street in San Diego, California, that is scheduled to expire in May 2023.

The initial lease term Phase I Commencement Date occurred in March 2022 when the Company was tendered possession of the Phase I portion of the Premises, and rent payments commence in September 2022 (the Phase I Rent Commencement Date). The Phase II Commencement Date is expected to occur upon the earlier of (i) the date upon which the Company first commences business in the Phase II portion of the Premises, and (ii) May 1, 2025 (the Phase II Rent Commencement Date). The Tech Center Lease term expires in April 2035. The Company has two options to extend the term of the lease, with each option providing for an additional period of five years. The Tech Center Lease term was determined assuming the renewal options would not be exercised.

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

The initial base rent for the Tech Center Lease is approximately $906,000 per month beginning on the Phase I Rent Commencement Date, and the base rent increases by approximately $255,000 per month on the Phase II Rent Commencement Date. The monthly base rent will increase 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 right-of-use leased 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.

Supplemental Lease Disclosure Information

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

	Three Months Ended March 31,	
	2022	2021
Operating lease cost	$ 3,018	$ 2,006
Short-term lease cost	34	22
Total lease cost	$ 3,052	$ 2,028

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

Years Ending December 31,		
2022 (remaining)	$	6,387
2023		12,805
2024		17,057
2025		17,475
2026		17,528
Thereafter		120,235
Total undiscounted lease payments		191,487
Less: amount representing interest		(54,212)
Present value of operating lease liabilities		137,275
Less: current portion of operating lease liabilities		(8,080)
Operating lease liabilities - long-term	$	129,195

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

	March 31, 2022	**December 31, 2021**
Weighted-average remaining lease term (in years)	11.2	5.0
Weighted-average discount rate used to determine operating lease liabilities	5.4 %	5.6 %

Cash paid for amounts included in the measurement of lease liabilities, representing operating cash flows from operating leases, was $3.4 million and $2.3 million for the three months ended March 31, 2022 and 2021, respectively.

Leases For Which Accounting Has Not Yet Commenced

As of March 31, 2022, the Commencement Date for the High Bluff Lease described below, and Phase II of the Tech Center Lease, had not yet occurred. Accordingly, the condensed consolidated balance sheet at March 31, 2022 does not include operating lease right-of-use assets and operating lease liabilities, and the condensed consolidated statement of operations for the three months ended March 31, 2022 does not include any lease costs, related to the High Bluff Lease and Phase II of the Tech Center Lease. In addition, the above disclosures of the Company’s lease costs, maturities of operating lease liabilities, and the weighted-average remaining lease term and weighted-average discount rate, do not include any amounts related to the High Bluff Lease and Phase II of the Tech Center Lease.

High Bluff Lease

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

Tech Center Lease - Phase II

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

7. Debt

Convertible Senior Notes

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

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

The Notes are convertible into cash, shares of the Company’s common stock, or a combination of cash and shares of the Company’s common stock, at the Company’s election, at an initial conversion rate of 8.8836 shares of common stock per $1,000 principal amount of the Notes, which is equivalent to an initial conversion price of $112.57 (Conversion Price) per share of the Company’s common stock. The conversion rate is subject to customary adjustments for certain events as described in the Indenture. The Company expects to settle conversions through a combination settlement, which involves payment in cash equal to the principal portion and delivery of shares of common stock for the excess of the conversion value over the principal portion.

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

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

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

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

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

- on the occurrence of specified corporate events.

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

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

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

	March 31, 2022	December 31, 2021
Principal amount	$ 287,500	$ 287,500
Unamortized debt issuance costs	(5,595)	(6,033)
Net carrying amount	$ 281,905	$ 281,467

As of March 31, 2022, the unamortized debt issuance costs of $5.6 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 three years.

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

	Three Months Ended	
	March 31, 2022	March 31, 2021
Contractual interest expense	$ 1,078	$ 1,078
Amortization of debt issuance costs	438	428
Total interest expense	$ 1,516	$ 1,506

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 March 31, 2022, the if-converted value of the Notes exceeded the principal amount by $9.5 million. As of December 31, 2021, the if-converted value of the Notes exceeded the principal amount by $96.9 million.

Capped Call Transactions

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

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

8. Stockholders' Equity

Shares Reserved for Future Issuance

The following shares of the Company's common stock were reserved for future issuance at March 31, 2022 (in thousands):

Shares reserved for issuance upon conversion of Convertible Senior Notes	2,554
Shares underlying outstanding warrants	211
Shares underlying outstanding stock options	4,671
Shares underlying unvested restricted stock units	772
Shares authorized for issuance pursuant to awards granted under the ESPP	1,216
Shares authorized for future equity award grants	1,258
Total	10,682

Common Stock Warrants

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

Issue Date	Exercise Price Per Share	Warrants Outstanding	Expiration Date of Warrants Outstanding
October 2017	$3.50	1,000	October 2022
March 2017	$23.50	193,788	March 2027
August 2011 - August 2012	$73.73	16,212	May 2022 - August 2022
		211,000	

Each warrant allows the holder to purchase one share of the Company's common stock at the exercise price per share of the respective warrant. The Company issued 1,835 and 125,000 shares of its common stock upon the exercise of warrants during the three months ended March 31, 2022 and 2021, respectively.

Stock Plans

The Company's Amended and Restated 2013 Stock Incentive Plan (2013 Plan) was originally approved by the Company's board of directors in October 2013. Under the 2013 Plan, the Company may grant stock options, stock appreciation rights, restricted stock and restricted stock units to individuals who are then employees, officers, directors or consultants of the Company.

The ESPP enables eligible employees to purchase shares of the Company's common stock using their after-tax payroll deductions, subject to certain conditions. 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. There were no shares of common stock purchased under the ESPP during the three months ended March 31, 2022 and 2021.

Stock-Based Compensation

Common Stock Options

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

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

	Three Months Ended March 31,	
	2022	2021
Stock options granted	—	115,400
Weighted average grant date fair value (per share)	N/A	$ 60.98
Risk-free interest rate	N/A	0.9 %
Expected dividend yield	N/A	0.0 %
Expected volatility	N/A	75.6 %
Expected term (in years)	N/A	6.1

Restricted Stock Units

Restricted stock units (RSUs) have a grant price equal to the closing price of the Company's common stock on the award date. RSUs granted prior to March 2022, generally vest over a four year period based only on service as to 25% of the underlying shares on the first anniversary of the award, with the balance of the RSUs vesting quarterly over the following three years. RSUs granted in March 2022 vest over a three year period based only on service 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.

The number of RSUs granted and the respective weighted average grant date fair value were as follows:

	Three Months Ended March 31,	
	2022	2021
RSUs granted	187,076	3,208
Weighted average grant date fair value (per share)	$ 109.97	$ 93.49

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):

	Three Months Ended March 31,	
	2022	2021
Cost of sales	$ 1,846	$ 1,476
Selling, general & administrative	11,854	9,409
Research and development	4,410	2,062
Total stock-based compensation expense	$ 18,110	$ 12,947

The total stock-based compensation capitalized as part of the cost of the Company's inventories was $0.8 million and $1.0 million at March 31, 2022 and December 31, 2021, respectively.

9. Employee Benefits

Employee 401(k) Plan

The Company has a defined contribution 401(k) plan for employees in the United States who are at least 18 years of age. Employees are eligible to participate in the plan beginning on the first day of the calendar month following their date of hire. Unless they affirmatively elect otherwise, employees are automatically enrolled in the plan following 30 days from date of rehire or entry date. Under the terms of the plan, employees may make voluntary contributions as a percent of compensation, and the Company may elect to match a discretionary percentage of employee contributions. The Company did not provide a matching contribution prior to 2022, but began making a discretionary match in the first quarter of 2022.

10. Income Taxes

For the three months ended March 31, 2022, the Company recognized an income tax benefit of $1.7 million on a pre-tax loss of $16.4 million, compared to an income tax benefit of $0.1 million on a pre-tax loss of $5.2 million for the three months ended March 31, 2021. The income tax benefit for the three months ended March 31, 2022 and 2021, was primarily attributable to the Company's pre-tax loss position, offset by state and foreign income tax expense as a result of current taxable income in certain jurisdictions.

The Company calculated the provision (benefit) for income taxes for the three months ended March 31, 2022 and 2021, by applying an estimate of the annual effective tax rate for the full year to ordinary income (loss) adjusted by the tax impact of discrete items.

The Company continues to maintain a full valuation allowance against its net deferred tax assets as of March 31, 2022, based on the current assessment that it is not more likely than not these future benefits will be realized before expiration.

11. Business Segment and Geographic Information

Segment Reporting

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

Disaggregation of Revenue

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

Revenues by Geographic Region and Customer Sales Channel

During the three months ended March 31, 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).

	Three Months Ended March 31,	
	2022	2021
United States	$ 131,283	$ 103,339
Outside the United States	44,624	37,698
Total Sales	$ 175,907	$ 141,037

Sales to distributors accounted for 65% and 68% of the Company's total United States sales for the three months ended March 31, 2022 and 2021, respectively. Sales to distributors accounted for 96% and 96% of the Company's total sales outside the United States for the three months ended March 31, 2022 and 2021, respectively.

12. Commitments and Contingencies

Legal and Regulatory Matters

In May 2020, the Company was named as a defendant in three California state court class action lawsuits arising from the same data breach. Collectively, these lawsuits seek statutory, compensatory, actual, and punitive damages; equitable relief, including restitution; pre- and post-judgment interest; injunctive relief; and attorney fees, costs, and expenses from the Company. On July 24, 2020, these three pending lawsuits were consolidated into a single case in the Superior Court of the State of California in the County of San Bernardino entitled *Joseph Deluna et al v. Tandem Diabetes Care, Inc*. The consolidated case alleges violations of the Confidentiality of Medical Information Act (CMIA), California Consumer Privacy Act (CCPA), California's Unfair Competition Law (UCL), and breach of contract. The Company filed a demurrer seeking dismissal of all claims, which was heard by the Court on October 27, 2020, and which resulted in the following outcome: (i) the demurrer to the CMIA claim was denied; (ii) the demurrer to the CCPA claim was sustained; and (iii) the demurrer to the UCL and contract claims were sustained with leave to amend the pending complaint. A second demurrer was heard by the Court on March 29, 2021 with the following outcome: (i) the demurrer to the CMIA claim was denied; and (ii) the demurrer to the UCL and contract claims was sustained without leave to amend as to three of the named plaintiffs. The plaintiffs filed a motion for class certification on January 7, 2021 to which the Company filed its opposition on April 11, 2022. The Company filed a motion for summary adjudication on the CMIA claim on April 7, 2021, which is still pending. Although the Company continues to vigorously defend against these claims, there is no guarantee that the Company will prevail. The Company presently is unable to determine the ultimate outcome of these lawsuits or determine the amount (or range) of possible losses associated with the lawsuits.

In September 2020, the Company was named as a defendant in a lawsuit entitled Buck Walsh, individually and on behalf of others similarly situated v. Tandem Diabetes Care, Inc., which was filed in the Superior Court of the State of California in the County of San Diego. The alleged violations include business and professions code and labor code violations for failure to compensate wages, unpaid meal and rest periods, and failure to reimburse for necessary business-related expenses. The case was brought as a class action and was later amended to also include a representative action under the California Private Attorney General Act, or PAGA. The class of plaintiffs includes hourly paid or non-exempt employees of the Company who were employed from April 6, 2016 through the date of adjudication. The parties recently agreed to resolve all claims in the lawsuit. The settlement of claims covered by the PAGA matter were approved by the Superior Court of the State of California in the County of San Diego on September 21, 2021 and settlement amounts were disbursed in 2021. In October 2021, a settlement of the class action related claims was preliminarily approved by an independent arbitrator mutually acceptable to both parties. The class action is intended to resolve the claims of the individual plaintiff, as well as the remaining members of the class, unless an individual class member submits a timely request for exclusion. The material terms of the settlement are set forth in a binding Memorandum of Agreement dated as of July 1, 2021, which was approved by the independent arbitrator on April 18, 2022. Subsequent to this filing, the Company anticipates receipt of the final settlement amount from the settlement administrator. This lawsuit will be resolved and closed upon disbursement of the settlement amount.

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

Except as set forth above, as of March 31, 2022, there were no legal proceedings, regulatory matters, or other disputes or claims for which a material loss was considered probable or for which the amount (or range) of loss was reasonably estimable. However, regardless of the merits of the claims raised or the outcome, legal proceedings, regulatory matters, and other disputes and claims may have an adverse impact on the Company because of as a result of defense and settlement costs, diversion of management time and resources, and other factors.

Letters of Credit

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

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis together with our financial statements and related notes in Part I, Item 1 of this Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 (Quarterly Report).

This Quarterly 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 Quarterly 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 Quarterly Report may relate to, among other things, our future or assumed financial condition, results of operations, liquidity, trends impacting our financial results, business forecasts and plans, research and product development plans, manufacturing plans, strategic plans and objectives, capital needs and financing plans, product launches, geographic expansion, distribution plans, production capacity, clinical trials, regulatory approvals, competitive position and the impact of changes in the competitive environment, the impact of the COVID-19 global pandemic on our business, supply chain, and the businesses of our contract manufacturers and suppliers, integration of acquisitions and partner technologies, 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 Quarterly Report.

Our forward-looking statements are based on our management's current assumptions and expectations about future events and trends, which affect or may affect our business, strategy, operations or financial performance. Although we believe that these forward-looking statements are based upon reasonable assumptions, they are subject to numerous known and unknown risks and uncertainties and are made in light of information currently available to us. Our actual financial condition and results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below in the section entitled "Risk Factors" in Part II, Item 1A, and elsewhere in this Quarterly Report, as well as the other public filings we make with the Securities and Exchange Commission. You should read this Quarterly Report with the understanding that our actual future financial condition and 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 Global 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.

Overview

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

Since our initial commercial launch, we have rapidly innovated and brought more products to market than our competitors. We have commercially launched seven insulin pump configurations in the United States since 2012 and three insulin pump configurations outside the United States since 2018. Today, our software-updatable t:slim X2 Insulin Delivery System (t:slim X2) hardware platform represents 100% of our new pump shipments. In the four-year period ended March 31, 2022, we shipped more than 350,000 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. More than 250,000 of these pumps were shipped to customers in the United States and nearly 100,000 were shipped to more than 20 countries in which we operate outside the United States.

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

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

In February 2022, the FDA provided clearance for our t:slim X2 pump users to bolus insulin from a compatible smartphone. This is the first-ever FDA-cleared smartphone app capable of initiating insulin delivery on both iOS and Android operating systems. We intend to offer in-warranty t:slim X2 users in the United States with the pump software update to use this new feature at no cost through TDU.

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

For the three months ended March 31, 2022 and 2021, our consolidated sales were $175.9 million, and $141.0 million, respectively. For the three months ended March 31, 2022 and 2021, our net loss was $14.7 million, and $5.0 million, respectively. Pump sales accounted for 54% and 58%, of our total worldwide sales, for the three months ended March 31, 2022 and 2021, respectively, while pump-related supplies and accessories accounted for the remainder in each year.

COVID-19 Global Pandemic Impact and Considerations

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

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

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

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

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

Our facilities have been closed for non-essential purposes throughout most of the pandemic, while our manufacturing operations were deemed essential due to the critical nature of our product and the communities that we serve. To help ensure the safety and health of those employees working in our facilities, we have implemented various preventative measures throughout the pandemic. In the first quarter of 2022, we began implementing a return-to-office strategy for the rest of the organization that incorporates a hybrid approach to meet the needs of our employees, as well as optimize usage of our facilities.

Overall, we anticipate that our sales and operating results will continue to be impacted and subject to unpredictable variability. The full extent of the impact of the pandemic on our future business and operations is difficult to estimate and will depend on a number of factors including the scope and duration of the COVID-19 global pandemic, and the relative impact of COVID-19 on the business operations of our contract manufacturers, suppliers and competitors.

Products Under Development

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

Delivery Devices

We are developing a family of delivery device solutions to meet the varying needs of people living with type 1 and type 2 diabetes by providing choice within our own portfolio. Preferences in the size, shape, and mode of operation that comprise an insulin pump's hardware often impact a person's pump purchasing decision and overall user experience.

Mobi

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

t:slim X3

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

Mobi: Tubeless

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

Patch

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

Device Software

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

Control-IQ Advancements

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

Mobile Control

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

Integration

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

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

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

Data and Insights

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

Tandem Source

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

Settings Automation

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

Pump Shipments

From inception in 2012 through June 2018, we derived nearly all of our sales from the shipment of insulin pumps and associated supplies to customers in the United States. Starting in the third quarter of 2018, we commenced sales of our t:slim X2 insulin pump in select geographies outside the United States and now offer our technology solutions in more than 20 countries worldwide. We consider the number of insulin pump units shipped to be an important metric for managing our business.

Insulin pumps in the markets we serve worldwide are generally subject to a four-year reimbursement cycle, imposed by the third-party insurance carrier, government plan or healthcare system that serves as the primary payor. In the past four years, we have shipped more than 350,000 insulin pumps worldwide, which is representative of our estimated global in-warranty installed customer base.

At the end of the typical four-year reimbursement cycle, customers may be eligible for the purchase of a new insulin pump, subject to the rules and requirements of their primary insurance payor. While warranties generally expire four years from the original pump shipment date, our typical renewal cycle, or time from original pump purchase to a subsequent pump purchase by the same customer, averages five years. The majority of our insulin pump sales through the current period have been generated by new customers, but the opportunity for existing customers to purchase a renewal insulin pump increases each period as additional customer warranties expire. With programs dedicated to customer retention efforts, we expect such renewal purchases to represent a more significant portion of our shipments in the long-term.

More than 250,000 of pumps were shipped to customers in the United States in the past four years, which aligns with the standard four-year warranty period. Pump shipments to customers in the United States by fiscal quarter for the last five years, which aligns more closely with our typical renewal cycle, were as follows:

	United States Pump Unit Shipments for Each of the Three Months Ended in Respective Years				
	March 31	June 30	September 30	December 31	Total
2017	2,816	3,427	3,868	6,950	17,061
2018	4,444	5,447	7,379	12,935	30,205
2019	9,669	12,799	13,814	17,453	53,735
2020	13,158	14,735	18,380	24,552	70,825
2021	16,644	20,665	20,296	25,712	83,317
2022	18,658	N/A	N/A	N/A	18,658

Since commencing sales outside the United States in the third quarter of 2018, we have shipped nearly 100,000 pumps to customers in more than 20 countries, and have yet to complete a full four-year reimbursement cycle. Pump shipments to customers outside the United States by fiscal quarter were as follows:

	Outside the United States Pump Unit Shipments for Each of the Three Months Ended in Respective Years				
	March 31	June 30	September 30	December 31	Total
2018	N/A	N/A	1,055	3,233	4,288
2019	5,063	8,459	4,025	2,149	19,696
2020	4,220	3,952	3,641	8,133	19,946
2021	8,708	13,152	11,262	11,873	44,995
2022	9,437	N/A	N/A	N/A	9,437

Trends Impacting Financial Results

Overall, we have experienced considerable sales growth each year since the commercial launch of our first product in the third quarter of 2012, only recognizing an operating profit on a full year basis for the first time in 2021. Our operating results have historically fluctuated on a quarterly or annual basis, particularly in periods surrounding anticipated regulatory approvals, the commercial launch of new products by us and our competitors, the commercial launch of our products in geographies outside of the United States and due to general seasonality in the United States. We expect these periodic fluctuations in our operating results to continue.

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

- market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers;
- the introduction of new products, treatment techniques or technologies for the treatment of diabetes, including the timing of the commercialization of new products by us and our competitors;
- seasonality in the United States associated with annual insurance deductibles and coinsurance requirements associated with the medical insurance plans utilized by our customers and the customers of our distributors;
- incidence of disease or illness, including the COVID-19 global pandemic, that may impact customer purchasing patterns or disrupt our supply chain, or create uncertainty or delay with respect to regulatory approvals;
- timing of holidays and summer vacations, which may vary by geography and may be further influenced by the lifting or relaxation of COVID-19 related restrictions and broader availability of vaccines;
- the buying patterns of our distributors and other customers;
- changes in the competitive landscape, including as a result of companies entering or exiting the diabetes therapy market;
- access to adequate coverage and reimbursement for our current and future products by third-party payors, and reimbursement decisions by third-party payors;
- the magnitude and timing of any changes to our facilities, manufacturing operations and other infrastructure, and factors impacting our ability to access our facilities;
- the impact of any potential claims, investigations, information requests, or legal, regulatory or administrative proceedings with respect to potential or asserted violations of law, including: sales and marketing practices, anti-corruption and the Foreign Corrupt Practices Act, antitrust, securities, employment, product liability, environmental, data privacy breaches and patent infringement, which may subject us to fines, penalties, expenses, or reputational harm;
- anticipated and actual regulatory approvals of our products and competitive products; and
- product recalls impacting, or the suspension or withdrawal of regulatory clearance or approval relating to, our products or the products of our competitors.

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

- the disruptions caused by the COVID-19 global pandemic on suppliers, third-party manufacturers, healthcare providers, distributors and our existing or potential customers;
- continued increase in demand following the commercial launch of t:slim X2 with Control-IQ technology in additional geographies, and the ability to access new pump software using our Tandem Device Updater;
- anticipated new product launches;

- increased opportunity to achieve customer renewals as customers become eligible for insurance reimbursement to purchase a new insulin pump at the end of the typical four-year reimbursement cycle;

- ability to enter into, maintain agreements, and accomplish continued success in current and future product integrations with CGM partners;

- expansion and new product launches in select geographies outside the United States, including initial orders to stock inventories; and

- ability to effectively scale our operations to support rapid growth, including expanding our facilities, advancing our research and development efforts, increasing manufacturing capacity through third-party manufacturers, and hiring and retaining employees in customer service and support functions.

In addition to working to achieve our sales growth expectations, in the long-term we intend to continue to leverage our infrastructure investments to realize additional manufacturing, sales, marketing and administrative cost efficiencies with the goal of improving our operating margins and ultimately achieving sustained profitability. While we have achieved profitability in each fourth quarter since 2018, we were profitable for the first time on a full-year basis in 2021. We believe we can ultimately achieve sustained profitability by driving incremental sales growth in markets worldwide, meeting our pump renewal sales objectives, maximizing manufacturing efficiencies on increased production volumes, and leveraging the investments made in our sales, clinical, marketing and customer support organizations.

Components of Results of Operations

Sales

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

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

In the third quarter of 2018, we began the launch of our t:slim X2 hardware platform through distribution partners outside the United States. Our products are now sold in more than 20 countries, including in Canada, France and Germany. Our independent distributor partners outside the United States and Canada perform all sales, customer support and training in their respective markets. In Canada, we market with a direct sales force and, similar to the United States, use a distributor partner for certain billing and fulfillment activities. Historically, we have experienced consistent levels of reimbursement for our products in the United States, but we expect the average sales price will vary in markets outside the United States based on a number of factors, such as the geographical mix, nature of the reimbursement environment, government regulations and the extent to which we rely on distributor relationships to provide sales, clinical and marketing support.

In general, in the United States we have experienced pump shipments being weighted heavily towards the second half of the year, with the highest percentage of pump shipments expected in the fourth quarter due to the nature of the reimbursement environment. Consistent with these historical seasonality trends, our pump shipments in the United States have typically decreased significantly from the fourth quarter to the following first quarter. Outside the United States, we do not expect this same impact from seasonality associated with reimbursement, although the quarterly sales trends may be impacted by a number of other factors, including summer vacations, the timing of product launches into new geographies and variability in the ordering patterns of our distributor partners.

Since early 2020, the COVID-19 global pandemic had a major impact on businesses around the world, as well as our own quarterly trends. Initially, the impact on our business was relatively consistent worldwide but we have since seen varying degrees of impact in individual markets based on local conditions. For example, during 2021, we saw a gradual increase in the amount of in-person sales and training activities in the United States as vaccination availability expanded and social-distancing requirements were relaxed. During the second half of 2021, we saw reduced availability of customers and healthcare providers relating to people taking time off to vacation, which adversely impacted our sales of new pumps to customers during the period. We anticipate that our sales may not follow historical trends and may be subject to unpredictable variability in the coming months based on varying levels of impact of the global pandemic across the markets in which we operate. The full extent of the impact of the COVID-19 global pandemic on our business and operations will depend on a number of factors, including the scope and duration of the pandemic, varying government responses to the pandemic and potential delays to product development timelines.

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

Cost of Sales

Historically, we have manufactured our pumps and disposable insulin cartridges at our manufacturing facility in San Diego, California. In early 2020, our third-party cartridge manufacturer completed validation and commenced commercial-scale manufacturing to supplement our existing cartridge manufacturing capacity. By the end of 2021, the majority of our t:slim cartridge manufacturing capacity transitioned to our partner in order to create capacity for t:sport cartridge manufacturing in the future. Infusion sets and pump accessories are manufactured by third-party suppliers. Cost of sales includes raw materials, labor costs, manufacturing overhead expenses, product training costs, royalties, freight, reserves for expected warranty costs, costs of supporting our digital health platforms, scrap and charges for excess and obsolete inventories. Manufacturing overhead expenses include expenses relating to quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management.

Over the long term, we expect our overall gross margin percentage, which for any given period is calculated as sales less cost of sales divided by sales, to improve, as our sales increase and our overhead costs are spread over larger production volumes. We expect we will be able to leverage our manufacturing cost structure across our products that utilize the same technology platform and manufacturing infrastructure and will be able to further reduce per unit costs with increased automation, process improvements and raw materials cost reductions. We also expect our warranty cost per unit to decrease as we release additional product features and functionality utilizing the Tandem Device Updater. Pumps have, and are expected to continue to have, a higher gross margin percentage than our pump-related supplies. Therefore, the percentage of pump sales relative to total sales could have a significant impact on our overall gross margin percentage. In the event that customers delay their pump purchasing decisions or physicians pause in prescribing new pumps, it is possible that we may experience a higher percentage of pump-related supply sales than anticipated, which in turn could adversely impact our overall gross margin percentage. However, our overall gross margin percentage may fluctuate in future quarterly periods as a result of numerous factors aside from those associated with production volumes and product mix. For instance, as a result of the COVID-19 global pandemic we implemented temporary operational changes that introduced variability to our cost of sales, such as supplemental staffing, incremental expenses to protect the health, safety and welfare of our employees working on-site and to enable other employees to work remotely. We are also experiencing higher costs as we manage global supply challenges and anticipate that this will continue for the remainder of 2022. In addition, as demand for our products increases, we may continue to make additional investments in manufacturing capacity or increase our reliance on third parties for manufacturing-related services, either of which could have a negative impact on our gross margins. Specifically, we have and will continue to evaluate investing in additional manufacturing equipment to substantially increase our existing capacity in order to meet anticipated long-term demand for our cartridges, which may initially place downward pressure on the gross margin percentage associated with our pump-related supplies.

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

Selling, General and Administrative

Our selling, general and administrative (SG&A) expenses primarily consist of salary, cash-based incentive compensation, fringe benefits and non-cash stock-based compensation for our sales, marketing and administrative functions, which also includes our clinical, customer support, technical services, insurance verification and regulatory affairs personnel. We had approximately 110 sales territories in the United States in the first quarter of 2022, up from approximately 95 in 2021. Our existing territories are generally maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel, which have also been rapidly expanding to support our growing installed base. Our operations in Canada are comprised of approximately ten sales territories. Other significant SG&A expenses typically include those incurred for product demonstration samples, commercialization activities associated with new product launches, travel, trade shows, outside legal fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs. While we experienced reduced spending in areas such as travel and trade shows in 2021 due to the COVID-19 global pandemic, we may experience additional costs as our employees return to work at our offices and as we adapt to alternative hybrid work models, or as needed to respond to general labor shortages and heightened competition for employees with specialized skills. Overall, we expect our SG&A expenses, including the cost of our customer support infrastructure, to continue to increase as our customer base grows worldwide. In addition, we will continue to evaluate, and may further increase, the number of our field sales and clinical personnel in order to optimize the coverage of our existing territories. In the longer term, SG&A expenses may also increase due to anticipated costs associated with additional compliance and regulatory reporting requirements.

Research and Development

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

Other Income and Expense

Other income and expense primarily consists of interest expense which includes the amortization of debt issuance costs related to our 1.50% Convertible Senior Notes due 2025, changes in the fair value of certain warrants issued in connection with our public offering of common stock in October 2017, and interest earned on our cash equivalents and short-term investments. We expect interest expense in future quarters to be comparable with the amount expensed in 2021, through the date of conversion or redemption of the Notes. We expect the revaluation of the outstanding Series A warrants will not have a significant impact on our other income and expense through their expiration in the fourth quarter of 2022.

Income Tax Expense (Benefit)

Because the Company maintains a full valuation allowance against its net deferred tax assets, income tax expense is expected to primarily consist of current state and foreign cash tax expense as a result of taxable income anticipated or incurred in those jurisdictions. Income tax expense (benefit) may fluctuate in future quarters due to adjustments related to non-recurring transactions and changes in certain tax assessments.

Results of Operations

(in thousands, except percentages)	Three Months Ended March 31, 2022	2021
Sales:		
United States	$ 131,283	$ 103,339
Outside the United States	44,624	37,698
Total sales	175,907	141,037
Cost of sales	84,814	67,750
Gross profit	91,093	73,287
Gross margin	52 %	52 %
Operating expenses:		
Selling, general and administrative	73,271	58,563
Research and development	33,160	17,961
Total operating expenses	106,431	76,524
Operating loss	(15,338)	(3,237)
Other income (expense), net:		
Interest income and other, net	381	272
Interest expense	(1,516)	(1,506)
Change in fair value of common stock warrants	34	(690)
Total other expense, net	(1,101)	(1,924)
Loss before income taxes	(16,439)	(5,161)
Income tax benefit	(1,724)	(117)
Net loss	$ (14,715)	$ (5,044)

Comparison of the Three Months Ended March 31, 2022 and 2021

Sales. For the three months ended March 31, 2022, sales were $175.9 million, which included $44.6 million of sales outside the United States. Sales were $141.0 million for the same period in 2021, which included $37.7 million of international sales.

The increase in worldwide sales of $34.9 million in the first quarter of 2022, compared to the first quarter of 2021, was driven by an 11% increase in worldwide pump shipments to 28,095 in the first quarter of 2022, compared to 25,352 in the first quarter of 2021, and a 35% increase in pump-related supply sales. Sales of pump-related supplies increased primarily due to 47% growth in our estimated worldwide installed base of customers.

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

	Three Months Ended March 31, 2022	2021
Pump	$ 73,497	$ 62,912
Infusion sets	39,741	27,392
Cartridges	17,677	12,765
Other	368	270
Total Sales in the United States	$ 131,283	$ 103,339

Pump sales in the United States were $73.5 million for the first quarter of 2022, compared to $62.9 million in the first quarter of 2021. Pump shipments in the United States were 18,658 in the first quarter of 2022, compared to 16,644 in the first quarter of 2021. The increase in pump shipments was primarily due to continued strong demand for our t:slim X2 insulin pump with Control-IQ technology despite the challenging COVID-19 environment which has impacted the availability of both customers and healthcare providers. Sales of pump-related supplies increased primarily due to a 36% increase year over year in our estimated installed base of customers in the United States. Sales to distributors accounted for 65% and 68% of our total sales in the United States for the three months ended March 31, 2022 and 2021, respectively. Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor.

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

	Three Months Ended March 31,	
	2022	**2021**
Pump	$ 22,332	$ 18,908
Infusion sets	14,999	12,734
Cartridges	7,177	5,949
Other	116	107
Total Sales Outside the United States	$ 44,624	$ 37,698

Pump sales outside the United States were $22.3 million for the first quarter of 2022, compared to $18.9 million in the first quarter of 2021. Pump shipments increased 8% compared to the same period in the prior year due to strong demand for our products as we continue to expand the launch of Control-IQ technology outside the United States, which began in the first quarter of 2020. Sales of pump-related supplies benefited from an 87% increase in our estimated installed base of customers outside the United States. The ordering patterns of our distributors outside the United States for pumps and supplies is highly variable from period to period as they continue to gain familiarity with the markets in which they operate and the acceptance of our products in those markets. This variability was compounded during the period by the differing levels of impact from the global pandemic with regard to both access to physicians and customers, as well as shipping logistics. Sales to distributors accounted for 96% of our total sales outside the United States for both of the three month periods ended March 31, 2022 and 2021.

Cost of Sales and Gross Profit. Our cost of sales for the three months ended March 31, 2022 was $84.8 million, resulting in gross profit of $91.1 million, compared to cost of sales of $67.8 million and gross profit of $73.3 million for the same period in 2021. The gross margin for the three months ended March 31, 2022 and 2021 was 52%.

The increase in our gross profit for the three months ended March 31, 2022 was primarily the result of the $34.9 million increase in total sales. Gross margin benefited from an increase in average selling prices as well as improvement in per unit manufacturing costs across all products from manufacturing efficiencies, leverage of fixed overhead and increased volumes from our third-party cartridge manufacturer. On an aggregate basis, non-manufacturing costs, which primarily consist of warranty, training, royalty and freight, were negatively impacted by increased supply chain costs due to the global pandemic. We anticipate continued pressure from increased supply chain and material costs through the end of this year as we continue to navigate the challenges of the global pandemic. Other factors that have and may continue to impact the gross margin percentage are changes in product and geographical mix and the level of non-cash stock-based compensation allocated to cost of sales. Pump sales, which have the highest gross margin, were 54% of total worldwide sales in the first quarter of 2022 versus 58% in the first quarter of 2021.

Selling, General and Administrative Expenses. SG&A expenses increased 25% to $73.3 million for the three months ended March 31, 2022, from $58.6 million for the same period in 2021. Employee-related expenses for our SG&A functions comprise the majority of SG&A expenses. The increase compared to 2021 was primarily the result of a $12.8 million increase in salaries, incentive compensation, non-cash stock-based compensation, and other employee benefits due to an increase in personnel to support additional sales territories, higher sales and other services in support of our growing installed customer base. Non-cash stock-based compensation expense allocated to SG&A was $11.9 million for the three months ended March 31, 2022, compared to $9.4 million in the same period in 2021. We also experienced a $1.8 million increase in other non-employee discretionary spending, including outside services, and supplies costs.

Research and Development Expenses. R&D expenses increased 85% to $33.2 million for the three months ended March 31, 2022 from $18.0 million for the same period in 2021. The increase in R&D expenses was primarily the result of an increase of $8.9 million in salaries, incentive compensation, non-cash stock-based compensation, and other employee benefits due to an increase in personnel to support our product development efforts. Non-cash stock-based compensation expense allocated to R&D was $4.4 million for the three months ended March 31, 2022, compared to $2.1 million in the same period in 2021. We also experienced a $6.3 million increase in other non-employee discretionary spending, including clinical trial expenses, outside consulting and services, information technology and equipment costs attributable to R&D.

Other Income (Expense), Net. Total other expense, net for the three months ended March 31, 2022 was $1.1 million compared to $1.9 million in the same period in 2021. Total other expense, net for both periods primarily consisted of $1.5 million of interest expense which included the amortization of debt issuance costs related to our Notes, partially offset by interest earned on our cash equivalents and short-term investments. Total other expense, net for the three months ended March 31, 2021 also included a $0.7 million loss on revaluation from the change in fair value of certain warrants.

Liquidity and Capital Resources

At March 31, 2022, we had $635.4 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.

Historically, our principal sources of cash have included cash collected from product sales, private and public offerings of equity securities, exercises of employee stock awards, and debt financing.

Our historical cash outflows have primarily been associated with cash used for operating activities such as the development and commercialization of our products, the expansion and support of our sales, marketing, clinical and customer support organizations, the expansion of our R&D activities, the expansion of our commercial activities to select geographies outside the United States, the acquisition of intellectual property and equity investments, expenditures related to increases in our manufacturing capacity and improvements to our manufacturing efficiency, overall expansion of our facilities and operations, and other working capital needs. Additionally, we have used cash to pay the interest expense associated with our convertible senior notes.

The following table shows a summary of our cash flows for the three months ended March 31, 2022 and 2021 (in thousands):

	Three Months Ended March 31,	
	2022	2021
Net cash provided by (used in):		
Operating activities	$ 13,800	$ 28,685
Investing activities	5,197	(6,094)
Financing activities	3,500	3,573
Effect of foreign exchange rate changes on cash	3	14
Net increase in cash and cash equivalents	$ 22,500	$ 26,178

Operating Activities. Net cash provided by operating activities was $13.8 million for the three months ended March 31, 2022, compared to $28.7 million in the same period in 2021. The reduction in net cash provided by operating activities for 2022 compared to 2021 was primarily a result of a $9.7 million increase in net loss as well as working capital changes. Working capital changes during the first three months of 2022, primarily consisted of decreases in accounts receivable and employee-related liabilities, and increases in inventories and accounts payable and accrued expenses. Accounts receivable decreased to $94.1 million at March 31, 2022, from $110.7 million at December 31, 2021, as a result of lower sales in the first quarter of 2022 as compared to the fourth quarter of 2021. Inventories increased to $80.0 million at March 31, 2022 from $68.6 million at December 31, 2021.

Investing Activities. Net cash provided by investing activities was $5.2 million for the three months ended March 31, 2022, which was primarily related to $118.6 million in proceeds from maturities and sales of short-term investments, offset by $110.7 million of purchases of short-term investments, and $2.6 million in purchases of property and equipment. Net cash used by investing activities was $6.1 million for the three months ended March 31, 2021, which was primarily related to $154.3 million of purchases of short-term investments, and $3.5 million in purchases of property and equipment, offset by $151.7 million in proceeds from maturities and sales of short-term investments.

Financing Activities. Net cash provided by financing activities was $3.5 million for the three months ended March 31, 2022, which primarily consisted of proceeds from the issuance of common stock under our stock plans. Net cash provided by financing activities was $3.6 million for the three months ended March 31, 2021, which consisted of $3.1 million in proceeds from the issuance of common stock under our stock plans, and $0.4 million in proceeds from the exercise of common stock warrants.

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

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

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

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

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

Indebtedness

In May 2020, the Company entered into a purchase agreement with certain counterparties for the sale of an aggregate of $287.5 million principal amount of 1.50% Convertible Senior Notes due 2025 in a private offering to qualified institutional buyers (the Notes). The proceeds from the issuance of the Notes were $244.6 million, net of debt issuance costs and cash used to pay the cost of the Capped Call Transactions (see Note 7, “Debt”). The Notes are the Company’s senior unsecured obligations. Interest is payable in cash semi-annually in arrears beginning on November 1, 2020 at a rate of 1.50% per year. The Notes mature on May 1, 2025 unless repurchased, redeemed, or converted in accordance with their terms prior to the maturity date.

Cash payments due by calendar year for our Convertible Senior Notes at March 31, 2022 are as follows (in thousands):

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

(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.

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 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.

There have been no material changes to our critical accounting policies and estimates from the information provided in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Policies Involving Management Estimates and Assumptions,” included in our Annual Report on Form 10-K for the year ended December 31, 2021.

Off-Balance Sheet Arrangements

As of March 31, 2022, we are a party to certain standby letter of credit arrangements in support of our operating lease obligations. For a description of the arrangements we consider significant, see Note 12 “Commitments and Contingencies” to the condensed consolidated financial statements in Part I, Item 1 of this Quarterly Report.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

Credit and Interest Rate Risks

We invest our excess cash in marketable securities consisting primarily of commercial paper, corporate debt securities, U.S. Treasury securities and U.S. Government-sponsored enterprise securities. Some of the financial instruments in which we invest subject us to market risk, in that a change in prevailing interest rates may cause the principal amount of the instrument to fluctuate. Other financial instruments in which we invest subject us to credit risk, in that the value of the instrument may fluctuate based on the issuer's ability to pay. As a result of the COVID-19 global pandemic and the perceived increased credit risks associated with certain securities, credit rating agencies have, from time to time, issued downgrades or revised outlooks to negative for certain issuers of the debt securities held in our short-term investments portfolio. Unrealized losses on available-for-sale debt securities at March 31, 2022 were primarily due to the recent increase in market interest rates. Based on the credit quality of the available-for-sale debt securities that are in an unrealized loss position, and our current estimates of future cash flows to be collected from those securities, we believe the unrealized losses were not credit losses (see Note 3, "Short-Term Investments").

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

Because of the short-term maturities of our financial instruments, we do not believe that an increase or decrease in market interest rates would have any significant impact on the realized value of our investment portfolio. If a 10% change in interest rates were to have occurred on March 31, 2022, it would not have had a material effect on the fair value of our investment portfolio as of that date.

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

Foreign Currency Exchange Rate Risk

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

Item 4. Controls and Procedures.

Evaluation of 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 March 31, 2022, we carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures. Based on this evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of March 31, 2022.

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 March 31, 2022 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings.

In May 2020, we were named as a defendant in three California state court class action lawsuits arising from a data breach that we experienced in January 2020. Collectively, these lawsuits seek statutory, compensatory, actual, and punitive damages; equitable relief, including restitution; pre- and post-judgment interest; injunctive relief; and attorney fees, costs, and expenses from us. On July 24, 2020, these three pending lawsuits were consolidated into a single case in the Superior Court of the State of California in the County of San Bernardino entitled *Joseph Deluna et al v. Tandem Diabetes Care, Inc.* The consolidated case alleges violations of the Confidentiality of Medical Information Act (CMIA), CCPA, California's Unfair Competition Law (UCL), and breach of contract. We filed a demurrer seeking dismissal of all claims, which was heard by the Court on October 27, 2020, and which resulted in the following outcome: (i) the demurrer to the CMIA claim was denied; (ii) the demurrer to the CCPA claim was sustained; and (iii) the demurrer to the UCL and contract claims were sustained with leave to amend the pending complaint. A second demurrer was heard by the Court on March 29, 2021 with the following outcome: (i) the demurrer to the CMIA claim was denied; and (ii) the demurrer to the UCL and contract claims was sustained without leave to amend as to three of the named plaintiffs. The plaintiffs filed a motion for class certification on January 7, 2021 to which the Company filed its opposition on April 11, 2022. The Company filed a motion for summary adjudication on the CMIA claim on April 7, 2021, which is still pending.

In September 2020, we were named as a defendant in a lawsuit entitled *Buck Walsh, individually and on behalf of others similarly situated v. Tandem Diabetes Care, Inc.*, which was filed in the Superior Court of the State of California in San Diego County. The alleged violations include business and professions code and labor code violations for failure to compensate wages, unpaid meal and rest periods, and failure to reimburse for necessary business-related expenses. The proposed class of plaintiffs includes hourly paid or non-exempt employees of the Company who were employed from April 6, 2016 through the date of adjudication. The material terms of the settlement are set forth in a binding Memorandum of Agreement dated as of July 1, 2021, which was approved by the independent arbitrator on April 18, 2022. Subsequent to this filing, the Company anticipates receipt of the final settlement amount from the settlement administrator. This lawsuit will be resolved and closed upon disbursement of the settlement amount.

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

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

Item 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 Quarterly Report, as well as in our other filings with the SEC, in evaluating our business. If any of the following risks actually occur, our business, financial condition, operating results and future prospects could be materially and adversely affected. In that case, the trading price of our common stock may decline and you might lose all or part of your investment. The risks described below are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business, financial condition, operating results, liquidity, and future prospects. Certain statements below are forward-looking statements. For additional information, see Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations of this Quarterly Report.

The risk factors set forth below marked with an asterisk (*) next to the title contain changes to the description of the risk factors previously disclosed in Part I, Item 1A of our Annual Report.

Summary of Risk Factors

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

Risks Related to Our Business and Our Industry

- We have incurred significant operating losses since inception and may not achieve sustained profitability.
- We currently rely on sales of insulin pump products to generate a significant portion of our revenue, and any factors that negatively impact sales of these products may adversely affect us.
- Our ability to maintain and grow our revenue depends on retaining a high percentage of our customer base.
- Failure to secure or retain adequate coverage or reimbursement for our products by third-party payors could adversely affect our business.
- We may fail to meet our sales forecasts if we are unable to maintain our existing sales, marketing, clinical and customer service infrastructure.
- If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.
- Our failure to successfully complete clinical trials and development-stage testing could prevent us from obtaining regulatory approvals for or commercializing our products.
- We depend on a limited number of third-party suppliers for certain components and products.
- Any disruption at one of our facilities could adversely affect our business and operating results.
- Global economic and market uncertainty may adversely impact our business, financial condition and operating results.

Risks Related to Our Future Financings and Financial Results

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

Risks Related to Our Intellectual Property and Potential Litigation

- Our ability to comprehensively protect our intellectual property and proprietary technology is uncertain.
- Patent litigation is not uncommon in the medical device industry, and we may be subject to such litigation.
- We may be subject to damages resulting from claims that we have wrongfully used or disclosed patient health information or trade secrets, or are in breach of non-competition or non-solicitation agreements.

Risks Related to Our Legal and Regulatory Environment

- Our products and operations are subject to extensive governmental regulation, and regulatory approvals could be denied or delayed.
- New products or modifications to our existing products may require new regulatory approvals, or require us to cease marketing or recall modified products.
- If we or our third-party suppliers, contract manufacturers or service providers fail to comply with manufacturing regulations, it could impair our ability to market our products.

Risks Related to Our Common Stock

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

Risks Related to Our Convertible Senior Notes

- The Notes could adversely affect our financial condition.
- We may not have sufficient cash flow from our business to service the Notes.
- We may take actions which could limit our ability to make payments on the Notes.

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 March 31, 2022, we had an accumulated deficit of $649.3 million. To date, we have funded our operations primarily through cash collected from product sales, private and public offerings of our equity securities, and debt financing. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing and business operations, and the research and development of our current products and products under development.

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

Since the first quarter of 2013, we have been able to manufacture and sell our insulin pump products at a cost and in volumes sufficient to allow us to achieve a positive overall gross margin. For the years ended December 31, 2021 and 2020, our gross profit was $376.2 million and $260.5 million, respectively. Although we have achieved a positive overall gross margin and generated net income on an annual basis for the first time for the year ended December 31, 2021, we may still operate at a net loss from time to time due to fluctuations in our business.

To implement our business strategy and achieve consistent profitability, we need to, among other things, increase sales of our products and the gross profit associated with those sales, maintain an appropriate customer service, training and support infrastructure, fund ongoing R&D activities, create additional efficiencies in our manufacturing processes while adding to our capacity, and obtain regulatory clearance or approval to commercialize our products currently under development both in the United States and the more than 20 countries in which we operate outside the United States. We expect our expenses will continue to increase as we pursue these objectives and make investments in our business. Additional increases in our expenses without commensurate increases in sales could significantly increase our operating losses.

The extent of our future operating losses and the timing of our profitability are highly uncertain in light of a number of factors, including the timing of the launch of new products and product features by us and our competitors, market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers, the timing of regulatory approval of our products and the products of our competitors, the actual efficiencies gained in our manufacturing processes, and the scope and duration of the impacts caused by the COVID-19 global pandemic. Any additional operating losses will have an adverse effect on our stockholders' equity, and we cannot assure you that we will be able to sustain profitability.

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

We generate nearly all of our revenue from the sale of t:slim X2 insulin pumps and the related insulin cartridges and infusion sets. Sales of these products may be negatively impacted by many factors, including:

- market acceptance of the insulin pumps and related products manufactured and sold by our key competitors, including Medtronic;
- the potential that breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pumps obsolete or less desirable;
- adverse regulatory or legal actions relating to our products, or similar products or technologies of our competitors;
- failure of our Tandem Device Updater to accurately and timely provide customers with remote access to new product features and functionality as anticipated, or our failure to obtain regulatory approval for any such updates;
- changes in reimbursement rates or policies relating to insulin pumps or similar products or technologies by third-party payors;

- our inability to enter into contracts with third-party payors on a timely basis and on acceptable terms;
- problems arising from the expansion of our manufacturing capabilities and commercial operations, or destruction, loss, or temporary shutdown of our manufacturing facilities;
- concerns regarding the perceived safety, reliability or cybersecurity of any of our products, or any component thereof, particularly in connection with the launch of additional mobile app features and functionality and other software products; and
- claims that any of our products, or any component thereof, infringes on patent rights or other intellectual property rights of third parties.

In addition, sales of any of our current or future insulin pump products with CGM integration are subject to the continuation of our applicable agreements with Dexcom, Abbott, or other third parties which, under some circumstances, may be subject to termination, with or without cause, on relatively short notice. Sales of our current or future products may also be negatively impacted in the event of any regulatory or legal actions relating to CGM products that are compatible with our pumps, or in the event of any disruption to the availability of the applicable CGM-related supplies, such as sensors or transmitters, in a given market in which our products are sold. Sales of our products may also be adversely impacted if the CGM products that are compatible with our pumps are not viewed as superior to competing CGM products in markets where our products are sold, or if the price of these products is not competitive with similar products available in the market.

Because we currently rely on sales of our t:slim X2 insulin pump and related products to generate a significant majority of our revenue, any factors that negatively impact sales of these products (or negatively impact the products or components integrated with these products), or result in sales of these products increasing at a lower rate than expected, could adversely affect our business, financial condition and operating results. We believe the COVID-19 global pandemic has had, and that it may continue to have, an adverse impact on sales of our products. Furthermore, any disruption in our supply chain could negatively impact our ability to manufacture or otherwise supply sufficient product quantities to meet current customer demand, or any unexpected increase in demand, which could also have the effect of magnifying the negative impact of any of the factors described above.

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

Public health threats and other highly communicable diseases and outbreaks could adversely impact our operations, the operations of our customers, suppliers, distributors and other business partners, as well as the healthcare system in general. The overall scope of the COVID-19 global pandemic and its impacts continue to fluctuate, and in some instances worsen, in various regions worldwide. Although the overall negative impact from the COVID-19 global pandemic on our business is difficult to estimate, our sales and operating results have been adversely impacted, and we anticipate that they will continue to be impacted and subject to unpredictable variability in future periods. Further, certain development activities, such as human factors studies associated with our product development efforts, activities to support the manufacturing scale-up for new products and the recruitment of participants in ongoing clinical studies, were modified or delayed due to impacts of the COVID-19 global pandemic, which has and continues to impact our development timelines and regulatory strategies and also could have a negative impact on our product commercialization efforts and the future demand for our products.

The COVID-19 global pandemic, or other similar outbreaks or epidemics, may have an adverse effect on the overall productivity of our workforce, and we expect to continue to take appropriate measures to protect the health and safety of our employees and our business partners and reduce the risk of disruptions to our operations. We temporarily increased our staffing in certain operations in order to mitigate potential risks associated with increases in unplanned employee absences or illness. Our adoption of these preventive measures has resulted in incremental costs that have negatively impacted our gross margin, and could impact future periods. In addition, for the duration of the COVID-19 global pandemic, some of our employees may be required to continue to operate within a remote work environment for extended periods of time due to illness, travel restrictions, government-imposed orders, school closures or for other reasons, any of which could result in reduced productivity of our workforce. As the COVID-19 global pandemic improves, we anticipate adapting to a hybrid work model, and we may experience additional costs as our employees return to work, or as we respond to general labor shortages and heightened competition for employees with specialized skills.

In addition to the foregoing impacts, disruptions from the COVID-19 global pandemic, or other similar outbreaks or epidemics, could result in delays in or the suspension of our manufacturing operations, research and product development activities, regulatory work streams, clinical development programs and other important commercial functions. In particular, if we or our third-party manufacturers are required to delay or suspend our manufacturing operations, we may encounter severe product shortages, which would adversely affect our results of operations and harm our reputation. We are also dependent upon our third-party suppliers for many of our product components and for our manufacturing-related equipment, and the COVID-19 global pandemic has and could continue to have a material adverse impact on the operations of one or more of our suppliers. These adverse impacts on our suppliers could prevent them from delivering products to us or supporting our requirements for manufacturing-related equipment on a timely basis, or at all. Additionally, we have been and may continue to be negatively impacted by global shortages of semiconductors and copper, which could limit our insulin pump manufacturing capacity. If we continue to experience these or similar manufacturing challenges, or if these challenges worsen in the future, it could increase our manufacturing costs, disrupt our manufacturing operations, negatively impact our product sales and harm our reputation.

The full extent of the impact of the COVID-19 global pandemic on our business and operations is highly uncertain and subject to change, and will continue to depend on a number of factors, including the scope and duration of the pandemic and any resulting changes to general economic conditions in the countries in which we operate and sell our products. Further spread or escalation of the COVID-19 global pandemic, a resurgence of the pandemic in the United States, or even the threat or perception that this could occur, or any protracted duration of decreased economic activity or increase in inflation, could have a material adverse impact on our business, operations and financial results and could negatively impact or disrupt our plans to have employees return to our facilities.

Our ability to maintain and grow our revenue depends in part on retaining a high percentage of our customer base.

A key to maintaining and growing our revenue is the retention of a high percentage of our customers due to the potentially significant revenue generated from ongoing purchases of disposable infusion sets, insulin cartridges and other supplies. In addition, our pumps are designed and tested to remain effective for at least four years and a customer may consider purchasing another product from us when the time comes to replace the pump. We have developed retention programs aimed at our customers, their caregivers and healthcare providers, which include training specific to our products, ongoing support by our sales and clinical employees, and technical support and customer service. Demand for our products from our existing customers could decline or could fail to increase as anticipated or projected as a result of a number of factors, including the introduction of competitive products, breakthroughs for the monitoring, treatment or prevention of diabetes, changes in reimbursement rates or policies, manufacturing problems, perceived safety or reliability issues with our products or components or the products of our competitors, the failure to secure regulatory clearance or approvals for products or product features in a timely manner or at all, product development or commercialization delays, the impacts and disruptions caused by the COVID-19 global pandemic, or for other reasons.

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

The failure to retain a high percentage of our customers and increase sales to these customers consistent with our forecasts would have a material adverse effect on our business, financial condition and operating results.

We operate in a very competitive industry and if we fail to compete successfully against our existing or potential competitors, or if the competitive environment harms our business partners, our financial condition and operating results may be negatively affected.*

The medical device industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products, treatment techniques or technologies, as well as other activities of industry participants. We believe our products compete, and will continue to compete, directly with a number of traditional insulin pumps, as well as other methods for the treatment of diabetes, including multiple daily injection (MDI) therapy.

Our primary competitors are major medical device companies that are publicly traded companies or divisions or subsidiaries of publicly traded companies, including Insulet and Medtronic. In addition, Eli Lilly has announced a collaboration to commercialize an existing third-party insulin pump as part of a to-be-developed system and Becton Dickinson and Company recently completed the spin off its diabetes care business as a separate publicly-traded company, Embecta. There are also a number of other companies developing and marketing their own insulin delivery systems and/or related software applications, including insulin pumps and Bluetooth-enabled insulin pens to support MDI therapy. While these industry changes are significant, it is difficult to know how they will impact our business or the competitive landscape in which we operate. Our key competitors, most notably Medtronic, enjoy several competitive advantages over us, including:

- greater financial and human resources for sales and marketing, product development, customer service and clinical resources;
- greater ability to respond to competitive pressures, regulatory uncertainty, or challenges within the financial markets;
- established relationships with healthcare providers, third-party payors and regulatory agencies;
- established reputation and name recognition among healthcare providers and other key opinion leaders in the medical industry generally and the diabetes industry in particular;
- larger and more established distribution networks;
- greater ability to cross-sell products or provide incentives to healthcare providers to use their products; and
- more experience in conducting R&D, manufacturing, clinical trials, and obtaining regulatory approval or clearance.

In some instances, our competitors offer products that include features that we do not currently offer. For instance, Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set and Medtronic is selling a connected insulin pen delivery device. Additionally, Medtronic recently announced the launch in select European countries of an infusion set that can be worn for up to seven days.

In addition, the competitive environment in which we operate has resulted and may continue to result in competitive pressures on our manufacturers, suppliers, distributors, collaboration partners and other business constituents. For example, we have entered into development agreements with Dexcom, which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. Abbott also offers glucose sensors which compete with Dexcom CGMs. Further, we have entered into an agreement with Abbott to develop and commercialize integrated diabetes solutions using Abbott’s glucose sensor. There can be no assurance that our collaborations with Dexcom and Abbott will be successful or that we will not experience delays, business disputes, or other unanticipated challenges. Competitive pressures within our industry, as well as the impacts and disruptions associated with the COVID-19 global pandemic, could negatively impact the financial condition of our business partners and impact their ability to fulfill contractual obligations to us, which could negatively impact our product sales, result in delays in obtaining regulatory approvals for new products, harm our reputation, and result in harm to our financial condition and operating results.

For these and other reasons, we may not be able to compete successfully against our current or potential future competitors, which could have a material adverse impact on our financial condition and operating results.

Competitive products or other technological developments and breakthroughs for the monitoring, treatment or prevention of diabetes may render our products obsolete or less desirable.

Our ability to grow our business and achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the treatment of diabetes that offer distinct features and functionality, are easy-to-use, provide superior treatment outcomes, receive adequate coverage and reimbursement from third-party payors, and are otherwise more appealing than available alternatives. Our primary competitors, as well as a number of other companies and medical researchers are pursuing new delivery devices, delivery technologies, sensing technologies, treatment techniques, procedures, drugs and other therapies for the monitoring, treatment and prevention of diabetes. Any breakthroughs in diabetes monitoring, treatment or prevention could reduce the potential market for our products or render our products obsolete altogether, which would significantly reduce our sales or cause our sales to grow at a slower rate than we currently expect. In addition, even the perception that new products may be introduced, or that technological or treatment advancements could occur, could cause consumers to delay the purchase of our products.

Because the insulin-dependent diabetes market is large and growing, we anticipate companies will continue to dedicate significant resources to developing competitive products and technologies. The introduction by competitors of products that are or claim to be superior to our products may create market confusion that may make it difficult to differentiate the benefits of our products over competitive products. In addition, some of our competitors employ aggressive pricing strategies, including the use of discounts, rebates, low cost product upgrades or other financial incentives that could adversely affect sales of our products. If a competitor develops a product that competes with or is perceived to be superior to our products, or if competitors continue to utilize strategies that place downward pressure on pricing within our industry, our sales may decline, our operating margins could be reduced and we may fail to meet our financial projections, which would materially and adversely affect our business, financial condition and operating results.

Moreover, we have designed our hardware products to resemble modern consumer electronic devices to address certain embarrassment and functionality concerns consumers have raised with respect to traditional pumps. Similarly, our newer mobile software applications are being designed to incorporate features and functions that are common to other consumer-oriented applications. These consumer industries are themselves highly competitive, and characterized by continuous new product introductions, rapid developments in technology, and subjective and changing consumer preferences. If, in the future, consumers cease to view our products as contemporary or convenient as compared to then-existing consumer technology, our products may become less desirable.

The failure of our insulin pump and related products to achieve and maintain market acceptance could result in us achieving sales below our expectations, which would cause our business, financial condition and operating results to be materially and adversely affected.

Our current business and growth strategy is highly dependent on our insulin pump and related products achieving and maintaining market acceptance. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that our products are an attractive alternative to competitive products for the treatment of diabetes, including traditional insulin pump products and MDI therapies, as well as alternative diabetes monitoring, treatment or prevention methodologies. Market acceptance and adoption of our products depends on educating people with diabetes, as well as their caregivers and healthcare providers, about the distinct features, ease-of-use, beneficial treatment outcomes, and other perceived benefits of our products as compared to competitive products. If we are not successful in convincing existing and potential customers of the benefits of our products, or if we are not able to achieve the support of caregivers and healthcare providers for our products, our sales may decline or we may achieve sales below our expectations.

Market acceptance of our products could be negatively impacted by many factors, including:

- the failure of our products to achieve and maintain wide acceptance among people with insulin-dependent diabetes, their caregivers, healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;

- lack of evidence supporting the safety, ease-of-use or other perceived benefits of our products over competitive products or other currently available insulin treatment methodologies;

- perceived risks or uncertainties associated with the use of our products, or components thereof, or of similar products or technologies of our competitors;

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

In addition, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements or breakthroughs, or the perception that advancements or breakthroughs could occur, in our products or the products offered by our competitors. It is also possible that consumers interested in purchasing any of our future products currently under development may delay the purchase of one of our current products. We anticipate that customers may continue to delay their purchasing decisions, or physicians may continue to pause prescriptions of our products, as a result of the COVID-19 global pandemic.

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 20 countries in which we operate outside the United States with third-party payors and add coverage for future products under our current agreements, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis. In particular, we have limited experience securing reimbursement in international markets 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 international markets. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have limited experience marketing and selling our products to customers with type 2 diabetes.

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

Our financial condition and operating results are and will continue to be highly dependent on our ability to adequately promote, market and sell our insulin pump and related products, and the ability of our diabetes educators to train new customers on the use of our products. If our sales and marketing representatives or diabetes educators continue to be restricted in their ability to interact with healthcare providers and customers, our sales could decrease or may not increase at levels that are in line with our forecasts.

If we are unable to maintain our existing sales, marketing, clinical and customer service infrastructure, we may fail to increase our sales to meet our forecasts.

A key element of our business strategy involves our sales, marketing, clinical and customer service personnel driving adoption of our products. We have significantly increased the number of sales, marketing, clinical and customer service personnel employed by us since we commenced commercial sales. However, we have faced considerable challenges in growing and managing these resources, including with respect to recruiting, training and assimilation of sales territories and new clinical training staff. We expect to continue to face significant challenges as we seek to further increase the number of our sales, clinical and customer service personnel in order to optimize the coverage of our existing sales territories, as well as expand the number and scope of our existing sales territories. These challenges may be even greater in connection with our commercial expansion outside of the United States, where we have limited experience. Unexpected turnover among our sales, marketing, clinical and customer service personnel, or unanticipated challenges in recruiting additional personnel, would have a negative impact on our ability to achieve our sales projections. Further, if a sales, marketing or clinical representative was to depart and be retained by one of our competitors, we may fail to prevent him or her from helping competitors solicit business from our existing customers, which could adversely affect our sales. Similarly, if we are not able to recruit and retain a network of diabetes educators and customer service personnel, we may not be able to successfully train and service new customers, which could delay new sales and harm our reputation. These risks may be greater now than in the past due to current general labor shortages in the United States, and in particular in our office locations in San Diego, California and Boise, Idaho.

We expect the oversight of our sales, marketing, clinical and customer service personnel will continue to place significant burdens on our management team, which may be compounded as we manage remote employees during the COVID-19 global pandemic and as we work towards returning personnel to our facilities. If we are unable to retain our personnel in line with our strategic plans, we may not be able to effectively commercialize our existing products or products under development, or enhance the strength of our brand, either of which could result in the failure of our sales to increase in line with our projections or cause sales to decline.

Our sales and marketing efforts are dependent on independent distributors who are free to market products that compete with our products. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.*

We believe a majority of our sales will continue to be to independent distributors for the foreseeable future, and it is possible that the percentage of our sales to independent distributors could increase, particularly in light of our reliance on independent distributors outside of the United States. For example, our dependence upon independent distributors in the United States could increase if third-party payors decide to contract with independent distributors directly in lieu of contracting with us to supply our products to their members directly. Our dependence upon independent distributors could also increase if customers prefer to purchase all of their diabetes supplies through a single source, instead of purchasing pump-related products through us and other diabetes supplies through other suppliers. None of our independent distributors in the United States have been required to sell our products exclusively and each of them may freely sell the products of our competitors. If we are unable to maintain or expand our network of independent distributors, our sales may be negatively affected.

For the year ended December 31, 2021, our two largest independent distributors in the United States collectively comprised approximately 21% of our worldwide sales, and our three largest independent international distributors collectively comprised approximately 55% of our international sales. If any of our key independent distributors were to cease to distribute our products or reduce their promotion of our products as compared to the products of our competitors, our sales could be adversely affected. In that case, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, the terms of the arrangements could result in our product margins being lower than if we directly marketed and sold our products.

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

As our clinical infrastructure expands, we expect to increasingly rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct some of our current and anticipated pre-clinical investigations and clinical trials. If we are not able to reach mutually acceptable agreements with these third parties on a timely basis, these third parties do not successfully carry out their commitments or regulatory obligations or meet expected deadlines, or the quality or accuracy of the data they obtain is compromised due to the failure to adhere to agreed-upon clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance or approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected.

We are increasingly dependent on clinical investigators and clinical sites to enroll participants in our current and anticipated clinical trials and human factors studies, and the failure to successfully complete those trials and studies could prevent us from obtaining regulatory approvals for or commercializing our products.

As part of our product development efforts, we expect to increasingly rely on clinical investigators and clinical sites to enroll participants in our clinical trials or users in our human factors testing and other third parties to manage such trials and testing and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials or other studies. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients, fail to ensure compliance by patients with clinical protocols, or fail to comply with regulatory requirements, we may be unable to successfully complete our clinical trials or other studies, which could prevent us from obtaining regulatory approvals for our products and commercializing our products, which would have an adverse impact on our business.

If important assumptions about the potential market for our products are inaccurate, or if we have failed to understand what people with insulin-dependent diabetes are seeking in an insulin pump, our business and operating results may be adversely affected.

Our business strategy was developed based on a number of important assumptions about the diabetes industry in general, and the insulin-dependent diabetes market in particular, any one or more of which may prove to be inaccurate or may change over time. For example, we believe that the benefits of insulin pump therapy as compared to other common insulin treatment alternatives will continue to drive growth in the market for insulin pump therapy. In addition, we believe the incidence of diabetes in the United States and worldwide is increasing. Further, our view is that diabetes management can vary greatly from person to person, creating multiple market segments based on clinical needs and personal preferences. However, each of these assumptions may prove to be inaccurate and limited sources exist to compare treatment alternatives and obtain reliable market data. The actual incidence of diabetes, and the actual demand for our products or competitive products, could differ materially from our projections if our assumptions are incorrect. In addition, our strategy of focusing exclusively on the insulin-dependent diabetes market may limit our ability to increase sales or achieve profitability.

Another key element of our business strategy is utilizing market research to understand what people with diabetes are seeking to improve in their diabetes therapy management. This strategy underlies our entire product design, marketing and customer support approach and is the basis on which we developed our current products and are pursuing the development of new products. However, our market research is based on interviews, focus groups and online surveys involving people with insulin-dependent diabetes, their caregivers and healthcare providers, which represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we receive may not be reflective of the broader market and may not provide us accurate insight into the desires of people with insulin-dependent diabetes. In addition, understanding the meaning and significance of such market research responses necessarily requires that analysis be conducted and conclusions be drawn. We may not be able perform an analysis that yields meaningful results, or the conclusions we draw from the analysis could be misleading or incorrect. Moreover, even if our market research has allowed us to better understand the features and functionality consumers are seeking in an insulin pump to improve management of their diabetes therapy, there can be no assurance that consumers will actually purchase our products or that our competitors will not develop products with similar features.

We expect to face complexities frequently encountered by companies in competitive and rapidly evolving markets, which may make it difficult to evaluate our business and forecast our future sales and operating results.

We operate in a competitive and rapidly evolving market. Important industry changes, such as the FDA approval and launch of new products by our competitors, as well as changes specific to our business, such as the timing of our launch of new products currently in development, increasing reliance on digital health products and connected devices, and our potential expansion of commercial sales in international markets, combine to make it more difficult for us to predict our future sales and operating results, as well as our expected timeframe to achieve profitability. The significant uncertainty resulting from the COVID-19 global pandemic has made, and may continue to make, it more difficult for us to accurately forecast our financial results and achieve sustained profitability. In assessing our business prospects, you should consider these factors as well as the various risks and difficulties frequently encountered by companies in competitive and rapidly evolving markets, particularly those companies that manufacture and sell medical devices.

These risks include our ability to:

- implement and execute our business strategy;
- manage and improve the productivity of our sales, marketing, clinical and customer service infrastructure to grow sales of our existing and proposed products, and enhance our ability to provide service and support to our customers;
- achieve and maintain market acceptance of our products and increase awareness of our brand among people with insulin-dependent diabetes, their caregivers and healthcare providers;
- comply with a broad range of regulatory requirements within a highly regulated industry;
- enhance our manufacturing capabilities, increase production of products efficiently while maintaining quality standards, and adapt our manufacturing facilities to the production of new products;

- respond effectively to competitive pressures and developments;
- enhance our existing products and develop proposed products;
- manage cybersecurity and other technological risks associated with our expanding portfolio of digital health products, and align these products to a dynamic threat landscape.
- obtain and maintain regulatory clearance or approval to enhance our existing products and commercialize proposed products;
- perform clinical trials and other studies with respect to our existing products and proposed products; and
- attract, retain and motivate qualified personnel in various areas of our business.

As a result of these or other risks, we may not be able to execute key components of our business strategy, and our business, financial condition and operating results may suffer.

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

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

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

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

In addition, the per-unit cost of our products is significantly impacted by our overall production volumes, and any factors that prevent our products from achieving market acceptance, cause our production volumes to decline, alter our product mix, result in our sales growing at a slower rate than we expect, or result in the closure of our manufacturing facilities, would significantly impact our expected per-unit costs, which would adversely impact our gross margins. Further, we may not achieve anticipated improvements in manufacturing efficiency as we undertake actions to expand our manufacturing capacity. We are also subject to other general market and economic conditions that may increase our expenses, including unpredictable variability in commodity prices, wage increases and inflation. If we are unable to effectively manage our overall costs while increasing our production volumes and lowering our per-unit costs, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results.

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

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

- quality or reliability defects in product components that we source from third-party suppliers;
- our inability to secure product components in a timely manner due to shipping delays at ports of entry or exit, the impact of the COVID-19 global pandemic, or other issues, in sufficient quantities and on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our failure to increase production of products to meet demand;
- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently produce future products or implement changes in current products in response to consumer demand or regulatory requirements;
- our inability to manufacture multiple products simultaneously while utilizing common manufacturing equipment;
- government-mandated or voluntary closures of, or operational limitations impacting, our manufacturing facilities; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facilities.

As demand for our products increases, and as the number of our commercial products expands, we will have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes and quality systems. We may also increase our utilization of third parties to perform contracted manufacturing services for us, and we may need to acquire additional custom designed equipment to support the expansion of our manufacturing capacity. In addition, although we expect some of our products under development to share product features and components with our current products, manufacturing of these products may require modification of our production lines, hiring of specialized employees, identification of new suppliers for specific components, qualifying and implementing additional equipment and procedures, obtaining new regulatory approvals, or developing new manufacturing technologies. Ultimately, it may not be possible for us to manufacture these products at a cost or in quantities sufficient to make these products commercially viable.

In response to the COVID-19 global pandemic, in early 2020 we initiated discussions with our key suppliers regarding their abilities to fulfill existing orders and we have continued to regularly assess their capacity. At various times, our primary infusion set manufacturer experienced certain inventory constraints which resulted in us requesting some customers to accept substitutions of similar products to prevent delays in order fulfillment. Additionally, at various times our cartridge inventory was below our targeted stocking levels and our inventory of certain pump and cartridge components are currently below our targeted stocking levels. We continue to monitor factors that could negatively impact our supply chain, such as shortages of semiconductors and copper that are needed to manufacture our insulin pumps and accessories and custom components for our insulin pumps and cartridges where we rely on a limited number of qualified suppliers. If we continue to experience these or similar manufacturing challenges, or if these challenges worsen in the future, it could have a negative impact on product sales and harm our reputation.

If we and our suppliers fail to increase our production capacity to meet consumer demand while also maintaining product quality standards, obtaining and maintaining regulatory approvals, and efficiently managing costs, our sales and operating margins could be negatively impacted, which would have an adverse impact on our financial condition and operating results.

We depend on a limited number of third-party suppliers for certain components and products, and the loss of any of these suppliers, their inability to provide us with an adequate supply of components or products, or our ability to adequately forecast customer demand, could harm our business.

We currently rely, and expect to continue to rely, on third-party suppliers to supply components of our current products and our potential future products, including our disposable insulin cartridges. For example, we rely on plastic injection molding companies to provide plastic molded components, electronic manufacturing suppliers to provide electronic assemblies, and machining companies to provide machined mechanical components. We also purchase all of our infusion sets and pump accessories from third-party suppliers. For our business strategy to be successful, our suppliers must be able to provide us with components and products in sufficient quantities, in compliance with regulatory requirements and quality control standards, in accordance with agreed-upon specifications, at acceptable costs and on a timely basis.

Although we have long-term supply agreements with many of our suppliers, these agreements do not include long-term capacity commitments. Under most of our supply agreements, we make purchases on a purchase order basis and have no obligation to buy any given quantity of components or products until we place written orders, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of components or products until they accept an order. In addition, our suppliers may encounter problems that limit their ability to manufacture components or products for us, including financial difficulties, damage to their manufacturing equipment or facilities, inability to obtain raw materials or other components, or problems with their own suppliers. For instance, we are currently subject to allocation limits for certain semiconductor components. As a result, our ability to purchase adequate quantities of our components or products may be limited. If we fail to obtain sufficient quantities of high-quality components to meet demand on a timely basis, we could lose customer orders, our reputation may be harmed, and our business could suffer.

We generally use a small number of suppliers for our components and products, some of which are located outside the United States, including in China, Mexico and Costa Rica. Depending on a limited number of suppliers exposes us to risks, including limited control over costs, including tariffs, availability, quality and delivery schedules. Moreover, in some cases we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us at acceptable prices, or at all. We have in the past been, and we may in the future be, required to make significant “last time” purchases of component inventories that are being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. We are actively pursuing alternative suppliers of several existing components and qualifying new alternatives to existing select components, but there is no assurance that we will be able to identify alternative sources that meet our requirements and at comparable prices, or at all. Because of factors such as the proprietary nature of our products, our quality control standards and applicable regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. These risks associated with the procurement of critical components from a limited number of suppliers may be increased as a result of the COVID-19 global pandemic. Failure of any of our suppliers to deliver products at the level our business requires could harm our reputation and limit our ability to meet our sales projections, which could have a material adverse effect on our business, financial condition and operating results.

We place orders with our suppliers using our forecasts of customer demand, which are based on a number of assumptions and estimates, in advance of purchase commitments from our customers. As a result, we incur inventory and manufacturing costs in advance of anticipated sales, which sales ultimately may not materialize or may be lower than expected. If we overestimate customer demand, we may experience higher inventory carrying costs and increased excess or obsolete inventory, which would negatively impact our results of operations. By the same token, if we underestimate future demand we may be unable to meet future production requirements or our inventory of critical materials may be below our targeted stocking levels. We expect it will be particularly difficult to accurately forecast demand during the global pandemic and even for some time while travel and social-distancing restrictions are lifted.

We may also have difficulty obtaining components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of our suppliers to comply with regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. Such a failure by our suppliers could also require us to cease using the components, seek alternative components or technologies, and modify our products to incorporate alternative components or technologies, which could necessitate additional regulatory approvals. Any disruption of this nature, or any increased expenses associated with any such disruption, could negatively impact our ability to manufacture our products on a timely basis, in sufficient quantities, or at all, which could harm our commercialization efforts and have a material adverse impact on our operating results.

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

Although we operate in multiple locations, most of our current operations are still conducted in San Diego, California, including our final pump assembly, some manufacturing processes, and the majority of our research and development, management and administrative functions. In addition, the majority of our inventories of component supplies and finished goods is stored at two facilities in San Diego. Over the past two years we substantially expanded various quality and customer and technical support activities in Boise, Idaho. We take precautions to safeguard our facilities 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 from the transition of our manufacturing and warehousing operations.

At the beginning of 2018 we completed the transition of our manufacturing operations to a facility located on Barnes Canyon Road in San Diego, and during the fourth quarter of 2019 we commenced operations at a logistics warehouse in San Diego. We expect that both of these actions will allow for future capacity for product manufacturing and warehousing expansion. However, we may not experience the anticipated operating efficiencies at either facility as we continue to scale our business operations and add manufacturing requirements for products currently under development. In addition, beginning in 2020 we outsourced a portion of our cartridge manufacturing demand to an experienced third-party contract manufacturer and we expect to increase our reliance on this third party cartridge manufacturer over the next 24 months while reducing our own internal t:slim cartridge manufacturing capacity in our existing facility. We may consider outsourcing other aspects of our operations in the future. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which would have a material adverse impact on our operating results. In addition, we or our third-party contract manufacturers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints and environmental factors, any of which could delay or impede our ability to meet customer demand and have a material adverse impact on our business, financial condition and operating results. Further, because of the custom nature of our cartridge manufacturing process and product components, and the highly regulated nature of our products overall, in the event of any problems with a contract manufacturer, we may not be able to quickly establish additional or alternative arrangements.

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

If we do not enhance our product portfolio to meet the demands of our market, we may fail to effectively compete, which may impede our ability to become profitable.

In order to increase our sales and market share in the insulin-dependent diabetes market, we must enhance and broaden our product portfolio in response to the evolving demands of people with insulin-dependent diabetes, their caregivers and healthcare providers, as well as competitive pressures and technologies. We may not be successful in developing, obtaining regulatory approval for, or marketing our proposed products when anticipated, or at all. In addition, notwithstanding our market research efforts, our future products may not be accepted by people with insulin-dependent diabetes, their caregivers, healthcare providers or third-party payors. The success of any proposed product offerings will depend on numerous factors, including our ability to:

- identify the product features and functionality that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in an insulin pump, and successfully incorporate those features into our products;
- develop and introduce products in sufficient quantities and in a timely manner;
- offer products at a price that is competitive with other products then available;
- work with third-party payors to obtain reimbursement for our products;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of proposed products; and
- obtain the necessary regulatory approvals for proposed products on a timely basis.

If we fail to generate demand by continuing to develop products that incorporate features and functionality requested by people with insulin-dependent diabetes, their caregivers or healthcare providers, or if we do not obtain regulatory clearance or approval for proposed products in time to meet market demand, we may be unable to compete and may fail to generate sales sufficient to achieve or maintain profitability. We have in the past experienced, and may in the future experience, delays in various phases of product development and commercialization, including during research and development, manufacturing, limited release testing, marketing and customer education efforts. We have also recently experienced delays in the regulatory review and approval process, including due to the impacts of the current global pandemic. Any delays in our anticipated regulatory submissions or approvals, or subsequent product launches, may significantly impede our ability to successfully compete in our markets. In particular, such delays could cause customers to delay or forego purchases of our products, or to purchase our competitors' products. Even if we are able to successfully develop proposed products when anticipated, these products may not produce sales in excess of the costs of development, and they may be quickly rendered obsolete by changing consumer preferences or the introduction by our competitors of products embodying new technologies or features, or alternative methods for the treatment of diabetes.

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

Studies to evaluate the safety or effectiveness of our latest products in a controlled setting are only available over the past few years. As a result, people with insulin-dependent diabetes and healthcare providers may not be familiar with our studies and may be slower to adopt or recommend our products. Further, even with data from controlled studies third-party payors may not be willing to provide coverage or reimbursement for our products. We remain subject to regulatory and product liability risks, and these and other factors could slow the adoption of our products and result in our sales being lower than anticipated. In addition, future studies or clinical experience may indicate that treatment with our products is not superior to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability.

If the results of clinical studies or other experience, such as our monitoring or investigation of customer complaints, indicate that our products may cause or create an unacceptable risk of unexpected or serious complications or other unforeseen negative effects, we could be required to inform our customers of these risks or complications or, in more serious circumstances, we could be subject to mandatory product recalls, suspension or withdrawal of FDA clearance or approval, which could result in significant legal liability, harm to our reputation, and a decline in our product sales.

Any alleged illness or injury associated with any of our products or product recalls may negatively impact our financial results and business prospects depending on a number of factors, including the scope and seriousness of the problem, degree of publicity, reaction of our customers and healthcare professionals, competitive response, and consumer perceptions generally. Even if such an allegation or product liability claim lacks merit, cannot be substantiated, is unsuccessful or is not fully pursued, the negative publicity surrounding any assertion that our products have caused or carry a risk of causing illness, injury or death could adversely affect our reputation with customers, healthcare professionals, third-party payors, and existing and potential collaborators, and could adversely affect our operating results and cause a decline in our stock price. Furthermore, general concerns regarding the perceived safety or reliability of any of our products, or any component thereof, may have a similar adverse effect on us.

We may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

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

Additionally, we may not be in a position to exercise sole decision-making authority regarding a collaboration, licensing or other similar arrangement, which could create the potential risk of creating impasses on decisions. Further, our collaborators and business partners may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control or other licenses of intellectual property rights. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators, such as Dexcom and Abbott, or any future collaborators devote to our arrangement with them or our future products. Disputes between us and our current, future or potential collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

For example, we have entered into multiple development and commercialization agreements with Dexcom, which provide us non-exclusive licenses to integrate various currently available and future generations of Dexcom’s CGM technology with our insulin pump products. Under certain circumstances, these agreements may be terminated by either party without cause or on short notice. Our current agreements with Dexcom do not grant us rights to integrate future generations of Dexcom CGM technology, other than G7 CGM devices, with any of our current or future products. Termination of any of our agreements with Dexcom would require us to redesign certain current products and products under development, and attempt to integrate an alternative CGM system into our insulin pump systems, which would require significant development and regulatory activities that could result in an interruption or substantial delay in the availability of the product to our customers. The termination of our existing commercial agreements with Dexcom would disrupt our ability to commercialize our existing products and our development of future products, which could have a material adverse impact on our financial condition and results of operations, negatively impact our ability to compete and cause our stock price to decline.

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

The efficient operation of our business depends on our information technology and communication systems, as well as those of our suppliers, contract manufacturers, distributors and other third-party business partners. We rely on such systems to effectively store, process and transit proprietary sales and marketing data, accounting and financial functions, manufacturing and quality records, inventory management, product development tasks, research and development data, customer service and technical support functions. Our information technology systems, including those that support our t:connect uploader software and cloud-based web application, our current and future mobile applications, our Tandem Source data management platform, as well as those involved in the operation of our Tandem Device Updater, are vulnerable to damage or interruption from a number of causes, including earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, malware, ransomware or other destructive software, cyber-attacks, power losses, and computer system or data network failures. Should any of those risks occur, it could adversely impact the availability, confidentiality and integrity of information assets contained in those systems.

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

In addition to the risks regarding information technology systems and processing of sensitive information, our insulin pumps and other products rely on software, some of which is developed by third-party service providers, that could contain unanticipated vulnerabilities, which could make our products subject to computer viruses, cyber-attacks, or failures. These risks significantly increased when we commenced use of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps and may be higher following the launch of our new mobile application in the second half of 2020. These risks may increase further when we enable users to control insulin boluses through the mobile app. We may also face new risks relating to our information technology systems as we continue to commercialize our products outside of the United States and are subject to additional regulations relating to the use and protection of personal information and as we launch new mobile applications or new features to our existing applications. As this is a rapidly evolving area, compliance with any future requirements, regulations, and evolving threat models may require the investment of additional resources in the form of capital, personnel or technology.

The failure of our or our service providers' information technology systems or our pumps' software or other mobile applications to perform as we anticipate, or our failure to effectively identify, investigate and mitigate potential threats through ongoing maintenance and enhancement of software applications, information technology systems and privacy policies and controls, could disrupt our entire operation or adversely affect our software products. For example, we market our Tandem Device Updater as having the unique capability to deploy software updates to our pumps, which may allow customers remote access to new and enhanced features. The failure of our Tandem Device Updater to provide software updates as we anticipate, including as a result of our inability to secure and maintain necessary regulatory approvals, the inability of our pumps to properly receive software updates, errors or viruses embedded within the software being transmitted, or the failure of our customers to properly utilize the system to complete the update, could result in decreased sales, increased warranty costs, and harm to our reputation, any of which could have a material adverse effect on our business, financial condition and operating results.

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

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

The risks posed by this lawsuit and any future related matters include civil monetary damages, attorney fees and costs, other legal penalties, reputational damage, loss of goodwill, and competitive harm. It is possible that our legal expenses and defense costs, alone or together with any monetary damages, may exceed the limits of any applicable insurance coverage that we carry.

If we are found to have violated laws concerning the privacy and security of patient health information or other personal information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.*

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

If we, or any of our service providers who have access to the personal data for which we are responsible, are found to be in violation of the privacy or security requirements of HIPAA, PIPEDA, GDPR, or applicable foreign, U.S. state and Canadian provincial laws, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and operating results. In addition, entities operating in the healthcare industry have increasingly become targets for hackers. Although we utilize a variety of measures to secure the data that we control, even compliant entities can experience security breaches or have inadvertent failures despite employing reasonable practices and safeguards.

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

We depend on the knowledge and skills of our senior management and other key employees, and if we are unable to retain and motivate them or recruit additional qualified personnel, our business may suffer.*

We have benefited substantially from the leadership and performance of our senior management, as well as certain key employees. For example, key members of our management have experience successfully scaling an early stage medical device company to achieve profitability. Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. Competition for senior management and key employees in our industry is intense and over the past year we have also experienced general labor shortages in various areas of our business. We cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. In addition, adoption of new work models and requirements about when or how often employees work on site or remotely may present new challenges. As certain jobs and employers increasingly operate remotely, competition for talent may change in ways that cannot be fully predicted at this time. Moreover, we may need to increase employee wages and benefits in order to attract and retain our personnel, which would increase our expenses. The loss of the services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements, and any general labor shortages could also negatively impact our ability to expand and scale functions that are needed to support the ongoing development of our products and the future growth of our business. Each member of senior management, as well as the vast majority of our employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

We depend upon key employees in a competitive market, and if we are unable to provide meaningful equity incentives to retain key personnel, it could adversely affect our ability to execute our business strategy.

We are highly dependent upon the members of our management team, as well as other key employees. In our industry, it is common to attract and retain executive talent and other employees with compensation packages that include a significant equity component. We have issued, and may continue to issue, additional equity incentives that we believe will enhance our ability to retain our current key employees and attract the necessary additional executive talent. It may be more difficult to continue to incentivize employees during a period of rapid growth in our overall headcount while limiting the utilization of the share reserve under our current stock incentive plans. However, even if we issue significant additional equity incentives, there can be no assurance that we will be able to attract and retain key executive talent. A loss of any of our key personnel, or our inability to hire new personnel, may have a material adverse effect on our ability to execute our business strategy.

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

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

- different regulatory requirements for product approvals in foreign countries;
- differing U.S. and foreign medical device import and export rules;
- more restrictive privacy laws relating to personal information of end-users and employees, including GDPR and other EU member state directives;
- reduced protection for our intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad or with U.S. regulations that would apply to activities in such foreign jurisdictions, such as the Foreign Corrupt Practices Act;

- foreign taxes, including withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and

- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters, or incidence of disease, including as a result of the COVID-19 global pandemic.

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

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

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

- problems assimilating, maintaining or operating the acquired products or technologies;

- issues maintaining uniform standards, procedures, controls and policies;

- unanticipated costs, impairment charges or write-offs associated with acquisitions or investments;

- diversion of management's attention from our existing business;

- risks associated with entering new markets in which we have limited or no experience; and

- increased legal and accounting costs relating to the acquisitions or to comply with regulatory requirements or other compliance matters.

We have experienced and may continue to experience one or more of these risks in connection with our acquisition of Sugarmate, which was completed in 2020. For example, as a result of an update to Dexcom's data systems in October 2021, Sugarmate users in all geographies were unable to receive Dexcom CGM data in the Sugarmate app. Connections for users in the United States were restored in December 2021 but we have not yet restored connections in other geographies. While we continue to work towards restoring service for most users outside the US, we may not be able to restore services to all countries on the same timeline, or restore services to all users. These service disruptions, or other problems utilizing the mobile app or other assets acquired from Sugarmate, could adversely affect our ability to realize the expected benefits from the Sugarmate acquisition. Further, it is possible that we could experience a loss of Sugarmate customers or reputational harm arising from this service outage or similar events, which could adversely affect our business, results of operations, and financial condition.

We do not know if we will be able to identify future acquisitions or investments we deem suitable, whether we will be able to successfully complete any such acquisitions or investments on favorable terms or at all, or whether we will be able to successfully integrate any acquired products or technologies into our business. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to Our Future Financings and Financial Results

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

At March 31, 2022, we had $635.4 million in cash, cash equivalents and short-term investments. Our management expects the continued growth of our business, including the expansion of our customer service infrastructure to support our growing base of customers, our plans to expand commercial sales of our products outside of the United States, the growth of our manufacturing and warehousing operations, increasing the size of our facility footprint due to increases in headcount and additional R&D activities, will continue to increase our expenses. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Accordingly, our future capital requirements will depend on many factors, including:

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

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

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

Our operating results may fluctuate significantly from quarter to quarter.

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

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

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

Risks Related to Our Intellectual Property and Potential Litigation

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

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of March 31, 2022, our patent portfolio consisted of approximately 122 issued U.S. patents and 80 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2024 and 2041. Our foreign patent portfolio consisted of approximately 41 issued patents and 16 pending patent applications in other countries throughout the world. Of these, our issued foreign patents expire between approximately 2025 and 2036. In addition, we also have 109 trademark registrations, including 22 U.S. trademark registrations and 87 foreign trademark registrations.

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

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

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

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

Patent litigation in the medical device industry is not uncommon, and from time to time, we may be subject to litigation that could be costly, result in the diversion of management's time and efforts, or require us to pay damages.

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

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

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

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

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

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

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

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

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

Risks Related to Our Legal and Regulatory Environment

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

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

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

- recalls and field safety corrective actions.

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

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

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

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

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

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

Since our inception we have been audited or inspected by various regulatory authorities on numerous occasions. We also regularly respond to routine inquiries from regulatory authorities. In some instances these audits, inspections and inquiries result in findings that require us to take corrective actions, which could include changes to our internal policies, procedures or operations, revisions to our product labeling, issuances of customer notifications or the initiation of product recalls, any of which could result in product liability claims and lawsuits. Since mid-2021 we have completed several audits and inspections, some of which include findings that require us to take one or more corrective actions. Our failure to appropriately respond to these findings and take corrective actions, or our failure to comply with applicable regulations for any other reason, could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, delays by the FDA or other regulators in granting clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. Any of these sanctions could result in higher than anticipated costs, lower than anticipated sales, and diversion of management time and resources, any of which could have a material adverse effect on our reputation, business, financial condition and operating results.

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

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

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

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

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

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

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

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

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

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

Any adverse event involving any products that we distribute could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. For example, the Australian Therapeutic Goods Administration (TGA) temporarily suspended our pump product sales in Australia commencing November 24, 2020, however sales of pump-related supplies were allowed to continue. Effective April 1, 2021, following discussions with the TGA, the temporary suspension was lifted for our t:slim X2 with Basal-IQ technology, subject to certain post-market surveillance obligations and other conditions. We have discontinued sales of earlier generation products in Australia and we only recently commenced offering our Control-IQ technology in Australia. There can be no assurance that the TGA will not reimpose the suspension of our pump product sales or impose other regulatory restrictions in the future. In addition, other regulatory bodies may take similar actions against us, and any regulatory challenges we encounter could have a negative impact on our product sales and harm our reputation. Any corrective actions we take in response to this action or future matters with the TGA or other regulatory bodies, whether voluntary or involuntary, will require the dedication of our time and capital, may distract management from operating our business, may harm our reputation and financial results or could result in additional regulatory scrutiny in other geographies.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

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

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

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

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

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

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

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

- authorize the issuance of preferred stock with powers, preferences and rights that may be senior to our common stock, which can be created and issued by the board of directors without prior stockholder approval;

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

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

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

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

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

As of December 31, 2021, we had accumulated federal and state net operating loss (NOL) carryforwards of approximately $301.2 million, and $291.0 million, respectively, which included the reduction recorded in 2019 discussed below. Of the total federal NOL carryforwards, approximately $112.1 million were generated after January 1, 2018, and therefore do not expire. NOL generated after January 1, 2018, is subject to 80% limitation in accordance with the Tax Cuts and Jobs Act of 2017. The remaining federal NOL carryforwards of $189.1 million will begin to expire in 2026, and state tax loss carryforwards continue to expire in 2022, unless previously utilized. If there is an “ownership change” with respect to our company, as defined under Section 382 of the Code, the utilization of our NOL and research credit carryforwards may be subject to substantial limitations imposed by the Code, and similar state provisions. Limitations imposed on our ability to utilize NOL carryforwards could cause U.S. federal income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause NOL carryforwards to expire unused, in each case reducing or eliminating the benefit of our NOL carryforwards. In general, an ownership change occurs whenever there is a shift in ownership of our company by more than 50% by one or more 5% stockholders over a specified time period.

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

We do not intend to pay cash dividends.

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

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

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

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

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

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

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

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

Risks Related to Our Convertible Senior Notes

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

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

As a result of our increased level of indebtedness due to the Notes Offering:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
10.1*	Tandem Diabetes Care, Inc. 2022 Senior Management Cash Bonus Plan					X
31.1	Certification of John F. Sheridan, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1**	Certification of John F. Sheridan, Chief Executive Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2**	Certification of Leigh A. Vosseller, Chief Financial Officer, pursuant to U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document.					X
101.SCH	XBRL Taxonomy Extension Schema Document.					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document contained in Exhibit 101)					X

* Indicates management contract or compensatory plan.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

	Tandem Diabetes Care, Inc.	
Dated: May 4, 2022	By:	/s/ John F. Sheridan
		John F. Sheridan President and Chief Executive Officer (on behalf of the registrant and as the registrant’s Principal Executive Officer)
Dated: May 4, 2022	By:	/s/ Leigh A. Vosseller
		Leigh A. Vosseller Executive Vice President, Chief Financial Officer and Treasurer (on behalf of the registrant and as the registrant’s Principal Financial and Accounting Officer)

Tandem Diabetes Care, Inc.
2022 Sr. Management Cash Bonus Plan

The Tandem Diabetes Care, Inc. 2022 Sr. Management Cash Bonus Plan (the "***Bonus Plan***") has been designed to align plan participants with the business goals and strategies of Tandem Diabetes Care, Inc. ("***Tandem***" or the "***Company***") and to further the objectives of the Company's executive compensation program. This Bonus Plan is an important part of the Company's commitment to recognizing key employees who contribute to the achievement of important Company performance goals. Specifically, the objectives of the Bonus Plan are as follows:

- Attract, retain and motivate executives, with the background and experience required for the Company's future growth and success;
- Align the interests of plan participants with those of the Company's stockholders by tying a meaningful portion of their compensation opportunity to the achievement of predetermined performance objectives that are important to our growth and success, which can increase or decrease to reflect achievement with respect to the objective;
- Together with base salary, long-term equity incentives and other components of compensation, create a total compensation package with an appropriate balance of cash versus non-cash, and guaranteed versus at risk compensation opportunities that is competitive with other medical device and technology companies' similar in size, growth and stage.

Performance Period
The Bonus Plan is primarily intended to reward plan participants for their individual contributions to the Company's achievement with respect to Company performance objectives for the 2022 fiscal year. However, the Company's Board of Directors or the Compensation Committee of the Board of Directors (the "***Compensation Committee***") also has the discretion to consider individual or Company performance after December 31, 2022 and until the date of any actual bonus determination under the Bonus Plan in measuring performance and determining the amount of an award, if any, under the Bonus Plan.

Eligibility
Employees of the Company eligible for an award under this Bonus Plan will be limited to individuals serving as a Vice President or more senior management role within the Company, as determined by the Board of Directors or the Compensation Committee. If, following January 1, 2022, an individual is promoted or hired and becomes an eligible participant under the Bonus Plan at any time during the 2022 calendar year, then the individual will be eligible to participate under the Bonus Plan on a pro-rata basis, calculated in the reasonable discretion of the Compensation Committee, unless otherwise specifically provided by the Board of Directors or the Compensation Committee.

Bonus Opportunity
A target cash incentive amount (a "***Target Bonus Amount***") for each eligible plan participant will be set as a percentage of the participant's base salary and calculated based on 2022 salaries paid. Cash incentives may be earned under the Bonus Plan based on the achievement of a financial performance objective, a product development objective, and a customer-related objective. The financial performance objective represents 80% of the overall Target Bonus Amount. The product development objective and customer satisfaction-related objective will each represent 10% of the overall Target Bonus Amount, which together with the financial performance objective, represent 100% of the overall Target Bonus Amount.

Financial Performance Objective

The portion of the cash bonuses that relate to the financial performance objective may be earned based on the Company's actual revenue for fiscal year 2022 as compared to a pre-established 2022 revenue target (the "***Revenue Target***"). Subject to the foregoing, the financial objective portion of the cash bonuses may be earned under the Bonus Plan as follows:

- A minimum percentage growth rate over the Company's actual 2021 revenue, which places the Company's revenue for 2022 at 90% of the Revenue Target (the ***"Minimum Revenue Target"***), must be achieved for 50% bonus to be earned under the financial performance objective portion of the Bonus Plan.

- If the Company's actual revenues are between the Minimum Revenue Target and the Revenue Target, the goal achievement for the financial performance objective will be calculated proportionately in a straight-line from 50% to 100%.

- If the Company's actual revenues exceed the Revenue Target, up to 200% of the bonus may be earned upon achievement of 110% or greater of the Revenue Target (the "***Outperformance Revenue Target***"). The outperformance goal achievement will be calculated proportionately on a straight-line basis from 100% at the Revenue Target up to 200% at the Outperformance Revenue Target. In the event of an outperformance achievement, the Company must also achieve at least a minimum adjusted Earnings before Interest, Taxes, Depreciation and Amortization (and further excluding non-cash stock-based compensation expense and any accrual for the payment pursuant to the Bonus Plan) ("***EBITDA***") margin percentage (the "***Minimum Operating Percentage Target***").

Product Development Objective

The portion of the cash bonuses that relates to the Company product development milestone generally requires the Company to achieve regulatory submission of the product. An individual product development milestone must be achieved within a required time period for the applicable portion of the 2022 Cash Bonus Plan to be achieved. Defined time periods serve as both a minimum threshold for achieving 50% payout and an outperformance threshold for achieving up to 200% payout under this portion of the 2022 Cash Bonus Plan. Overall goal achievement is subject to the Compensation Committee's final discretion, and determination of the Company's product development milestone will be based on the level of achievement by the Company during fiscal year 2022.

Customer Satisfaction-Related Objective

The portion of the cash bonuses that relates to the Company customer satisfaction-related objective generally requires the Company to achieve a minimum annual metric related to customer support and services. Defined metrics serve as both a minimum threshold for achieving 50% payout and an outperformance threshold for achieving up to 200% payout under this portion of the 2022 Cash Bonus Plan. Overall goal achievement is subject to the Compensation Committee's final discretion, and determination of the Company's customer-related objective will be based on the level of achievement by the Company during fiscal year 2022.

Award Determination
Bonus payments under the Bonus Plan, if any, will be made at the discretion of the Board or the Committee. The financial performance component, product development component, and customer-related component of the Bonus Plan may be earned independent of one another. If the Company does not achieve any portion of any of the components of the Bonus Plan, no payouts will be made unless the Board of Directors or the Compensation Committee, in their sole discretion, determines that there are other factors that merit consideration in the determination of bonus awards, which may be determined on an individual basis. All determinations and decisions made by the Board of Directors or the Compensation Committee pursuant to the provisions of the Bonus Plan shall be final, conclusive and binding on all persons, and shall be given the maximum deference permitted by law.

Payout and Administration
Bonus calculations will be based on 2022 salaries paid. Payment of bonuses will be made as soon as practical after the end of the plan year, but not later than March 15, 2022. Participants must be actively employed at the time of payout to be eligible for any bonus payment. The Board of Directors or the Compensation Committee may approve payments to any eligible plan participant. The Board of Directors or the Compensation Committee can modify the Bonus Plan, including timing and form of payments, at any time in their sole discretion. Amounts payable under the Bonus Plan are intended to comply with the "short-term deferral" rule set forth in Section 1.409A-1(b)(4) of the Treasury Regulations and thus be exempt from the provisions of Section 409A of the Internal Revenue Code of 1986, as amended. The Board of Directors and the Compensation Committee intend to administer the Bonus Plan in a manner consistent with this rule. Any amounts paid hereunder shall be subject to recoupment in accordance with The Dodd-Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company or as is otherwise required by applicable law.

Exhibit 31.1

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

I, John F. Sheridan, certify that:

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

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

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

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

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

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

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

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

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

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

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

Tandem Diabetes Care, Inc.

By: /s/ John F. Sheridan

John F. Sheridan
President, Chief Executive Officer and Director

Dated: May 4, 2022

Exhibit 31.2

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

I, Leigh A. Vosseller, certify that:

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

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

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

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

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

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

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

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

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

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

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

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

Dated: May 4, 2022

Exhibit 32.1

CERTIFICATION
Pursuant to U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q of Tandem Diabetes Care, Inc. (the "Company") for the period ended March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John F. Sheridan, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: May 4, 2022

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION
Pursuant to U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the Quarterly Report on Form 10-Q of Tandem Diabetes Care, Inc. (the "Company") for the period ended March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leigh A. Vosseller, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods presented.

Date: May 4, 2022

/s/ Leigh A. Vosseller
Leigh A. Vosseller
Executive Vice President, Chief Financial Officer and Treasurer

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.