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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, 2020

OR

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

For the Transition Period from to

Commission File Number 001-36189

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

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

(858) 366-6900

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Symbol	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 21, 2020, there were 60,102,978 shares of the registrant's Common Stock outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2020 (Unaudited)	December 31, 2019 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 74,485	$ 51,175
Short-term investments	85,723	125,283
Accounts receivable, net	53,962	46,585
Inventories	60,469	49,073
Prepaid and other current assets	6,234	4,025
Total current assets	280,873	276,141
Property and equipment, net	37,626	32,923
Operating lease right-of-use assets	23,014	15,561
Other long-term assets	1,814	1,485
Total assets	$ 343,327	$ 326,110
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 21,783	$ 17,745
Accrued expenses	5,896	8,014
Employee-related liabilities	22,059	28,320
Deferred revenue	4,377	3,869
Common stock warrants	25,290	23,509
Operating lease liabilities	8,320	6,320
Other current liabilities	11,922	11,619
Total current liabilities	99,647	99,396
Operating lease liabilities - long-term	19,547	14,063
Other long-term liabilities	16,957	17,672
Total liabilities	136,151	131,131
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized, 60,071 and 59,396 shares issued and outstanding at March 31, 2020 (unaudited) and December 31, 2019, respectively.	60	59
Additional paid-in capital	847,056	819,626
Accumulated other comprehensive income (loss)	(245)	122
Accumulated deficit	(639,695)	(624,828)
Total stockholders' equity	207,176	194,979
Total liabilities and stockholders' equity	$ 343,327	$ 326,110

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,	
	2020	2019
Sales	$ 97,926	$ 65,995
Cost of sales	47,665	32,642
Gross profit	50,261	33,353
Operating expenses:		
Selling, general and administrative	49,717	34,961
Research and development	14,117	9,389
Total operating expenses	63,834	44,350
Operating loss	(13,573)	(10,997)
Other income (expense), net:		
Interest and other income	726	757
Interest and other expense	—	(6)
Change in fair value of common stock warrants	(1,922)	(12,746)
Total other expense, net	(1,196)	(11,995)
Loss before income taxes	(14,769)	(22,992)
Income tax expense	98	—
Net loss	$ (14,867)	$ (22,992)
Other comprehensive loss:		
Unrealized gain on short-term investments	$ 42	$ 50
Foreign currency translation gain (loss)	(409)	4
Comprehensive loss	$ (15,234)	$ (22,938)
Net loss per share, basic and diluted	$ (0.25)	$ (0.40)
Weighted average shares used to compute basic and diluted net loss per share	59,740	57,771

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, 2020

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	59,396	$ 59	$ 819,626	$ 122	$ (624,828)	$ 194,979
Exercise of stock options	673	1	11,474	—	—	11,475
Exercise of common stock warrants	2	—	7	—	—	7
Fair value of common stock warrants at time of exercise	—	—	141	—	—	141
Stock-based compensation	—	—	15,808	—	—	15,808
Unrealized gain on short-term investments, net of deferred tax	—	—	—	42	—	42
Foreign currency translation adjustments	—	—	—	(409)	—	(409)
Net loss	—	—	—	—	(14,867)	(14,867)
Balance at March 31, 2020	60,071	$ 60	$ 847,056	$ (245)	$ (639,695)	$ 207,176

Three Months Ended March 31, 2019

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	57,554	$ 57	$ 731,306	$ (13)	$ (600,075)	$ 131,275
Exercise of stock options	409	1	1,898	—	—	1,899
Exercise of common stock warrants	19	—	64	—	—	64
Fair value of common stock warrants at time of exercise	—	—	910	—	—	910
Stock-based compensation	—	—	9,752	—	—	9,752
Unrealized gain on short-term investments	—	—	—	50	—	50
Foreign currency translation adjustments	—	—	—	4	—	4
Net loss	—	—	—	—	(22,992)	(22,992)
Balance at March 31, 2019	57,982	$ 58	$ 743,930	$ 41	$ (623,067)	$ 120,962

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended March 31,	
	2020	2019
Operating Activities		
Net loss	$ (14,867)	$ (22,992)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	1,830	1,438
Provision for expected credit losses	862	342
Provision (benefit) for inventory obsolescence	(363)	679
Change in fair value of common stock warrants	1,922	12,746
Amortization of discount on short-term investments	(66)	(94)
Stock-based compensation expense	15,865	9,834
Other	19	27
Changes in operating assets and liabilities:		
Accounts receivable, net	(8,292)	1,821
Inventories, net	(11,095)	(3,690)
Prepaid and other current assets	(2,231)	(1,036)
Other long-term assets	(383)	(225)
Accounts payable	4,294	4,376
Accrued expenses	(2,124)	(553)
Employee-related liabilities	(6,253)	(6,982)
Deferred revenue	1,524	861
Other current liabilities	431	(2,120)
Other long-term liabilities	(1,704)	1,444
Net cash used in operating activities	(20,631)	(4,124)
Investing Activities		
Purchases of short-term investments	(9,727)	(42,914)
Proceeds from maturities of short-term investments	30,859	43,700
Proceeds from sales of short-term investments	18,550	1,400
Purchases of property and equipment	(6,766)	(1,408)
Net cash provided by investing activities	32,916	778
Financing Activities		
Proceeds from exercise of common stock warrants	7	64
Proceeds from issuance of common stock under Company stock plans	11,474	1,898
Net cash provided by financing activities	11,481	1,962
Effect of foreign exchange rate changes on cash	(456)	3
Net increase (decrease) in cash and cash equivalents	23,310	(1,381)
Cash and cash equivalents at beginning of period	51,175	41,826
Cash and cash equivalents at end of period	$ 74,485	$ 40,445
Supplemental disclosures of cash flow information		
Income taxes paid	$ 91	$ —
Supplemental schedule of non-cash investing and financing activities		
Right-of-use assets obtained in exchange for operating lease obligations	$ 8,805	$ 3,053
Property and equipment included in accounts payable	$ 1,880	$ 130

See accompanying notes to unaudited condensed consolidated financial statements.

TANDEM DIABETES CARE, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Basis of Presentation

The Company

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

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

The Company has commercially launched seven insulin pumps in the United States since 2012 and two pumps outside the United States since 2018. Four of the insulin pumps have featured integration with CGM technology, of which two have also featured an automated insulin delivery (AID) algorithm. In June 2018, the t:slim X2 was the first insulin pump designated as compatible with integrated CGM (iCGM) devices; in February 2019, the t:slim X2 was the first insulin pump in a new device category called Alternate Controller Enabled Infusion Pumps (ACE pumps); and in December 2019, Control-IQ technology for the t:slim X2 insulin pump was the first automated insulin dosing software in a new interoperable automated glycemic controller category. The Company believes that the three new classifications by the United States Food and Drug Administration (FDA) for the interoperability of devices for AID will help support continued rapid innovation by streamlining the regulatory pathway for integrated products.

As of March 31, 2020, the Company had $160.2 million in cash and cash equivalents and short-term investments. The Company has incurred operating losses since its inception and had an accumulated deficit of $639.7 million as of March 31, 2020, which included a net loss of $14.9 million for the three months ended March 31, 2020. Management believes that the cash, cash equivalents and short-term investments on hand will be sufficient to satisfy the Company's liquidity requirements for at least the next 12 months from the date of this filing.

The Company's ability to execute on its business strategy, meet its future liquidity requirements, and achieve and maintain profitable operations, is dependent on a number of factors, including its ability to continue to gain market acceptance of its products and achieve a level of revenues adequate to support its cost structure, achieve renewal pump sales objectives, develop and launch new products, expand the commercialization of products into new international markets, maximize manufacturing efficiencies, satisfy increasing production requirements, leverage the investments made in its sales, clinical, marketing and customer support organizations, and operate its business and manufacture and sell products without infringing on third-party intellectual property rights.

The Company has funded its operations primarily through cash collected from product sales, private and public offerings of equity securities, and through debt financing which has since been fully repaid. The Company may in the future seek additional capital from public or private offerings of equity or debt securities, or it may elect to borrow capital under new credit arrangements or from other sources. If the Company issues equity or debt securities to raise additional funds, its existing stockholders may experience dilution, it 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 its existing stockholders. There can be no assurance that equity or debt financing will be available on acceptable terms, or at all.

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, 2019 (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 subsidiary in Canada. All significant intercompany balances and transactions have been eliminated in consolidation.

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

Reclassification

Prior year amounts related to the presentation of proceeds from maturities and sales of short-term investments on the Company's condensed consolidated statement of cash flows, have been reclassified to conform to the current year presentation.

2. Summary of Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the three months ended March 31, 2020, as compared to those disclosed in the 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.

Segment Reporting

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

Accounts Receivable

The Company grants credit to various customers in the ordinary course of business and is paid directly by customers who use the products, distributors and third-party insurance payors. The Company maintains an allowance for its current estimate of expected credit losses. Provisions for expected credit losses are estimated based on historical experience, assessment of specific risk, review of outstanding invoices, forecasts about the future, and various assumptions and estimates that are believed to be reasonable under the circumstances. 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 Company believes the fair value of its operating lease liabilities at March 31, 2020 approximated their carrying value, based on the borrowing rates that were available for loans with similar terms as of that date. The estimated fair value of certain of the Company's common stock warrants was determined using the Black-Scholes pricing model as of March 31, 2020 and December 31, 2019 (see Note 5, "Fair Value Measurements").

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 their 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. Rent expense on noncancelable leases containing known future scheduled rent increases is recorded on a straight-line basis over the term of the respective leases beginning on the Commencement Date. The difference between rent expense and rent paid is accounted for as a component of operating lease right-of-use assets on the Company's consolidated balance sheet. Landlord improvement allowances and other such lease incentives are recorded as property and equipment and as reduction of the right-of-use leased assets, and are amortized on a straight-line basis as a reduction to operating lease costs. Leases with an initial term of 12 months or less are expensed as incurred and are not recorded as right-of-use assets on the consolidated balance sheets (see Note 6, "Leases").

Revenue Recognition

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

Revenue Recognition for Arrangements with Multiple Deliverables

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

	March 31, 2020	December 31, 2019
Deferred revenue	$ 3,833	$ 3,465
Other long-term liabilities	6,626	5,656
Total	$ 10,459	$ 9,121

Sales Returns

The Company offers a 30-day right of return to customers in the U.S. and Canada from the date of shipment of its insulin pumps, provided a physician's confirmation of the medical reason for the return is received. Estimated allowances for sales returns are based on historical returned quantities as compared to pump shipments in those same periods of return. The return rate is then applied to the sales of the current period to establish a reserve at the end of the period. The return rates used in the reserve are adjusted for known or expected changes in the marketplace when appropriate. The allowance for sales returns is recorded as a reduction of revenue and an increase in deferred revenue in the period in which the related sale is recorded. The amount recorded in deferred revenue on the Company's consolidated balance sheets for allowances for sales returns was $0.5 million and $0.4 million at March 31, 2020 and December 31, 2019, respectively. Actual product returns have not differed materially from estimated amounts recorded in the accompanying condensed consolidated financial statements.

Warranty Reserve

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

The following table provides a reconciliation of the change in product warranty liabilities from December 31, 2019 through March 31, 2020 (in thousands):

Balance at December 31, 2019	$ 16,724
Provision for warranties issued during the period	4,814
Settlements made during the period	(3,390)
Decreases in warranty estimates	(1,387)
Balance at March 31, 2020	$ 16,761

As of March 31, 2020 and December 31, 2019, total product warranty reserves of $16.8 million and $16.7 million, respectively, were included in the following consolidated balance sheet accounts (in thousands):

	March 31, 2020	December 31, 2019
Other current liabilities	$ 6,427	$ 4,707
Other long-term liabilities	10,334	12,017
Total warranty reserves	$ 16,761	$ 16,724

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the estimated fair value of the award, and the portion that is ultimately expected to vest is recognized as compensation expense over the requisite service period on a straight-line basis. The Company estimates the fair value of stock options issued under the Company's Amended and Restated 2013 Stock Incentive Plan (2013 Plan), and the fair value of the employees' purchase rights under the Company's 2013 Employee Stock Purchase Plan (ESPP), using the Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model requires the use of assumptions about a number of variables, including stock price volatility, expected term, dividend yield and risk-free interest rate (see Note 7, "Stockholders' Equity"). For awards that vest based on the achievement of service conditions, the Company recognizes expense using the straight-line method less estimated forfeitures based on historical experience.

Net Loss Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares that were outstanding for the period, without consideration for common stock equivalents. Diluted loss per share is calculated in accordance with the treasury stock method and reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted to common stock.
Dilutive common share equivalents are comprised of warrants, potential awards granted pursuant to the ESPP, and stock options outstanding under the Company's equity incentive plans. For warrants that are recorded as a liability in the accompanying condensed consolidated balance sheets, the calculation of diluted loss per share requires that, to the extent the average market price of the underlying shares for the reporting period exceeds the exercise price of the warrants and the presumed exercise of the warrants is dilutive to loss per share for the period, an adjustment is made to net loss used in the calculation to remove the change in fair value of the warrants from the numerator for the period. Likewise, an adjustment to the denominator is required to reflect the related dilutive shares, if any, under the treasury stock method. For the three months ended March 31, 2020 and 2019, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Potentially dilutive securities 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,	
	2020	2019
Warrants to purchase common stock	609	686
Options to purchase common stock	5,710	5,475
Awards granted under the ESPP	198	142
	6,517	6,303

Recent Accounting Pronouncements

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

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. The updated guidance was effective for the Company starting in the first quarter of fiscal 2020. As a result, the Company modified certain fair value measurement disclosures primarily related to its Level 3 liabilities (see Note 5, "Fair Value Measurements").

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, which is intended to simplify various aspects of the income tax accounting guidance, including requirements such as tax basis step-up in goodwill obtained in a transaction that is not a business combination, ownership changes in investments, and interim-period accounting for enacted changes in tax law. ASU 2019-12 is effective for public business entities for fiscal years beginning after December 15, 2020, including interim periods within those fiscal years, and early adoption is permitted. The Company is in the process of assessing the impact of the adoption of the standard on its consolidated financial statements.

3. Short-Term Investments

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

At March 31, 2020	Maturity (in years)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Estimated Fair Value
Available-for-sale securities:					
Commercial paper	Less than 1	$ 17,352	$ 11	$ —	$ 17,363
U.S. Government-sponsored enterprise	Less than 2	20,255	63	—	20,318
U.S. Treasury securities	Less than 1	12,721	93	—	12,814
Corporate debt securities	Less than 2	35,251	39	(62)	35,228
Total		$ 85,579	$ 206	$ (62)	$ 85,723

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

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

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

4. Accounts Receivable and Inventories

Accounts Receivable

Accounts receivable consisted of the following (in thousands):

	March 31, 2020	December 31, 2019
Accounts receivable	$ 57,346	$ 49,889
Less allowance for credit losses	(3,384)	(3,304)
Accounts receivable, net	$ 53,962	$ 46,585

Allowance for Credit Losses

The following table provides a reconciliation of the change in the estimated allowance for expected accounts receivable credit losses for the three months ended March 31, 2020 and 2019 (in thousands):

	For the Three Months Ended	
	March 31, 2020	March 31, 2019
Balance at beginning of the period	$ 3,304	$ 1,837
Provision for expected credit losses	862	342
Write-offs and adjustments, net of recoveries	(782)	(163)
Balance at end of the period	$ 3,384	$ 2,016

Inventories

Inventories consisted of the following as of March 31, 2020 and December 31, 2019 (in thousands):

	March 31, 2020	December 31, 2019
Raw materials	$ 31,795	$ 20,699
Work-in-process	14,543	16,532
Finished goods	14,131	11,842
Inventories	$ 60,469	$ 49,073

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, 2020 and December 31, 2019, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value (in thousands):

		Fair Value Measurements at March 31, 2020		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash equivalents[1]	$ 69,346	$ 69,346	$ —	$ —
Commercial paper	17,363	—	17,363	—
U.S. Government-sponsored enterprise	20,318	—	20,318	—
U.S. Treasury securities	12,814	12,814	—	—
Corporate debt securities	35,228	—	35,228	—
Total assets	$ 155,069	$ 82,160	$ 72,909	$ —
Liabilities				
Common stock warrants	$ 25,290	$ —	$ —	$ 25,290
Total liabilities	$ 25,290	$ —	$ —	$ 25,290

		Fair Value Measurements at December 31, 2019		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash equivalents[1]	$ 49,077	$ 49,077	$ —	$ —
Commercial paper	24,157	—	24,157	—
U.S. Government-sponsored enterprise	33,099	—	33,099	—
U.S. Treasury securities	17,979	17,979	—	—
Corporate debt securities	50,048	—	50,048	—
Total assets	$ 174,360	$ 67,056	$ 107,304	$ —
Liabilities				
Common stock warrants	$ 23,509	$ —	$ —	$ 23,509
Total liabilities	$ 23,509	$ —	$ —	$ 23,509

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

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

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

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

	March 31, 2020	December 31, 2019
Risk-free interest rate	0.3%	1.6%
Expected dividend yield	0.0%	0.0%
Expected volatility	74.9%	77.2%
Expected term (in years)	2.5	2.8

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, 2020 and 2019:

	Three Months Ended March 31,	
	2020	2019
Balance at beginning of the period	$ 23,509	$ 17,926
Loss recognized from the change in fair value of common stock warrants	1,922	12,746
Decrease in fair value from warrants exercised during the period	(141)	(910)
Balance at end of the period	$ 25,290	$ 29,762

Of the loss recognized from the change in fair value of common stock warrants for the three months ended March 31, 2020 and 2019, $1.9 million and $12.5 million, respectively, was attributable to the change in the unrealized loss related to warrants outstanding as of March 31, 2020 and 2019.

During the three months ended March 31, 2020 and 2019, the Company issued 2,115 shares and 18,285 shares of common stock, respectively, upon the exercise of Series A warrants issued in October 2017. As of March 31, 2020 and 2019, there were Series A warrants outstanding to purchase 415,200 shares and 492,500 shares, respectively, of the Company's common stock (see Note 7, "Stockholders' Equity").

6. Leases

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

The Company's leases consist primarily of operating leases for general office space, laboratory, manufacturing and warehouse facilities, and equipment. 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 in determining the present value of future lease payments. The Company used the incremental borrowing rate on January 1, 2019 for operating leases that commenced prior to that date. For lease agreements entered into or reassessed after the adoption of ASC 842, the Company combines lease and non-lease components.

Certain leases include an option to renew, with renewal terms that can extend the lease term for additional periods. The exercise of lease renewal options is at the Company's sole discretion. The depreciable life of assets and leasehold improvements are limited by the expected lease term, unless there is a transfer of title or purchase option that is reasonably certain to be exercised.

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

In November 2019, the Company entered into a lease agreement for approximately 94,562 square feet of additional general office space located on Shoreline Drive, in Boise, Idaho (Shoreline Lease). Subject to limited exceptions, the initial lease term is expected to begin on the earlier of (i) the date on which the Company substantially completes certain specified work related to tenant improvements, (ii) the date on which the Company begins use of the premises for their intended purpose, or (iii) July 1, 2020, and will expire 84 months from the first day of the first full month following the start of the lease term. The Company has a one-time option to extend the term of the Shoreline Lease for a period of three years. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of approximately $6.5 million on the consolidated balance sheet on the Commencement Date in the first quarter of 2020. Future minimum payments due under the Shoreline Lease are approximately $8.2 million as of March 31, 2020.

In January 2020, the Company entered into a sub-lease agreement for approximately 30,703 square feet of general office space located on High Bluff Drive, in San Diego, California (High Bluff Lease). The lease term begins in April 2020 and expires in March 2022. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of approximately $2.3 million on the consolidated balance sheet on the Commencement Date in the first quarter of 2020. Future minimum payments due under the High Bluff Lease are approximately $2.4 million as of March 31, 2020.

The Company's total lease cost recorded in the condensed consolidated statements of operations was $1.8 million and $0.7 million, respectively, for the three months ended March 31, 2020 and 2019, which included $1.7 million and $0.7 million, respectively, of operating lease cost and $0.1 million of short-term lease cost in 2020. Cash paid for amounts included in the measurement of lease liabilities, representing operating cash flows from operating leases, was $1.6 million and $0.9 million for the three months ended March 31, 2020 and 2019, respectively.

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

Years Ending December 31,		
2020 (remaining)	$	5,994
2021		9,422
2022		7,314
2023		3,388
2024		1,881
Thereafter		3,975
Total undiscounted lease payments		31,974
Less: amount representing interest		(4,107)
Present value of operating lease liabilities		27,867
Less: current portion of operating lease liabilities		(8,320)
Operating lease liabilities - long-term	$	19,547

As of March 31, 2020, the weighted average remaining lease term for operating leases was 4.1 years and the weighted-average discount rate used to determine the operating lease liabilities was 6.3%. As of December 31, 2019, the weighted average remaining lease term for operating leases was 3.6 years and the weighted-average discount rate used to determine the operating lease liabilities was 6.6%.

7. Stockholders' Equity

Shares Reserved for Future Issuance

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

Shares underlying outstanding warrants	705
Shares underlying outstanding stock options	6,684
Shares authorized for future equity award grants	2,961
Shares authorized for issuance pursuant to awards granted under the ESPP	1,692
	12,042

Common Stock Warrants

As of March 31, 2020, there were Series A warrants outstanding to purchase 415,200 shares of the Company's common stock at an exercise price of $3.50 per share, which were issued in connection with a financing in October 2017, and which expire in October 2022. Also outstanding as of March 31, 2020, were warrants to purchase 193,788 shares of the Company's common stock at an exercise price of $23.50 per share, which were issued in March 2017, and which expire in March 2027, and warrants to purchase 95,781 shares of the Company's common stock at an exercise price of $73.73 per share, which were issued between August 2011 and August 2012, and which expire between August 2021 and August 2022. The Company issued 2,320 shares of its common stock upon the exercise of warrants during the three months ended March 31, 2020, and 18,285 shares of its common stock upon the exercise of warrants during the three months ended March 31, 2019.

Stock Plans

The Company issued 672,442 and 408,964 shares, respectively, of its common stock upon the exercise of stock options during the three months ended March 31, 2020 and 2019.

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 in the three months ended March 31, 2020 and 2019.

Stock-Based Compensation

The Company granted options to purchase 229,911 shares and 1,294,053 shares of common stock, respectively, under the 2013 Plan during the three months ended March 31, 2020 and 2019. These options have an exercise price equal to the closing price of the Company's common stock on the applicable award date, and generally vest 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.

In addition, during the three months ended March 31, 2019, the Company awarded stock options to purchase 1,035,000 shares of common stock, which were subject to and conditioned upon the approval by its stockholders of an increase in the number of shares of common stock reserved for issuance under our 2013 Plan prior to December 31, 2019. No stock-based compensation expense was recognized for these contingent stock option grants during the three months ended March 31, 2019, because the approval by our stockholders of the increase in the number of shares of common stock reserved for issuance under our 2013 Plan did not occur until June 2019.

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

	Stock Options	
	Three Months Ended March 31,	
	2020	2019
Weighted average grant date fair value (per share)	$43.40	$32.51
Risk-free interest rate	1.1%	2.5%
Expected dividend yield	0.0%	0.0%
Expected volatility	72.5%	71.6%
Expected term (in years)	6.1	6.1

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

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

	Three Months Ended March 31,	
	2020	2019
Cost of sales	$ 2,164	$ 1,139
Selling, general & administrative	11,501	7,000
Research and development	2,200	1,695
Total	$ 15,865	$ 9,834

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

8. Income Taxes

For the three months ended March 31, 2020, the Company’s income tax expense is primarily attributable to state and foreign income tax expense as a result of current taxable income in those jurisdictions. The Company used the year-to-date effective tax rate method to determine its interim income tax expense for federal and state jurisdictions where a reliable estimate of the annual effective tax rate could not be made.

The Company maintains a full valuation allowance against its net deferred tax assets as of March 31, 2020 based on the current assessment that it is not more likely than not these future benefits will be realized before expiration.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which are expected to impact the Company’s financial statements include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. Due to the recent enactment of the CARES Act, the Company is unable to quantify the impact, if any, that the CARES Act will have on its financial position, results of operations or cash flows but it is not anticipated to be significant.

9. Commitments and Contingencies

Legal and Regulatory Matters

From time to time, the Company may be subject to legal proceedings or regulatory matters arising in the ordinary course of business, including actions with respect to intellectual property, employment, regulatory, product liability and contractual matters. In connection with these proceedings or matters, the Company regularly assesses the probability and amount (or range) of possible issues based on the developments in these proceedings or matters. A liability is recorded in the consolidated financial statements if it is determined that it is probable that a loss has been incurred, and that the amount (or range) of the loss can be reasonably estimated. Because of the uncertainties related to any pending proceedings or matters, the Company is currently unable to predict their ultimate outcome and, with respect to any legal proceeding or regulatory matter where no liability has been accrued, to make a reasonable estimate of the possible loss (or range of loss) that could result from an adverse outcome. As of March 31, 2020 and December 31, 2019, there were no legal proceedings, regulatory matters, or other disputes or claims for which a material loss was considered probable or for which the amount (or range) of loss was reasonably estimable. However, regardless of the outcome, legal proceedings, regulatory matters, and other disputes and claims can have an adverse impact on the Company because of legal costs, diversion of management time and resources, and other factors.

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, 2020 (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, business forecasts and plans, research and product development plans, manufacturing plans, strategic plans and objectives, capital needs, financing plans and objectives, product launches, distribution plans, clinical trials, regulatory approvals and competitive environment. 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. In particular, as discussed in greater detail below, our financial condition and results could be materially adversely affected by the impacts and disruptions caused by the novel coronavirus (COVID-19) global pandemic. 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 with an innovative approach to the design, development and commercialization of products for people with insulin-dependent diabetes. Our goal is to lead in insulin therapy management by building a robust ecosystem and portfolio of data-driven products and services around our flagship insulin pumps. We believe our competitive advantage is rooted in our consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing, sales and support activities principally focus on our flagship pump platform, the t:slim X2 Insulin Delivery System (t:slim X2), which is capable of remote feature updates and is designed to display continuous glucose monitoring (CGM) sensor information directly on the pump home screen, as well as our complementary product offerings, such as our t:connect data management application (t:connect) and the Tandem Device Updater. We aim to improve and simplify the lives of people with diabetes and those of their healthcare providers, by delivering innovative hardware and software solutions, as well as best-in-class customer support.

Since our initial commercial launch, we have been able to rapidly innovate and bring more products to market than our competitors. We have commercially launched seven insulin pumps in the United States since 2012, two of which we also launched outside the United States since 2018. Four of our insulin pumps have featured integration with CGM technology, of which two have also featured an automated insulin delivery (AID) algorithm. The United States Food and Drug Administration (FDA) has defined requirements for the interoperability of devices as a complete AID system, which we believe will help support continued rapid innovation by streamlining the regulatory pathway for integrated products. This interoperability designation is comprised of three categories: alternate controller enabled (ACE) infusion pumps, integrated continuous glucose monitor (iCGM) devices, and interoperable automated glycemic controller (iAGC) technology. In June 2018, the t:slim X2 was the first insulin pump designated as compatible with iCGM devices; in February 2019 the t:slim X2 was the first insulin pump to receive ACE pump designation, and in December 2019 our Control-IQ technology for the t:slim X2 was cleared as the first iAGC.

In the four-year period ended March 31, 2020, we shipped approximately 155,000 insulin pumps, which is representative of our estimated global installed customer base, assuming the typical four-year reimbursement cycle. Approximately 127,000 of these pumps were shipped to customers in the United States and approximately 28,000 were shipped to international markets.

Today, our t:slim X2 hardware platform represents 100% of our new pump shipments. The simple-to-use t:slim X2 is the smallest durable insulin pump available, and the only commercial insulin pump that allows users to update their pumps' software quickly and easily from a personal computer using our revolutionary Tandem Device Updater tool. This unique offering positions us to bring future innovations, including our next generation AID algorithms, to our in-warranty t:slim X2 customers faster than the industry has been able to in the past and independent of the typical four-year insurance pump reimbursement cycle. We have offered in-warranty t:slim customers in the United States four different software updates for no-cost since the Tandem Device Updater was approved in July 2016, including our two AID algorithms, Basal-IQ technology and Control-IQ technology. Basal-IQ technology launched in August 2018 and is a predictive low glucose suspend feature that is designed to temporarily suspend insulin delivery to help reduce the frequency and duration of hypoglycemic events. Control-IQ technology launched in January 2020 and is an advanced hybrid-closed loop feature, designed to help increase a user's time in targeted glycemic range. It is the first and only system cleared to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. Outside the United States we began selling efforts with t:slim X2 with Dexcom G5 CGM integration in the third quarter of 2018, offering no-cost software updates for Basal-IQ technology in the third quarter of 2019, and intend to begin offering Control-IQ technology updates in select geographies in the second half of 2020, subject to required regulatory and reimbursement approvals.

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.

For the three months ended March 31, 2020 and 2019, our consolidated sales were $97.9 million and $66.0 million, respectively. For the three months ended March 31, 2020 and 2019, our net loss was $14.9 million and $23.0 million, respectively. Worldwide pump sales accounted for 61% and 70% of our total sales, respectively, for the three months ended March 31, 2020 and 2019, while pump-related supplies and accessories accounted for the remainder in each year. Our accumulated deficit as of March 31, 2020 and December 31, 2019 was $639.7 million and $624.8 million, respectively. These amounts included $234.4 million and $216.6 million of accumulated non-cash stock-based compensation charges and non-cash charges from the change in fair value of common stock warrants as of March 31, 2020 and December 31, 2019, respectively.

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

COVID-19 Impact and Considerations

We are deemed an essential healthcare business under applicable governmental orders based on the critical nature of the products we offer and the community we serve. During the first quarter of 2020, we experienced a modest impact from the COVID-19 global pandemic. However we anticipate that our sales and operating results will be adversely impacted in the coming months. We currently anticipate our sales outside the United States may experience a greater proportional impact due to differences in the sales process in domestic versus international markets. Additionally, the initiation of certain programs planned for the second quarter, such as human factors studies associated with our product development efforts, will likely be delayed. The full extent of the impact of COVID-19 on our business and operations is currently not estimable and will depend on a number of factors including the scope and duration of the global pandemic.

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

In response to developments surrounding the COVID-19 global pandemic, we initiated discussions with our key suppliers in early 2020 regarding their abilities to fulfill existing orders, and we have continued to regularly assess their capacity. At this time, we believe many of our suppliers are deemed essential businesses under applicable governmental orders, and we do not anticipate disruption in our ability to manufacture insulin pumps and cartridges due to component procurement limitations. Our finished goods and raw material inventory for insulin pumps, as well as available manufacturing capacity, meet or exceed our target levels and position us well to respond to unforeseen disruptions in the near term.

More recently, we observed customers purchasing cartridges and infusion sets at a higher rate than anticipated. Currently, our inventory for finished cartridges and infusion sets is below our targeted level. Near the end of the first quarter, our third-party cartridge manufacturer completed validation and commenced commercial-scale manufacturing to supplement our existing cartridge manufacturing capacity, which we believe will assist us in meeting product demand and allow us to build inventory levels in line with our targets. In addition, our primary infusion set manufacturer is currently working through inventory constraints and we have asked some customers to accept substitutions of similar products to prevent delays in order fulfillment. We are carefully managing our pump supplies inventory while we work to overcome these temporary challenges.

Commercially, we have been communicating with our customers and healthcare providers through social media, direct email outreach and our website, in addition to the regular communications from the supporting sales and clinical employees. We are leveraging the availability of our technology platforms, such as our t:connect diabetes management application, to support healthcare providers as many of them are expanding telehealth capabilities in their practices. By the end of the first quarter, we also expanded our remote new pump training offering to 100% of customers who purchase a t:slim X2 insulin pump.

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

Products Under Development

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

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

- *Connected (Mobile) Health Offerings* – We began a limited launch in the first quarter of 2020 and we are preparing for a full commercial launch in the second quarter of a mobile application that has been designed to utilize the Bluetooth radio integrated with the t:slim X2 to wirelessly upload pump data to the cloud-based t:connect diabetes management application, receive notification of pump alerts and alarms, and provide a discrete, secondary display of glucose and insulin data. Future updates of this app will integrate other health-related information from third-party sources and support future pump-control capabilities for our products under development.

    - The launch of the first generation of this app in the United States allows for the wireless upload of data to t:connect and is intended to reduce patient burden and increase healthcare provider office efficiency by reducing the manual steps historically required for data extraction.

    - Over time, we also intend to offer additional features and enhancements to the mobile application, including partial or full control of pump features.

Pump Shipments

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

In the four-year period ended March 31, 2020, we shipped approximately 155,000 insulin pumps, of which approximately 127,000 were shipped to customers in the United States and approximately 28,000 were shipped to international markets. In the first quarter of 2020, we shipped 17,378 insulin pumps worldwide compared to 14,732 insulin pumps shipped in the first quarter of 2019.

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

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

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

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

Trends Impacting Financial Results

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

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

- market acceptance of our products and competitive products by people with insulin-dependent diabetes, their caregivers and healthcare providers;
- the introduction of new products, treatment techniques or technologies for the treatment of diabetes, including the timing of the commercialization of new products by us and our competitors;
- seasonality in the United States associated with annual insurance deductibles and coinsurance requirements associated with the medical insurance plans utilized by our customers and the customers of our distributors;
- incidence of disease or illness, including regional or global pandemics that may impact customer purchasing patterns or disrupt our supply chain;
- timing of holidays and summer vacations, which may vary by geography;
- the buying patterns of our distributors and other customers, both domestically and internationally;
- changes in the competitive landscape, including as a result of companies entering or exiting the diabetes therapy market;

- access to adequate coverage and reimbursement for our current and future products by third-party payors, and reimbursement decisions by third-party payors;
- the magnitude and timing of any changes to our facilities, manufacturing operations and other infrastructure, and factors impacting our ability to access our facilities;
- the impact of any privacy breaches, which may subject us to legal and regulatory proceedings and substantial fines, penalties and expenses, as well as significant reputational harm;
- anticipated and actual regulatory approvals of our products and competitive products; and
- product recalls impacting, or the suspension or withdrawal of regulatory clearance or approval relating to, our products or the products of our competitors.

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

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

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

Recent Developments

Commercial Launch of the t:slim X2 Insulin Pump with Control-IQ Technology in the United States

In January 2020, we began shipping our t:slim X2 insulin pumps pre-loaded with Control-IQ technology, an advanced hybrid-closed loop feature designed to help increase time in range (70-180 mg/dL), to new customers in the United States. The t:slim X2 is the first and only system cleared to deliver automatic correction boluses in addition to adjusting insulin to help prevent high and low blood sugar. The system integrates with the Dexcom G6 CGM. In addition, we communicated the availability of Control-IQ technology to all of our in-warranty t:slim X2 customers in the United States, who have the option to add the new feature free of charge via the Tandem Device Updater. Customers interested in the remote software update are first required to obtain a prescription from their healthcare provider and complete a set of online training modules.

FDA Designation of Basal-IQ Technology as an Interoperable Automated Glycemic Controller

In February 2020, the FDA cleared our Basal-IQ technology as an iAGC. This is the second system to receive iAGC designation by the FDA, following the Company's clearance of the t:slim X2 insulin pump with Control-IQ technology in December 2019.

Cartridge Manufacturing Commences at Third-Party Contract Manufacturer

In the first quarter of 2020, we outsourced a portion of our cartridge manufacturing demand to an experienced third-party contract manufacturer. We believe our relationship with this contract manufacturer provides us additional flexibility in scaling our business and also mitigates some risk of having only a single site for cartridge manufacturing. We anticipate that this new manufacturing model will enable us to significantly increase our cartridge manufacturing capacity in the long term, without meaningfully increasing the cost of overhead associated with our manufacturing facilities.

Components of Results of Operations

Sales

We offer products for people with insulin-dependent diabetes. We commenced commercial sales of our original t:slim insulin pump platform in the United States in the third quarter of 2012 and continued to launch various iterations of that platform during the following years. In October 2016, we began shipping our flagship pump platform, the t:slim X2 insulin pump. The t:slim X2 insulin pump platform with advanced software algorithms and remote software update capabilities, now represents 100% of our new pump shipments. Accordingly, in the third quarter of 2018 we discontinued new sales of all prior platform versions. Our products also include disposable cartridges and infusion sets, as well as our complementary t:connect and Tandem Device Updater products. In addition, we offer accessories including protective cases, belt clips, and power adapters, although sales of these products are not significant.

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

In the third quarter of 2018, we began the launch of our t:slim X2 with Dexcom G5 CGM integration through distribution partners outside the United States, including in select European countries, Australia, New Zealand, and South Africa. During the second quarter of 2019, we began selling our t:slim X2 with Basal-IQ technology in certain of these geographies. In the first quarter of 2020, we delivered initial orders to support launches in Germany and France that are expected to occur in the second quarter of 2020. Our independent distributor partners perform all sales, customer support and training in their respective markets. In Canada, we market with a direct sales force and, similar to the United States, use a distributor partner for certain billing and fulfillment activities. Historically, we have experienced consistent levels of reimbursement for our products in the United States, but we expect the average sales price will vary in international markets based on a number of factors, such as the geographical mix, nature of the reimbursement environment, government regulations and the extent to which we rely on distributor relationships to provide sales, clinical and marketing support.

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

In the first quarter of 2020, the COVID-19 global pandemic had a major impact on businesses around the world. Although we experienced only a modest impact on our first quarter financial results, in March 2020 we ceased in-person sales, marketing and training activities and adopted numerous other changes to our daily business operations. These changes remain in effect as of the date of this report and it remains uncertain when we may be able to resume our normal operations. Accordingly, we anticipate that our sales will not follow historical trends and will be adversely impacted in the coming months as customers delay their purchasing decisions or physicians pause their prescriptions of new products. Our sales outside the United States may experience a greater proportional impact due to differences in the sales process in domestic versus international markets. The full extent of the impact of COVID-19 on our business and operations will depend on a number of factors, including the depth and duration of the global pandemic.

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

Cost of Sales

Historically, we have manufactured our pumps and disposable cartridges at our manufacturing facility in San Diego, California. Near the end of the first quarter, our third-party cartridge manufacturer completed validation and commenced commercial-scale manufacturing to supplement our existing cartridge manufacturing capacity. 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, scrap and charges for excess and obsolete inventories. Manufacturing overhead expenses include expenses relating to quality assurance, manufacturing engineering, material procurement, inventory control, facilities, equipment, information technology and operations supervision and management. We anticipate that our cost of sales will continue to increase as our product sales increase.

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

Other factors impacting our overall gross margin percentage may include the changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors in domestic and international markets, the timing and success of new regulatory approvals and product launches, the impact of the valuation and amortization of employee stock option grants on non-cash stock-based compensation expense allocated to cost of sales, changes in warranty estimates, training costs, licensing and royalty costs, 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 executive, financial, legal, marketing, sales, clinical, customer support, technical services, insurance verification, regulatory affairs and other administrative functions. We began expanding our U.S. field sales and clinical organization during the third quarter of 2019 to support an expected increase in demand for our products. We had approximately 90 sales territories as of March 31, 2020. 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 10 sales territories. Other significant SG&A expenses include those incurred for product demonstration samples, commercialization activities associated with new product launches, travel, trade shows, outside legal fees, independent auditor fees, outside consultant fees, insurance premiums, facilities costs and information technology costs. Overall, we expect our SG&A expenses, including the cost of our customer support infrastructure, to increase as our customer base grows in the United States and international markets. We will continue to evaluate, and may further increase, the number of our field sales and clinical personnel in order to optimize the coverage of our existing territories. Additionally, we realized a notable increase in non-cash stock-based compensation expense allocated to SG&A beginning in the third quarter of 2018, and again in the second quarter of 2019, due to the valuation of certain employee stock option grants and the impact on the valuation from the significant increase in our stock price over the previous year. We expect higher non-cash stock-based compensation expense will be sustained through the first half of 2020 and will begin to decline in future quarters. Our SG&A expenses may be affected by our response to the COVID-19 global pandemic, including reduced spending in areas such as non-essential employee travel, which may be offset by increased spending to support measures designed to prioritize the retention, health, safety and welfare of our employees. In the longer term, SG&A expenses may also increase due to anticipated costs associated with additional compliance and regulatory reporting requirements.

Research and Development

Our research and development (R&D) activities primarily consist of engineering and research programs associated with our products under development, as well as activities associated with our core technologies and processes. R&D expenses are primarily related to employee compensation, including salary, fringe benefits, non-cash stock-based compensation and temporary employee expenses. We also incur R&D expenses for supplies, development prototypes, outside design and testing services, depreciation, allocated facilities and information services, clinical trial costs, payments under our licensing, development and commercialization agreements and other indirect costs. We expect our R&D expenses to increase as we advance our products under development and develop new products and technologies, partially offset by future expected declines in non-cash stock-based compensation. 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.

Other Income and Expense

Other income and expense primarily consists of changes in the fair value of certain warrants issued in our public offering of common stock in October 2017, and interest earned on our cash equivalents and short-term investments. We expect other income and expense to fluctuate from period to period primarily due to the revaluation of the outstanding Series A warrants, which expire in the fourth quarter of 2022.

Results of Operations

(in thousands, except percentages)	Three Months Ended March 31, 2020	2019
Sales:		
Domestic	$ 79,546	$ 54,655
International	18,380	11,340
Total sales	97,926	65,995
Cost of sales	47,665	32,642
Gross profit	50,261	33,353
Gross margin	51%	51%
Operating expenses:		
Selling, general and administrative	49,717	34,961
Research and development	14,117	9,389
Total operating expenses	63,834	44,350
Operating loss	(13,573)	(10,997)
Other income (expense), net:		
Interest and other income	726	757
Interest and other expense	—	(6)
Change in fair value of common stock warrants	(1,922)	(12,746)
Total other expense, net	(1,196)	(11,995)
Loss before income taxes	(14,769)	(22,992)
Income tax expense	98	—
Net loss	$ (14,867)	$ (22,992)

Comparison of the Three Months Ended March 31, 2020 and 2019

Sales. For the three months ended March 31, 2020, sales were $97.9 million, which included $18.4 million of international sales. Sales were $66.0 million for the same period in 2019, which included $11.3 million of international sales.

The increase in total sales of $31.9 million was primarily driven by an 18% increase in worldwide pump shipments to 17,378 in the first quarter of 2020 compared to 14,732 in the first quarter of 2019, and a 93% increase in pump-related supply sales. Sales of pump-related supplies increased primarily due to a 61% increase in our estimated installed base of customers, as well as a more recent trend of customers purchasing cartridges and infusion sets at a higher rate than anticipated, which we believe may be associated with COVID-19.

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

	Three Months Ended March 31, 2020	2019
Pump	$ 49,719	$ 36,903
Infusion sets	20,214	11,954
Cartridges	9,455	5,671
Other	158	127
Total Domestic Sales	$ 79,546	$ 54,655

Domestic pump shipments were positively impacted by continued strong demand for our products following the January 2020 domestic launch of our t:slim X2 insulin pump with Control-IQ technology. Sales to distributors accounted for 69% and 74% of our total domestic sales for the three months ended March 31, 2020 and 2019, respectively. Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor.

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

	Three Months Ended March 31,	
	2020	2019
Pump	$ 9,816	$ 9,207
Infusion sets	6,246	1,297
Cartridges	2,233	822
Other	85	14
Total International Sales	$ 18,380	$ 11,340

International pump shipments for the three months ended March 31, 2020 benefited from initial orders shipped to independent distributors in new geographies. Pump shipments in 2019 were positively impacted by the transition of former Animas customers to our products, and the fulfillment of certain international pump demand from backlog that existed at the end of 2018 due to supply constraints. Sales to distributors accounted for 93% and 98% of our total international sales for the three months ended March 31, 2020 and 2019, respectively.

Cost of Sales and Gross Profit. Our cost of sales for the three months ended March 31, 2020 was $47.7 million, resulting in gross profit of $50.3 million, compared to $32.6 million of cost of sales for the same period in 2019 resulting in gross profit of $33.4 million. The gross margin percentage for the three months ended March 31, 2020 was 51%, consistent with the same period in 2019.

The increase in our gross profit for the three months ended March 31, 2020 was primarily the result of an 18% increase in pump shipments. Per unit manufacturing cost improvements from higher production volumes and continued overall manufacturing efficiencies also generated improvements in the gross margin percentage. The impact of these improvements was offset by changes in product mix. Pump sales, which have the highest gross margin, were 61% of total sales in the first quarter of 2020 versus 70% in the first quarter of 2019. Non-cash stock-based compensation expense allocated to cost of sales was $2.2 million for the three months ended March 31, 2020, compared to $1.1 million in the same period in 2019. Additionally, we recognized $1.3 million of product royalty costs in the first quarter of 2020 associated with the launch of Control-IQ technology in the United States. On an aggregate basis, other non-manufacturing costs, which primarily consist of warranty, freight and training costs, also reflected improvement on a per unit basis.

Selling, General and Administrative Expenses. SG&A expenses increased 42% to $49.7 million for the three months ended March 31, 2020 from $35.0 million for the same period in 2019. Employee-related expenses for our SG&A functions comprise the majority of SG&A expenses. The increase compared to 2019 was primarily the result of an $11.9 million increase in salaries, incentive compensation and other employee benefits due to an increase in personnel to support higher sales and our growing installed customer base, which included an increase of $4.5 million in non-cash stock-based compensation. Non-cash stock-based compensation expense allocated to SG&A was $11.5 million for the three months ended March 31, 2020, compared to $7.0 million in the same period in 2019. The increase in non-cash stock-based compensation expense was primarily due to the valuation of certain 2019 employee stock option grants and the impact on the valuation of the significant increase in our stock price. We also experienced increased costs for equipment and supplies, outside consulting and outside services of $2.4 million.

Research and Development Expenses. R&D expenses increased 50% to $14.1 million for the three months ended March 31, 2020 from $9.4 million for the same period in 2019. The increase in R&D expenses was primarily the result of an increase of $2.1 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts, as well as an increase of $2.6 million increase in clinical trials, outside services consulting services and equipment and maintenance attributable to R&D. Non-cash stock-based compensation expense allocated to R&D was $2.2 million for the three months ended March 31, 2020, compared to $1.7 million in the same period in 2019.

Other Income and Expense. Total other expense for the three months ended March 31, 2020 was $1.2 million compared to total other expense of $12.0 million in the same period in 2019. Other expense for the three months ended March 31, 2020 primarily consisted of a $1.9 million revaluation loss from the change in the fair value of certain warrants. Other expense for the three months ended March 31, 2019 primarily consisted of a $12.7 million revaluation loss from the change in the fair value of certain warrants due to the significant appreciation of our stock price. Interest and other income for the three months ended March 31, 2020 and 2019 primarily consisted of interest earned on our cash equivalents and short-term investments.

Liquidity and Capital Resources

As of March 31, 2020, we had $160.2 million in cash and cash equivalents and short-term investments. We believe that our cash and cash equivalents and short-term investments balance is sufficient to satisfy our liquidity requirements for at least the next 12 months from the date of this filing.

Historically, our principal sources of cash have included cash collected from product sales, private and public offerings of equity securities, and debt financing. Since the beginning of 2019, we completed the following financing activities:

- Between January 2019 and March 2020, we issued 2,091,395 shares of common stock upon the exercise of stock options, and 329,072 shares of common stock were purchased under our 2013 Employee Stock Purchase Plan, which generated aggregate proceeds of $35.7 million.
- Between January 2019 and March 2020, we received proceeds of $0.3 million from the exercise of 95,585 outstanding warrants which were originally issued in a registered public offering of common stock in October 2017. As of March 31, 2020, there were warrants to purchase 415,200 shares outstanding relating to the October 2017 offering.

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

We expect our sales performance and the resulting operating income or loss, as well as the status of each of our new product development programs, will significantly impact our cash flow from operations, liquidity position and cash management decisions. In light of the COVID-19 global pandemic, we are prudently managing our use of cash. We will continue to evaluate new information as it becomes available and make changes as are considered necessary.

The following table shows a summary of our cash flows for the three months ended March 31, 2020 and 2019:

	Three Months Ended March 31,	
(in thousands)	**2020**	**2019**
Net cash provided by (used in):		
Operating activities	$ (20,631)	$ (4,124)
Investing activities	32,916	778
Financing activities	11,481	1,962
Effect of foreign exchange rate changes on cash	(456)	3
Total	$ 23,310	$ (1,381)

Operating Activities. Net cash used in operating activities was $20.6 million for the three months ended March 31, 2020, compared to $4.1 million in the same period in 2019. The increase in net cash used in operating activities was primarily driven by changes in working capital requirements. Working capital changes in 2020 primarily consisted of increases in accounts receivable and inventories, and a decrease in employee-related liabilities, partially offset by an increase in accounts payable. Accounts receivable increased to $54.0 million at March 31, 2020 from $46.6 million at December 31, 2019, primarily due to the timing of sales. Inventories increased to $60.5 million at March 31, 2020 from $49.1 million at December 31, 2019, primarily to support the growth in our business.

Investing Activities. Net cash provided by investing activities was $32.9 million for the three months ended March 31, 2020, which was primarily related to $49.4 million in proceeds from maturities and sales of short-term investments, offset by $9.7 million of purchases of short-term investments and $6.8 million in purchases of property and equipment. Net cash provided by investing activities was $0.8 million for the three months ended March 31, 2019, which was primarily related to $45.1 million in proceeds from maturities and sales of short-term investments, offset by $42.9 million of purchases of short-term investments and $1.4 million in purchases of property and equipment.

Financing Activities. Net cash provided by financing activities was $11.5 million for the three months ended March 31, 2020, which primarily consisted of proceeds from the issuance of common stock under our stock plans. Net cash provided by financing activities was $2.0 million for the three months ended March 31, 2019, which primarily consisted of proceeds from the issuance of common stock under our stock plans.

Our liquidity position and capital requirements are subject to fluctuation based on a number of factors, including the following:

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

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

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

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

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, 2019.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We invest our excess cash primarily in commercial paper, corporate debt securities, U.S. Government-sponsored enterprise securities and U.S. Treasury securities. 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.

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 issued downgrades and revised outlooks to negative for a number of issuers of the debt securities held in our short-term investments portfolio. Unrealized losses on available-for-sale debt securities at March 31, 2020 were not significant. Based on the credit quality of the available-for-sale debt securities that are in an unrealized loss position, and our current estimates of future cash flows to be collected from those securities, the Company believes the unrealized losses are not credit losses (see Note 3, "Short-Term Investments").

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, 2020, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

Our operations are primarily located in the United States, and nearly all of our sales since inception have been made in U.S. dollars. With the exception of a portion of our sales in Canada, our sales outside of the United States are currently made to independent distributors under agreements denominated in U.S. dollars. Accordingly, we believe we do not currently have any material exposure to foreign currency rate fluctuations. As our business in markets outside of the United States increases, we may be exposed to foreign currency exchange risk. We believe this is currently limited to our operations in Canada, where fluctuations in the rate of exchange between the U.S. dollar and the Canadian dollar could adversely affect our financial results. In addition, from time to time, we may have foreign currency exchange risk related to existing assets and liabilities, committed transactions and forecasted future cash flows. In certain circumstances, we may seek to manage such foreign currency exchange risk by using derivative instruments such as foreign currency exchange forward contracts to hedge our risk. In general, we may hedge material 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 Securities Exchange Act of 1934, as amended (Exchange Act) that are designed to ensure that information required to be disclosed in the periodic and current reports we file with the Securities and Exchange Commission (SEC) 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 for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Control systems can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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

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, 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

Since April 1, 2020 we have been named as a defendant in four class action lawsuits. Each one was brought in response to a data breach we experienced in January 2020. Collectively, these lawsuits seek statutory, compensatory, actual, and punitive damages; declaratory and injunctive relief; disgorgement; restitution; and attorney fees, costs, and expenses from us. The four pending lawsuits are as follows:

- On April 1, 2020, *C.H., individually, and on behalf of all others similarly situated v. Tandem Diabetes Care, Inc.* was filed against us in the Southern District of the United States District Court. The complaint alleges negligence and violations of the California Confidentiality of Medical Information Act (CMIA).
- On April 8, 2020, *Joseph Deluna, on behalf of himself and all others similarly situated v. Tandem Diabetes Care, Inc.* was filed against us in the Central District of the United States District Court. The complaint alleges negligence and violations of the CMIA and the Federal Trade Commission Act (FTCA).
- On April 16, 2020, *Jose Lopez, individually and on behalf of all others similarly situated v. Tandem Diabetes Care, Inc.* was filed against us in the Southern District of the United States District Court. The complaint alleges negligence and violations of the FTCA, the CMIA, California's Unfair Competition Law, California's Consumer Record Act, and the California Consumer Privacy Act. This complaint also alleges that the security incident created a breach of contract and a breach of the implied covenant of good faith and fair dealing.
- On April 16, 2020, *Samantha Henrichsen, and her minor son, A.R., individually, and on behalf of all others similarly situated v. Tandem Diabetes Care, Inc.* was filed against us in the Southern District of the United States District Court. The complaint alleges negligence and violations of the CMIA, the Illinois Consumer Fraud and Deceptive Business Practices Act, and the Illinois Uniform Deceptive Trade Practices Act. This complaint also alleges that the security incident created a breach of contract.

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 and range of potential loss associated with the lawsuits.

From time to time, we are involved in various other legal proceedings, disputes and other claims arising in the ordinary course of our business, including actions with respect to intellectual property, employment, product liability and contractual matters. Although the results of legal proceedings, disputes and other claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not, individually or in the aggregate, have a material adverse effect on our business, financial position, results of operations, cash flows or future prospects. However, regardless of the outcome, legal proceedings, disputes and other claims can have an adverse impact on us because of legal costs, diversion of management time and resources, and other factors.

Item 1A. Risk Factors

An investment in our common stock involves risks. 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 and prospects. Certain statements below are forward-looking statements.

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 IA of our Annual Report.

Risks Related to Our Business and our Industry

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

Since our inception in January 2006, we have incurred a significant net loss. As of March 31, 2020, we had an accumulated deficit of $639.7 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 which has since been fully repaid. We have devoted substantially all of our resources to the design, development and commercialization of our products, the scaling of our manufacturing operations and commercial organization, the research and development of our current products and products under development, and the assembly of a management team to manage our business.

We began commercial sales of our first product, t:slim, in August 2012 and our 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 only selling our products in the United States.

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, 2019 and 2018, our gross profit was $194.2 million and $89.8 million, respectively. Although we have achieved a positive overall gross margin and have substantially reduced our operating loss, we still operate at a net loss on an annual basis and expect that we may continue to do so for the foreseeable future.

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

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

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

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

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

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

In addition, sales of any of our current or future insulin pump products with CGM integration are subject to the continuation of our applicable agreements with Dexcom or other third parties which, under some circumstances, may be subject to termination, with or without cause, on relatively short notice. Sales of our current 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 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 that the COVID-19 global pandemic could have a material adverse impact on sales of our products as it could result in customers delaying their purchasing decisions or physicians pausing prescriptions for our products. It could also have the effect of magnifying the negative impact of any of the factors described above.

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

Public health threats and other highly communicable diseases and outbreaks could adversely impact our operations, the operations of our customers, suppliers, distributors and other business partners, as well as the healthcare system in general. For example, the COVID-19 global pandemic, which is currently affecting various parts of the world, has resulted in a rapid rise in unemployment and a sudden decrease in global economic activity, and the scope of the pandemic and its impacts is continuing to expand. While we experienced only a modest impact from the COVID-19 global pandemic to our first quarter financial results, we anticipate that our sales and operating results will be adversely impacted in future periods. We anticipate that our sales outside the United States may experience a greater proportional impact due to differences in the sales process in domestic versus international markets. In addition, the recent rise in unemployment and decrease in economic activity due to the COVID-19 global pandemic may negatively impact the affordability of our products for certain customers, which could reduce demand for our products. Further, the initiation of certain programs planned for the second quarter, such as human factors studies associated with our product development efforts, will be delayed, which 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 may be required to take extraordinary measures to protect the health and safety of our employees and our business partners. For example, in March 2020, we restricted non-essential employee travel, banned visitors from all of our facilities, and transitioned those employees able to perform their job function outside of our facilities to a remote work environment. For our field-based sales and clinical employees, we have discontinued in-person activities and are utilizing technology to remotely engage healthcare providers and customers. For our employees in manufacturing and warehousing positions involved in production and fulfillment operations, we have implemented preventative measures to comply with social distancing requirements and have taken measures to help ensure safety, including requiring temperature checks for our employees before each shift. The adoption of these preventive measures have resulted in incremental costs that may negatively impact our gross margin. In addition, during the duration of the pandemic, our employees may be required to continue to operate within a remote work environment for extended periods of time due to illness, travel restrictions, government-imposed orders, school closures or for other reasons, any of which could result in reduced productivity of our workforce.

These impacts from the current pandemic, or other similar outbreaks or epidemics, could also 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 were 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 the pandemic could have a material adverse impact on the operations of one or more of our suppliers, which could prevent them from delivering products to us on a timely basis, or at all. For example, our current inventory level for insulin cartridges is below targeted levels and there is no guarantee that our third-party cartridge manufacturer will be able to manufacture cartridges in the quantities we require to rebuild inventories or meet product demand. In addition, our primary infusion set manufacturer is currently working through inventory constraints and there is no guarantee they will be able to provide infusion sets in the quantities we require. If these or similar manufacturing challenges persist, it could have a negative impact on product sales and harm our reputation.

The full extent of the impact of COVID-19 on our business and operations is highly uncertain and subject to change, and will depend on a number of factors, including the scope and duration of the global pandemic. We expect any further spread of the COVID-19 global pandemic, or even the threat or perception that this could occur, or any protracted duration of decreased economic activity, could have a material adverse impact on our business, operations and financial results.

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

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

Further, the COVID-19 global pandemic has resulted in substantial restrictions on our engagement efforts with customers and healthcare providers, including through the cancellation or postponement of Company-sponsored educational events, as well as third-party conferences, trade shows and similar events. These restrictions are likely to negatively impact 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, many of whom have greater resources than us, our sales 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 either publicly traded companies or divisions or subsidiaries of publicly traded companies, including Insulet and Medtronic MiniMed. In addition, Eli Lilly & Co. is developing an insulin pump. 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;
- greater market share and established base of customers;
- 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.

In addition, the competitive environment in which we operate has resulted and may continue to result in competitive pressures on our manufacturers, suppliers, distributors, collaboration partners and other business constituents. For example, we have entered into development agreements with Dexcom, which provide us non-exclusive licenses to integrate various generations of Dexcom CGM technology with our insulin pump products. In the fourth quarter of 2017, Abbott launched a new blood glucose sensing technology in the United States which competes with the Dexcom CGM technology, and another CGM product with CE Mark approval was approved in the second quarter of 2018 for sale in the United States. While we are currently in discussions with Abbott to develop and commercialize integrated diabetes solutions, there can be no assurance that we will enter into a definitive agreement with Abbott, that such an agreement will be on terms favorable to us, or that this collaboration will be successful. Competitive pressures within our industry, as well as the impacts and disruptions associated with the COVID-19 pandemic could negatively impact the financial condition of our business partners, impact their ability to fulfill contractual obligations to us, 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. As a result, our product sales may be negatively affected, 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 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 products to resemble modern consumer electronic devices to address certain embarrassment and functionality concerns consumers have raised with respect to traditional pumps. The consumer electronics industry is itself 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 electronics 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 strategy is highly dependent on our insulin pump and related products achieving and maintaining market acceptance. In order for us to sell our products to people with insulin-dependent diabetes, we must convince them, their caregivers and healthcare providers that our products are an attractive alternative to competitive products for the treatment of diabetes, including traditional insulin pump products and MDI therapies, as well as alternative diabetes monitoring, treatment or prevention methodologies. Market acceptance and adoption of our products depends on educating people with diabetes, as well as their caregivers and healthcare providers, about the distinct features, ease-of-use, beneficial treatment outcomes, and other perceived benefits of our products as compared to competitive products. If we are not successful in convincing existing and potential customers of the benefits of our products, or if we are not able to achieve the support of caregivers and healthcare providers for our products, our sales may decline or we may achieve sales below our expectations.

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

- the failure of our products to achieve and maintain wide acceptance among people with insulin-dependent diabetes, their caregivers, healthcare providers, third-party payors and key opinion leaders in the diabetes treatment community;
- lack of evidence supporting the safety, ease-of-use or other perceived benefits of our products over competitive products or other currently available insulin treatment methodologies;
- perceived risks or uncertainties associated with the use of our products, or components thereof, or of similar products or technologies of our competitors;
- adverse regulatory or legal actions relating to our insulin pump products or similar products or technologies; and
- results of clinical studies relating to our existing products or products under development or similar competitive products.

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

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

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

A substantial portion of the purchase price of an insulin pump is typically paid for by third-party payors, including private insurance companies, preferred provider organizations and other managed care providers. Future sales of our current and future products will be limited unless our customers can rely on third-party payors to pay for all or part of the associated purchase cost. Access to adequate coverage and reimbursement for our current and future products by third-party payors, both domestically and internationally, is essential to the acceptance of our products by customers.

As guidelines in setting their coverage and reimbursement policies, many third-party payors in the United States use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services (CMS), which administers the U.S. Medicare program. Medicare periodically reviews its reimbursement practices for diabetes-related products, and there is uncertainty as to the future Medicare reimbursement rate for our products. In addition to the currently existing reimbursement code for insulin pumps, CMS recently established additional reimbursement codes for insulin pumps with AID and CGM integration and associated supplies. The reimbursement rates for the new codes are expected to be established in 2020, but are not yet known. We are unable to determine the effect of these new reimbursement codes on the volume of our pump sales, revenues, and operating results, until the reimbursement rates are known and other details regarding their appropriate use are published. It is also possible that CMS may 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. It is possible that some third-party payors will not offer any coverage for our current or future products. For instance, UnitedHealthcare has designated one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers age seven or above. Unless UnitedHealthcare changes its coverage policies regarding insulin pumps, we expect this decision will prevent a majority of UnitedHealthcare members from purchasing our products. It is possible that other third-party payors may adopt similar policies in the future, which would adversely impact our ability to sell our products.

We currently have contracts establishing reimbursement for our insulin pump products with a number of national and regional third-party payors in the United States. While we may enter into additional contracts both domestically and internationally with third-party payors and add coverage for future products under our current agreements, we cannot guarantee that we will succeed in doing so or that the reimbursement contracts that we are able to negotiate will enable us to sell our products on a profitable basis. In particular, we have limited experience securing reimbursement in international markets. In addition, existing contracts with third-party payors generally can be modified or terminated by the third-party payor without cause and with little or no notice to us. Moreover, compliance with the administrative procedures or requirements of third-party payors may result in delays in processing approvals by those third-party payors for customers to obtain coverage for our products. Failure to secure or retain adequate coverage or reimbursement for our current and future products by third-party payors, or delays in processing approvals by those payors, could result in the loss of sales, which could have a material adverse effect on our business, financial condition and operating results.

Further, the healthcare industry in the United States is increasingly focused on cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with third-party payors. If third-party payors deny coverage or reduce their current levels of payment, or if our production costs increase faster than increases in reimbursement levels, we may be unable to sell our products on a profitable basis.

We may face unexpected challenges in marketing and selling our products, and training new customers on the use of our products, which could harm our ability to achieve our sales forecasts.*

We have limited experience marketing and selling our newer products as well as training new customers on their use, particularly in international markets. In addition, the vast majority of our existing customers are individuals with type 1 diabetes, and we have limited experience marketing and selling our products to customers with type 2 diabetes. We anticipate that selling our products to customers with higher insulin requirements, including customers with type 2 diabetes, may be even more difficult following our decision to discontinue sales of new t:flex pumps in the third quarter of 2018.

In addition, due to the current COVID-19 global pandemic, in March 2020 we discontinued in-person activities for our field-based sales and clinical employees and are utilizing technology to remotely engage healthcare providers and customers. The 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 the restrictions.

Our financial condition and operating results are and will continue to be highly dependent on our ability to adequately promote, market and sell our t:slim X2 insulin pump and related products, and the ability of our diabetes educators to train new customers on the use of our products. If our sales and marketing representatives or diabetes educators continue to be restricted in their ability to interact with healthcare providers and customers, our sales could decrease or may not increase at levels that are in line with our forecasts.

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

A key element of our business strategy involves our sales, clinical, marketing 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 in 2012. However, we have faced considerable challenges in growing and managing these resources, including with respect to recruiting, training and assimilation of new territories and accounts. We expect to continue to face significant challenges as we manage and grow our infrastructure in the future and work to motivate and retain the individuals who make up our existing infrastructure. These challenges may be even greater in connection with our commercial expansion outside of the United States, where we have limited experience. Unexpected turnover among our sales, marketing, clinical and customer service personnel, or unanticipated challenges in recruiting additional personnel, would have a negative impact on our ability to achieve our sales projections. Further, if a sales, marketing or clinical representative was to depart and be retained by one of our competitors, we may fail to prevent him or her from helping competitors solicit business from our existing customers, which could adversely affect our sales. Similarly, if we are not able to recruit and retain a network of diabetes educators and customer service personnel, we may not be able to successfully train and service new customers, which could delay new sales and harm our reputation.

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

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

For the year ended December 31, 2019, sales to approximately 55 independent distributors represented approximately 76% of our sales. We believe a majority of our sales will continue to be to independent distributors for the foreseeable future, and it is possible that the percentage of our sales to independent distributors could increase, particularly in light of our reliance on independent distributors outside of the United States. For example, our dependence upon independent distributors domestically could increase if third-party payors decide to contract with independent distributors directly in lieu of contracting with us to supply our products to their members directly. Our dependence upon independent distributors could also increase if customers prefer to purchase all of their diabetes supplies through a single source, instead of purchasing pump-related products through us and other diabetes supplies through other suppliers. None of our independent distributors domestically has been required to sell our products exclusively and each of them may freely sell the products of our competitors. Our distributor agreements in the United States generally have one-year initial terms with automatic one-year renewal terms, and are terminable in connection with a party's material breach. Our distributor agreements outside of the United States generally have longer initial terms and, in addition to being terminable in connection with a party's material breach, include provisions that allow us to terminate those agreements prior to their ordinary expiration in specified circumstances. 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, 2019, our two largest independent distributors in the United States collectively comprised approximately 31% of our worldwide sales, and our three largest independent international distributors collectively comprised approximately 60% of our international sales. If any of our key independent distributors were to cease to distribute our products or reduce their promotion of our products as compared to the products of our competitors, our sales could be adversely affected. In that case, we may need to seek alternative independent distributors or increase our reliance on our other independent distributors or our direct sales representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent we enter into additional arrangements with independent distributors to perform sales, marketing or distribution services, the terms of the arrangements could result in our product margins being lower than if we directly marketed and sold our products.

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

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

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

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

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

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

Another key element of our business strategy is utilizing market research to understand what people with diabetes are seeking to improve 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 that represent only a small percentage of the overall insulin-dependent diabetes market. As a result, the responses we received 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 the responses received during our market research 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 and our potential expansion of commercial sales in international markets, combine to make it more difficult for us to predict our future sales and operating results, as well as our expected timeframe to achieve profitability. The significant uncertainty resulting from the COVID-19 global pandemic will make it more difficult for us to accurately forecast our financial results and achieve sustained profitability. In assessing our business prospects, you should consider these factors as well as the various risks and difficulties frequently encountered by companies in competitive and rapidly evolving markets, particularly those companies that manufacture and sell medical devices.

These risks include our ability to:

- implement and execute our business strategy;
- manage and improve the productivity of our sales, clinical, marketing 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;
- obtain and maintain regulatory clearance or approval to enhance our existing products and commercialize proposed products;
- perform clinical trials with respect to our existing products and proposed products; and
- attract, retain and motivate qualified personnel in various areas of our business.

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

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

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

In response to the COVID-19 global pandemic, we have taken steps to prioritize the health and safety of our employees and customers, while working to maintain a continuous supply of products, training and support. For example, for our employees involved in production and fulfillment operations, we have implemented preventative safety measures. For employees in other functions, we have adopted measures designed to help employees remain effective in a work-from-home environment. Each of these measures has resulted in us incurring 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.

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, 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. In addition, we may not achieve anticipated improvements in manufacturing efficiency as we undertake actions to expand our manufacturing capacity. If we are unable to effectively manage our overall costs while increasing our production volumes and lowering our per-unit costs, we may not be able to achieve or sustain profitability, which would have an adverse impact on our business, financial condition and operating results.

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

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

- quality or reliability defects in product components that we source from third-party suppliers;
- our inability to secure product components in a timely manner, in sufficient quantities and on commercially reasonable terms;
- difficulty identifying and qualifying alternative suppliers for components in a timely manner;
- implementing and maintaining acceptable quality systems while experiencing rapid growth;
- our failure to increase production of products to meet demand;
- our inability to modify production lines and expand manufacturing facilities to enable us to efficiently produce future products or implement changes in current products in response to consumer demand or regulatory requirements;
- our inability to manufacture multiple products simultaneously while utilizing common manufacturing equipment;
- government-mandated or voluntary closures of 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. While we do not currently anticipate a significant disruption in our ability to manufacture insulin pumps and cartridges, our inventory for finished cartridges and infusion sets is below our targeted level and there is no guarantee that our third-party cartridge manufacturer will be able to manufacture cartridges in the quantities we require to rebuild inventories or meet product demand. In addition, our primary infusion set manufacturer is currently working through inventory constraints and we have asked some customers to accept substitutions of similar products to prevent delays in order fulfillment. While we are managing our inventory of cartridge and infusion set supplies, if these or similar manufacturing challenges persist, it could have a negative impact on product sales and harm our reputation.

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

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

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

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

We generally use a small number of suppliers for our components and products, some of which are located outside the United States including China and Mexico. Depending on a limited number of suppliers exposes us to risks, including limited control over cost such as tariffs, availability, quality and delivery schedules. Moreover, in some cases, we do not have long-standing relationships with our manufacturers and may not be able to convince suppliers to continue to make components available to us unless there is demand for such components from their other customers. As a result, there is a risk that certain components could be discontinued and no longer available to us. We have in the past been, and we may in the future be, required to make significant “last time” purchases of component inventories that are being discontinued by the manufacturer to ensure supply continuity. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our products, our quality control standards and applicable regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. These risks associated with the procurement of critical components from a limited number of suppliers may be increased as a result of the COVID-19 global pandemic. Failure

of any of our suppliers to deliver products at the level our business requires could harm our reputation and limit our ability to meet our sales projections, which could have a material adverse effect on our business, financial condition and operating results.

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

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

If we cannot reliably manufacture our proprietary infusion set connector, or if it does not achieve market acceptance, we may not achieve our financial projections.

In September 2017, we began commercial sales in the United States of products with our customized t:lock connector, which is used to connect our pump cartridge to our infusion set offerings. Our t:lock connector replaced the standard Luer-lok connector that historically joined an infusion set to our proprietary disposable insulin cartridges. Concurrently, we began selling infusion sets that are compatible with t:lock. Starting in 2018, we initially offered standard Luer-lok cartridges and infusion sets in select international markets, and transitioned to our t:lock connector in international markets during 2019.

We believe the transition to the t:lock connector, for our direct customers and distributors in the United States and international markets, is substantially complete. However, during 2020 there may be limited circumstances where we continue offering both styles of cartridges and infusion sets in international markets to facilitate the transition of customer supplies. Due to the variability in purchasing patterns, standard Luer-lok inventories may not be consumed at the predicted rates and we may be required to offer both styles of insulin cartridges and infusion sets for a longer period than anticipated or we may be left with excess quantities of standard Luer-lok inventories that we cannot sell at standard prices or at all, which would negatively impact our results of operations.

While the t:lock connector was designed based on customer feedback, and all standard Luer-lok infusion sets that we recently offered are now available with the t:lock connector, it is possible that t:lock may not continue to gain market acceptance by current or potential customers, their caregivers, or healthcare providers. Any negative market response to the t:lock connector may impact a current customer’s decision to purchase a new pump from us at the time of renewal. In addition, potential customers may decide not to purchase our insulin pumps if they do not prefer the t:lock connector or t:lock compatible infusion sets, which could have a material adverse impact on our business, financial condition and operating results.

Our business operations are primarily located in San Diego, California, and any disruption at one of our facilities could adversely affect our business and operating results.*

Substantially all of our current operations are conducted in San Diego, California, including our manufacturing processes, R&D activities and management and administrative functions. In addition, the majority of our inventories of component supplies and finished goods is stored at two facilities in San Diego. We also store finished goods at third-party warehouses in Texas for the fulfillment of certain customer orders. In the second half of 2019, we commenced limited customer and technical support activities in Boise, Idaho. We expect our operations in Boise to expand substantially during 2020. We take precautions to safeguard our facilities, including by acquiring insurance, employing back-up generators, adopting health and safety protocols and utilizing off-site storage of computer data. However, vandalism, terrorism or a natural disaster, such as an earthquake, fire or flood, or other catastrophic event, could damage or destroy our manufacturing equipment or our inventories of component supplies and finished goods, cause substantial delays in our operations, result in the loss of key information, result in reduced sales, and cause us to incur additional expenses. Our insurance coverage may not be sufficient to provide coverage with respect to the damages incurred in any particular case, and our insurance carrier may deny coverage with respect to all or a portion of our claims. Regardless of the level of insurance coverage or other precautions taken, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

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

At the beginning of 2018 we completed the transition of our manufacturing operations to our Barnes Canyon facility, and during the fourth quarter of 2019 we commenced operations at a new logistics warehouse in San Diego. We expect that both of these actions will allow for future capacity for product manufacturing and warehousing expansion. However, we may not experience the anticipated operating efficiencies at either facility. In addition, beginning in 2020 we outsourced a portion of our cartridge manufacturing demand to an experienced third-party contract manufacturer. If we fail to achieve the operating efficiencies that we anticipate, our manufacturing and operating costs may be greater than expected, which would have a material adverse impact on our operating results. In addition, we or our contract manufacturers may encounter problems during manufacturing for a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, component part supply constraints and environmental factors, any of which could delay or impede our ability to meet customer demand and have a material adverse impact on our business, financial condition and operating results. In addition, 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 our contract manufacturer, we may not be able to quickly establish additional or alternative arrangements.

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

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

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

- identify the product features and functionality that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in an insulin pump, and successfully incorporate those features into our products;
- develop and introduce products in sufficient quantities and in a timely manner;

- offer products at a price that is competitive with other products then available;
- work with third-party payors to obtain reimbursement for our products;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of proposed products; and
- obtain the necessary regulatory approvals for proposed products.

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

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

Currently there are only limited published studies to evaluate the safety or effectiveness of our products in a controlled setting. As a result, people with insulin-dependent diabetes and healthcare providers may be slower to adopt or recommend our products, we may not have comparative data that our competitors have or are generating, third-party payors may not be willing to provide coverage or reimbursement for our products and we may be subject to greater regulatory and product liability risks. These and other factors could slow the adoption of our products and result in our sales being lower than anticipated. In addition, future studies or clinical experience may indicate that treatment with our products is not superior to treatment with competitive products. Such results could slow the adoption of our products and significantly reduce our sales, which could prevent us from achieving our forecasted sales targets or achieving or sustaining profitability.

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

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

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

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

Additionally, we may not be in a position to exercise sole decision-making authority regarding a collaboration, licensing or other similar arrangement, which could create the potential risk of creating impasses on decisions. Further, our collaborators and business partners may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators and other business partners, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations, termination rights or the ownership or control or other licenses of intellectual property rights. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators, such as Dexcom and TypeZero, 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 agreements with Dexcom, which provide us non-exclusive licenses to integrate various currently available generations of Dexcom CGM technology with our insulin pump products. Our agreements with Dexcom related to G5 and G6 CGM currently run until June 2021 with automatic one-year renewals unless a party provides prior notice to the contrary. 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 with any of our current or future products. Termination of any of our agreements with Dexcom would require us to redesign certain current products and products under development, and attempt to integrate an alternative CGM system into our insulin pump systems, which would require significant development and regulatory activities that could result in an interruption or substantial delay in the availability of the product to our customers. The termination of our existing commercial agreements with Dexcom would disrupt our ability to commercialize our existing products and our development of future products, which could have a material adverse impact on our financial condition and results of operations, negatively impact our ability to compete and cause our stock price to decline.

We operate our business in regions subject to natural disasters and other catastrophic events, and any disruption to our business resulting from natural disasters will adversely affect our revenue and results of operations.*

We operate our business in regions subject to natural disasters, including earthquakes, hurricanes, floods, fires and other catastrophic events. For example, a portion of our office facilities located in San Diego are in an area that is prone to flooding, which has occasionally temporarily disrupted our business operations. Any natural disaster could adversely affect our ability to conduct business and provide products and services to our customers, and the insurance we maintain may not be adequate to cover our losses resulting from any business interruption resulting from a natural disaster or other catastrophic events. Any future disruptions to our operations could have a material adverse impact on our financial condition and results of operations in future periods.

A security breach or other significant disruption to our information technology systems, or failures of our pumps' software to perform as we anticipate, could materially disrupt our operations or result in the loss, theft, misuse, unauthorized disclosure, or unauthorized access to sensitive information relating to our customers, suppliers, employees or other individuals, which could damage our relationships, expose us to litigation or regulatory proceedings, or harm our

reputation, any of which could have an adverse and material effect on our business, financial condition and operating results.*

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

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

In addition to the risks regarding information technology systems and processing of sensitive information, our insulin pumps and other products rely on software that could contain unanticipated vulnerabilities, which could make our products subject to computer viruses, cyber-attacks, or failures. These risks significantly increased after July 2016, when we received FDA clearance of our Tandem Device Updater, which enables customers to remotely update software on their insulin pumps and may increase further following the launch of our new mobile application. 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.

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

We experienced a breach of our information technology systems on or around January 17, 2020.*

On January 17, 2020, we learned that an unauthorized person gained access to an employee's email account through a cyber-attack commonly known as "phishing." We investigated the incident, and learned that a limited number of our employee email accounts may have been accessed by an unauthorized user in a similar manner between January 17, 2020 and January 20, 2020. Our continued investigation indicated that customer information, as well as proprietary Company information, may have been contained in one or more of the employee email accounts affected by the incident. Our investigation has not determined whether an unauthorized person viewed any such information. As a result of this incident, we have been named a defendant in four putative class action lawsuits that we are aware of. The risks posed by these lawsuits include civil monetary damages, attorney fees and costs, other legal penalties, reputational damage, loss of goodwill, and competitive harm.

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

There are a number of domestic and international laws protecting the privacy and security of personal information. These laws include the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA) and related regulations, U.S. state laws, Canada's Personal Information and Electronic Documents Act (PIPEDA), 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 lawsuits described above allege violations of some of these laws.

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

We may also face new risks relating to data privacy and security as the United States, individual U.S. states, 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, the California Consumer Privacy Act, which took effect on January 1, 2020, may impose additional requirements on us and increase our regulatory and litigation risk. As we continue to expand, our business will need to adapt to meet these and other similar legal requirements.

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

We have benefited substantially from the leadership and performance of our senior management, as well as certain key employees. For example, key members of our management have experience successfully scaling an early stage medical device company to achieve profitability. Our success will depend on our ability to retain our current management and key employees, and to attract and retain qualified personnel in the future. Competition for senior management and key employees in our industry is intense and we cannot guarantee that we will be able to retain our personnel or attract new, qualified personnel. The loss of the services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives, or divert management's attention to seeking qualified replacements. Each member of senior management, as well as our key employees may terminate employment without notice and without cause or good reason. The members of our senior management are not subject to non-competition agreements. Accordingly, the adverse effect resulting from the loss of certain members of senior management could be compounded by our inability to prevent them from competing with us.

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

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

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

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

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

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. Accordingly, 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 complementary products or technologies, and the failure to successfully manage acquisitions, 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 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. Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- 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 compliance with regulatory matters.

We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions 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 Financial Results and Need for Financing

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, 2020, we had $160.2 million in cash, cash equivalents and short-term investments. Our management expects the continued growth of our business, including the expansion of our customer service infrastructure to support our growing base of customers, our plans to expand commercial sales of our products outside of the United States, the growth of our manufacturing and warehousing operations, increase the size of our facility footprint due to increasing headcount and additional R&D activities, will continue to increase our expenses. In addition, the amount of our future product sales is difficult to predict and actual sales may not be in line with our forecasts. Accordingly, our future capital requirements will depend on many factors, including:

- the revenue generated by sales of our insulin pump products, and the related insulin cartridges and infusion sets, and any other future products that we may develop and commercialize;
- the gross profits and gross margin we realize from the sales we generate;
- the costs associated with maintaining and expanding an appropriate sales, clinical and marketing infrastructure;
- the expenses we incur or other capital expenditures we make to maintain or enhance our manufacturing operations, including leasing additional property, hiring additional personnel, purchasing additional manufacturing equipment and other measures taken to add manufacturing capacity;
- the expenses associated with developing and commercializing our proposed products or technologies;
- the costs associated with maintaining and expanding our customer service infrastructure;
- the cost of obtaining and maintaining regulatory clearance or approval for our products and our manufacturing facilities;
- the cost of ongoing compliance with legal and regulatory requirements;
- the expenses we incur in connection with potential litigation or governmental investigations;
- expenses we may incur or other financial commitments we may make in connection with current and potential new 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.

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

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

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

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

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

Each of these factors may be negatively impacted by the COVID-19 global pandemic, which could have the effect of causing greater fluctuations in our operating results in future periods.

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

Risks Related to Our Intellectual Property and Potential Litigation

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

We rely primarily on patent, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements, to protect our proprietary technologies. As of March 31, 2020, our patent portfolio consisted of approximately 125 issued U.S. patents and 85 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2036. We are also seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we also have 34 trademark registrations, including 14 U.S. trademark registrations and 20 foreign trademark registrations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Legal and Regulatory Environment

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

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

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

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

During the first quarter of 2020 we submitted a 510(k) relating to an expanded age indication for use for our Control-IQ technology, for children 6 to 13 years of age. We may pursue 510(k) clearance for additional products or product modifications in the future. If the FDA requires us to go through a more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline or to not increase in line with our forecasts.

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

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

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared or approved products on a timely basis.

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

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

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

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

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

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

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

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

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

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

The FDA has the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. The FDA has broad discretion to require the recall 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 if any material deficiency in a product is found or alert customers of unanticipated safety risks. A government-mandated or voluntary recall 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 or 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, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, 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.

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. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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 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;
- federal and state laws, such as the Civil Monetary Penalties Law, that prohibit an individual or entity from offering or transferring remuneration to any person eligible for benefits under a federal or state health care program which such individual or entity knows or should know are likely to influence such eligible individual's choice of provider, practitioner or supplier of any item or service for which payment may be made under federal health care programs such as Medicare and state Medicaid programs;
- federal criminal laws enacted as part of HIPAA that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- federal disclosure laws, such as the Physician Payments Sunshine Act, which require certain manufacturers, including medical device manufacturers, to submit annual data pertaining to payments or other transfers of value to covered recipients, including physicians;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;
- foreign and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; and
- federal and state laws governing the use, disclosure and security of personal information, including protected health information, such as HIPAA and the Health Information Technology for Economic and Clinical Health.

Possible sanctions for violation of these laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other federal healthcare programs, and forfeiture of amounts collected in violation of those prohibitions and in some circumstances, treble damages. Any violation of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, financial condition and operating results. Recently, federal government agencies have published proposed rules for public comment which would make material modifications to several of these laws, including but not limited to the Anti-Kickback Statute, the Stark Law and HIPAA. It is unknown if or when these proposed rules may be adopted and what final form the proposed rules may take and how they may impact our business operations.

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

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

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

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

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

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

The Patient Protection and Affordable Care Act (PPACA) 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 PPACA was enacted, and legislation has also been proposed that could modify or repeal the PPACA. The uncertainties regarding the future of the PPACA, 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.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws.

The PPACA imposed, among other things, an excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, starting January 1, 2013. In December 2019, the medical device excise tax was repealed. Prior to the repeal, the tax had been suspended for calendar years 2016, 2017, 2018 and 2019. As a result of the repeal and the prior moratorium, sales of taxable medical devices after December 31, 2015, are not subject to the tax. We do not believe that our products were subject to this tax based on the retail exemption under applicable Treasury Regulations. However, the availability of this exemption is subject to interpretation by the Internal Revenue Service (IRS) and the IRS may disagree with our analysis. Additionally, Congress could enact future legislation or further change the law related to the medical device tax in a manner that could adversely affect us. The financial impact such taxes could have on our business is unclear and there can be no assurance that our business would not be materially adversely affected.

Risks Related to Our Common Stock

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

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

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

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

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

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

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

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

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

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

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

U.S. federal income tax reform could adversely affect us and our stockholders.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act (2017 Tax Act) which significantly reforms the Internal Revenue Code of 1986, as amended (the Code). The 2017 Tax Act, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest, allows for the expensing of capital expenditures, and puts into effect the migration from a "worldwide" system of taxation to a territorial system. We do not expect tax reform to have a material impact on our projection of minimal cash taxes. Our net deferred tax assets and liabilities were revalued at the newly-enacted U.S. corporate rate, and the impact was recognized in our tax expense, offset by a full valuation allowance, in the year of enactment. We continue to examine the impact that this tax reform legislation may have on our business. The impact of this tax reform on holders of our common stock is uncertain and could be adverse.

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

As of December 31, 2019, we had federal net operating loss (NOL) carryforwards of approximately $248.7 million, which includes the reduction recorded in 2019 discussed below. Of the total federal net operating loss carryforwards, $208.5 million will begin to expire in 2026, 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 an analysis through December 31, 2018 to determine whether our net operating losses and credits are likely to be limited by Section 382. Based on this study, 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 are 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.

With respect to our NOLs generated in 2018 and thereafter, the 2017 Tax Act may reduce the tax benefit of our NOLs. Under the 2017 Tax Act, our ability to carry back NOLs incurred after December 31, 2017 to previous tax years is eliminated. Under prior law, we could carry back NOLs for two years and carry forward NOLs for 20 years. Under the 2017 Tax Act, NOL carryforwards may be carried forward indefinitely. However, for NOLs arising after December 31, 2017, NOL carryforwards will be limited to 80% of our taxable income. Our NOLs generated in 2017 and in prior years will not be subject to the limitations under the 2017 Tax Act.

In response to the COVID-19 global pandemic, The CARES Act was enacted on March 27, 2020, to provide aid and economic stimulus to the economy. Among other provisions, the CARES Act eliminates the 80% NOL limitation for tax years 2018, 2019, and 2020, and allows NOLs generated in those years to be carried back for five years. Due to the recent enactment of the CARES Act, we are currently unable to quantify the impact that the CARES Act will have on our financial position, results of operations or cash flows, although we do not anticipate the impact to be significant.

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.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
10.1†	License Agreement, dated July 14, 2016, by and between Tandem Diabetes Care, Inc. and TypeZero Technologies, LLC					X
10.2*	Tandem Diabetes Care, Inc. 2020 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)					X

† Certain confidential portions of this exhibit were omitted because the identified confidential portions (i) are not material, and (ii) would be competitively harmful if publicly disclosed.

* 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: April 30, 2020

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: April 30, 2020

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)

LICENSE AGREEMENT

[***]: Certain confidential portions of this exhibit were omitted by means of marking such portions with asterisks because the identified confidential portions (i) are not material, and (ii) would be competitively harmful if publicly disclosed.

THIS LICENSE AGREEMENT (this "Agreement") dated as of July 14, 2016 (the "Effective Date"), is entered into between TypeZero Technologies LLC, a Delaware corporation ("TypeZero"), having a place of business at 212 East Main Street, Suite 202, Charlottesville, VA 22902, and Tandem Diabetes Care, Inc., a Delaware corporation ("Tandem"), having a place of business at 11045 Roselle Street, San Diego, CA 92121.

WHEREAS, TypeZero owns or has rights in the Technology (as defined below).

WHEREAS, Tandem desires to obtain a license under TypeZero's rights in the Technology on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants herein contained, the parties hereby agree as follows:

1. DEFINITIONS

For purposes of this Agreement, the terms defined in this Section 1 shall have the respective meanings set forth below:

1.1 "Affiliate" shall mean, with respect to any Person, any other Person that directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever.

1.2 "Artificial Pancreas System" means a system that aims to monitor and manage blood glucose levels via computer algorithms operating on one or more of an insulin pump or a smartphone or mobile device or other separate remote controller and to provide insulin and/or other medicaments.

1.3 "FDA" shall mean the Food and Drug Administration of the United States, or the successor thereto.

1.4 "Field" shall mean (a) insulin pumps and other medical devices for the delivery of insulin and/or other medicaments and (b) related software or mobile applications, in each case in connection with an Artificial Pancreas System.

1.5 "First Commercial Sale" shall mean, with respect to any Product, the first sale of such Product after all applicable marketing and pricing approvals (if any) have been granted by the applicable governing health authority of such country.

1.6 "Licensed IP Rights" shall mean, collectively, the Licensed Patent Rights and the Licensed Know-How Rights.

1.7 "Licensed Know-How Rights" shall mean all trade secret and other know-how rights in and to all data, information, compositions and other technology (including, but not limited to, formulae, procedures, protocols, techniques and results of experimentation and testing) which are necessary or useful for Tandem to make, use, develop, sell or seek regulatory approval for a product, or to

practice any method or process, at any time claimed or disclosed in any issued patent or pending patent application within the Licensed Patent Rights or which otherwise constitutes or relates to the Technology.

1.8 "Licensed Patent Rights" shall mean (a) the patents and patent applications listed on Exhibit A, (b) all patents and patent applications in any country of the world that claim or cover the Technology in which TypeZero heretofore or hereafter has an ownership or (sub)licensable interest, (c) all divisions, continuations, continuations-in-part, that claim priority to, or common priority with, the patent applications described in clauses (a) and (b) above or the patent applications that resulted in the patents described in clauses (a) and (b) above, and (d) all patents that have issued or in the future issue from any of the foregoing patent applications, including utility, model and design patents and certificates of invention, together with any reissues, renewals, extensions or additions thereto.

1.9 "Net Sales" shall mean, with respect to any Product, the gross sales price of such Product invoiced by Tandem or its Affiliate to customers who are not Affiliates (or are Affiliates but are the end users of such Product) less, to the extent actually paid or accrued by Tandem or its Affiliate (as applicable), (a) credits, allowances, discounts and rebates to, and chargebacks from the account of, such customers for nonconforming, damaged, outdated and returned Product; (b) freight and insurance costs incurred by Tandem or its Affiliate (as applicable) in transporting such Product to such customers; (c) cash, quantity and trade discounts, rebates and other price reductions for such Product given to such customers under price reduction programs; (d) sales, use, value-added and other direct taxes incurred on the sale of such Product to such customers; (e) customs duties, tariffs, surcharges and other governmental charges incurred in exporting or importing such Product to such customers; and (f) an allowance for uncollectible or bad debts determined in accordance with generally accepted accounting principles. Any deduction referenced in (a) through (f) above that is not calculated on a per Product basis shall be calculated and reported by Tandem in good faith and consistent with Tandem's internal accounting practices and procedures.

1.10 "Person" shall mean an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

1.11 "Pivotal Clinical Trial" shall mean a human clinical trial, the results of which are sufficient to file a PMA with the FDA.

1.12 "Product(s)" shall mean any product in the Field that (a) if made, used, sold, offered for sale or imported absent the license granted hereunder would infringe a Valid Claim, or (b) that otherwise uses or incorporates the Licensed IP Rights.

1.13 "Royalty Term" shall mean, commencing on the Effective Date and with respect to each Product in each country, until [***], unless earlier terminated in accordance with the provisions of this Agreement.

1.14 "Technology" shall mean all software, algorithms, know-how and data (including clinical data) constituting or related to delivery, management and monitoring of insulin and/or other medicaments, whether controlled on the device or by a separate remote controller or mobile device, and related software or mobile applications, in each case for the management, monitoring or treatment of diabetes (including both Artificial Pancreas System modules and mobile device security) and that is first owned or controlled by TypeZero prior to the Effective Date or within the first five (5) years after the Effective Date, including without limitation the "UVA Data" and "Related Works" referenced in the UVA-TypeZero License Agreement (as defined below).

1.15 "Territory" shall mean worldwide.

1.16 "Third Party" shall mean any Person other than TypeZero, Tandem and their respective Affiliates.

1.17 "Tier 1 License" shall mean a license agreement pursuant to which TypeZero or its Affiliate grants rights under the Licensed IP Rights for use in the Field to any of the following entities (or their Affiliates or successors): [***] and [***] (each a "Tier 1 Licensee").

1.18 "Tier 2 License" shall mean a license agreement pursuant to which TypeZero or its Affiliate grants rights under the Licensed IP Rights for use in the Field to any Third Party that is not a Tier 1 Licensee; provided, however, that a license agreement for [***] shall not constitute a Tier 2 License.

1.19 "TypeZero In-Licenses" shall mean all agreements (as modified, amended or restated as of the Effective Date), pursuant to which TypeZero or its Affiliates derive any right, title or interest in or to the Licensed IP Rights, including without limitation the UVA-TypeZero License Agreement (as defined below).

1.20 "UC IV Trial" means that certain multi-site International Diabetes Closed-Loop Trial denominated NIH/NIDDK Grant UC4 DK 108483 sponsored by the National Institutes of Health and scheduled to run during calendar years 2016 through 2019 (with a project period of 1/1/16 through 12/31/19) and any extensions thereof, which contemplates a trial of a "control to range" algorithm application, also known as an artificial pancreas system, that will use TypeZero's "inControl AP" running on a smartphone, and which system will be integrated with an insulin pump and continuous blood glucose monitor from one or more third-party manufacturers, as well as a cloud-based real-time monitoring/alerts/database system known as "inControl Cloud."

1.21 "UVA-TypeZero License Agreement" shall mean that certain Amended and Restated License Agreement by and between the University of Virginia Patent Foundation d/b/a University of Virginia Licensing and Ventures Group and TypeZero dated September 4, 2015.

1.22 "Valid Claim" shall mean a claim of an issued and unexpired patent included within the Licensed Patent Rights, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise. The invalidity of a particular claim in one or more countries shall not invalidate such claim in the remaining countries of the Territory.

2. REPRESENTATIONS AND WARRANTIES

2.1 Mutual Representations and Warranties. Each party hereby represents and warrants to the other party as follows:

2.1.1. Such party is a corporation or limited liability company, as the case may be, duly organized, validly existing and in good standing under the laws of the state in which it is incorporated.

2.1.2. Such party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms.

2.1.3. All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such party in connection with this Agreement have been obtained.

2.1.4. The execution and delivery of this Agreement and the performance of such party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations, and (b) do not conflict with, or constitute a default under, any contractual obligation of it.

2.2 TypeZero Representations and Warranties. TypeZero hereby represents and warrants to Tandem that TypeZero has provided Tandem with complete and correct copies of all TypeZero In-Licenses, and there have been no modifications, amendments or restatements thereto other than as provided to Tandem prior to the Effective Date. The TypeZero In-Licenses are in full force and effect in

accordance with their terms. After giving effect to this Agreement, there exist no breaches, defaults or events that would (with the giving of notice, the passage of time or both) give rise to a breach, default or other right to terminate or modify any TypeZero In-License.

3. LICENSE GRANT

3.1. Licensed IP Rights. Effective as of Tandem's payment of the License Fee set forth in Section 4.1, TypeZero hereby grants to Tandem a non-exclusive, non-transferable (subject to Section 10.3 hereof) license (without the right to grant sublicenses except as set forth below) under the Licensed IP Rights and solely within the Field to conduct research and to develop, make, have made, use, offer for sale, sell and import Products in the Territory. The license grant to use the Licensed IP Rights shall be extended to employees hired by Tandem or its Affiliates, independent contractors, consultants, and collaborators solely to the extent that such parties are performing services for, or working in connection with, Tandem or its Affiliates. Tandem shall also have the right to grant sublicenses to end users of the Products for the end users' use of the Products.

3.2. TypeZero In-Licenses. TypeZero shall timely pay in full all amounts required to be paid by TypeZero, and timely perform in full all obligations required to be performed by TypeZero, under all TypeZero In-Licenses. TypeZero promptly shall provide Tandem with copies of all notices and other deliveries received under the TypeZero In-Licenses that are material to this Agreement. Without the prior express written consent of Tandem, TypeZero shall not (and shall take no action or make no omission to) modify or waive any provision of any TypeZero In-License that could impair the value of the licenses to Tandem herein, or to terminate or have terminated any TypeZero In-License. If any TypeZero In-License is terminated for any reason, TypeZero shall use all commercially reasonable efforts to cause the licensor thereunder to grant a direct license under the Licensed IP Rights to Tandem containing terms and conditions no less favorable to Tandem than the payment terms of such TypeZero In-License.

3.3. Trade Secrets. TypeZero shall maintain in confidence and as a trade secret the source code of the software and algorithms included within the Technology.

3.4. Availability of the Licensed IP Rights. Promptly following the Effective Date, TypeZero shall provide Tandem with a copy of all information and technology available to TypeZero relating to the Licensed IP Rights and Technology, including without limitation: (a) software and source code, (b) algorithms, and (c) data (including results of past clinical trials). During the first five (5) years following the Effective Date, as TypeZero generates or acquires additional Technology, TypeZero shall promptly provide a copy of such additional Technology to Tandem.

3.5. Technical Assistance.

3.5.1. During the first [***] following the Effective Date, TypeZero shall provide to Tandem such technical assistance as is reasonably necessary to enable Tandem to utilize the Licensed IP Rights and Technology transferred to Tandem pursuant to Section 3.4, including without limitation providing guidance on the code and architecture of the applicable software and algorithms. TypeZero shall provide such initial technical assistance at no additional cost to Tandem, provided that Tandem shall [***].

3.5.2. During the first five (5) years after the Effective Date, appropriate representatives of TypeZero and Tandem shall meet in person (at a mutually agreed upon location) at least [***]. The subject of these meetings will be for Tandem to report on the status of product development efforts and for TypeZero to report on the development of additional Technology. Each party will bear its own costs to prepare and attend such meetings.

3.5.3. If Tandem desires technical assistance or services in addition to that described in Sections 3.5.1 and 3.5.2 (which may include, without limitation, product development assistance or clinical trial planning), then TypeZero shall provide such assistance on a time and materials basis and as mutually agreed upon by the parties and set forth in a Statement of Work that provides for the scope of the assistance and services and the applicable budget. Such Statements of Work shall likewise address ownership of any work product or inventions that may arise from such assistance and services (including any associated patent and intellectual property rights), depending upon the nature of the underlying work. TypeZero shall ensure that any such assistance or services shall be done by TypeZero personnel that are obligated to assign any inventions to TypeZero, and TypeZero shall not use any employee of the University of Virginia (or an employee of any Third Party).

3.5.4. TypeZero shall ensure that at least [***] of the insulin pump products used in the UC IV Trial are Tandem Products.

3.6. Additional Licenses. TypeZero shall notify Tandem in writing within [***] following the execution of a Tier 1 License or a Tier 2 License, and shall specify its identity as one or the other. TypeZero shall not sell its assets or stock to, and shall not directly or indirectly grant any license or other rights under the Licensed IP Rights to, [***]. TypeZero shall ensure that with respect to any agreements that TypeZero enters into with a Third Party to grant a license to such Third Party under the Licensed IP Rights, if such licensee acquires, or is acquired by, or otherwise becomes an Affiliate of, [***] then such agreement shall terminate.

3.7. New IP. If, after five (5) years following the Effective Date, [***] ("New IP"), then TypeZero shall notify Tandem in writing of such New IP within [***] following the date of development or acquisition thereof. TypeZero hereby grants to Tandem for a period of [***] following the date TypeZero provides such notice with respect to any New IP (the "Negotiation Period"), a right to [***]. During the applicable Negotiation Period, the parties shall negotiate in good faith and attempt to reach mutual agreement on commercially reasonable terms and conditions for [***]. If the parties are unable to agree upon such terms and conditions during the applicable Negotiation Period, then TypeZero may [***]; provided, however, that if [***].

3.8. Enforcement and Licensing of Patent Rights. Subject in all events to the attorney-client privilege (which TypeZero expressly reserves), TypeZero shall provide notice to Tandem within [***]. In such case, TypeZero shall [***] including, without limitation, to (a) [***], or (b) [***] to the extent permissible under this Agreement. TypeZero shall, however, [***], and shall notify Tandem promptly in the event of any such action. If TypeZero does not do either (a) or (b) by the end of [***], then for purposes of [***] TypeZero shall be deemed to have [***].

4. FINANCIAL CONSIDERATIONS

4.1. License Fee. Within [***] following the Effective Date, Tandem shall pay to TypeZero an upfront license fee of [***].

4.2. Royalties.

4.2.1. Royalty Rate.

a. With respect to Products and during the applicable Royalty Term for such Products, Tandem shall pay to TypeZero royalties, with respect to such Products, equal to (i) [***] of aggregate Net Sales of such Products by Tandem and its Affiliates up to [***] of aggregate Net Sales, and (ii) [***] of aggregate Net Sales of such Products by Tandem and its Affiliates above [***]. Only one royalty shall be owing for a Product regardless of how many Valid Claims cover such Product, and regardless of whether Tandem provides an update or upgrade to such Product with updated Technology. For the avoidance of doubt, and notwithstanding anything in this Agreement to the contrary, the parties mutually acknowledge and agree that Tandem shall have no obligation to pay royalties under this Agreement for any Tandem products that (i) are [***], recognizing that such product is likely to undergo revisions or modifications to hardware or software from time to time, including changes needed for interoperability with alternative continuous glucose sensors and/or other blood glucose monitoring devices (a "Tandem PLGS System"), and (ii) are not intended for use with, or otherwise marketed by Tandem to be used as part of, a [***].

b. Commencing with aggregate Net Sales above [***], the applicable royalty rate set forth in Section 4.2.1(a) shall be reduced by [***] in each instance that (i) TypeZero grants a Tier 1 License after the first (1st) Tier 1 License is granted, and/or (ii) TypeZero grants a Tier 2 License after the second (2nd) Tier 2 License is granted, for so long as each such Tier 1 License or Tier 2 License continues in effect (provided that (i) if any such Tier 1 License or Tier 2 License is terminated, then the applicable reduction will no longer apply starting with the next calendar quarter after the date of termination, and (ii) if a Tier 1 License or Tier 2 License is terminated as a result of a change of control or merger of TypeZero with another licensee under a Tier 1 License or Tier 2 License, or as a result of a change of control or merger of a licensee under a Tier 1 License or Tier 2 License with another licensee under a Tier 1 License or Tier 2 License, then the reduction shall continue); provided, however, that Tandem shall [***]. By way of example, if TypeZero grants [***], then the applicable royalty rate set forth in Section 4.2.1(a) shall be reduced by [***].

c. The royalty owing Section 4.2.1(a) is due on Products that at the time of sale are covered by a Valid Claim in the country of manufacture or sale during the applicable Royalty Term. If Tandem provides and update or upgrade to a product that was not previously subject to a royalty under Section 4.2.1(a), but after receiving the update or upgrade such product would constitute a Product that at the time of upgrade or update, as the case may be, is covered by a Valid Claim in the country of manufacture or sale, then Tandem shall pay to TypeZero a royalty equal to: (i) if Tandem [***] (subject to standard deductions as set forth in the Net Sales definition), or (ii) if Tandem [***] (subject to standard deductions as set forth in the Net Sales definition).

d. If at any time TypeZero has granted more than [***] Tier 1 Licenses and Tier 2 Licenses in any combination, then-upon the date that TypeZero notifies Tandem of the [***] such license pursuant to Section 3.6 hereof-Tandem shall receive a credit against future royalties equal to [***]. Tandem shall not have the right to take the foregoing credit until Tandem shall have achieved [***] in aggregate Net Sales of Product and, thereafter, Tandem shall have the right to take such credit against any subsequent royalty payments until fully credited.

4.2.2. Third Party Royalties. If Tandem or its Affiliates are required to pay royalties to any Third Party in order to exercise its rights hereunder to make, have made, use, sell, offer to sale or import any Product, then Tandem shall have the right to credit [***] of such Third Party royalty payments against the royalties owing to TypeZero under Section 4.2.1 with respect to sales of such Product in such country; provided, however, that Tandem shall not reduce the amount of the royalties paid to TypeZero under Section 4.2.1 by reason of this Section 4.2.2, with respect to sales of such Product in such country, to less than [***] of the royalties that would otherwise be due under Section 4.2.1.

4.3. Combination Products. If a Product consists of components that are covered by a Valid Claim and components that are not covered by a Valid Claim, then for purposes of the royalty payments under Section 4.2 for Net Sales of such Products, such Net Sales, prior to the royalty calculation set forth in Section 4.2, first shall be [***] as reasonably determined by Tandem, and such resulting amount shall be the "Net Sales" for purposes of the royalty calculation in Section 4.2 for such Product. For clarity, no royalty is due on sales of accessories such as infusion sets, cartridges, CGM sensors, CGM transmitters or CGM receivers not integrated into a pump.

4.4. Milestones. Tandem shall pay to TypeZero the following [***] milestone payments within [***] days following the first achievement of the applicable milestone by Tandem:

Milestone #	Milestone Event	Milestone Payment
1	Generation of data under the UC IV Trial sufficient for Tandem to initiate a Pivotal Clinical Trial for a Product, which shall be deemed to be data from [***]or approximately [***].	USD $[***]*
2	Enrollment of first patient in a Pivotal Clinical Trial for the first Product (excluding consumables such as cartridges, infusion sets and other accessories) that utilizes the Technology and is covered by a Valid Claim	USD $[***]
3	Receipt of approval from the FDA for a PMA for the first Product (excluding consumables such as cartridges, infusion sets and other accessories) that utilizes the Technology and is covered by a Valid Claim	USD $[***]

* In the event that TypeZero does not achieve Milestone #1 on or before [***] (the "Milestone 1 Date"), the Milestone Payment for Milestone #1 shall be reduced by [***]; provided, however, that if [***].

4.5. Supply of Materials. Upon request, Tandem agrees to supply to TypeZero, or its designee, with up to [***] and up to [***] for use in the performance of the UC IV Trial, subject to the terms of a material transfer agreement in a form reasonably acceptable to both parties with terms that are customary for the performance of a human clinical study of an unapproved product. Any such materials may not be used for any purpose other than the performance of the UC IV Trial. The materials supplied hereunder shall be deemed to have a fair market value of [***]. Any additional [***] shall be purchased from Tandem at a price of [***] and [***] and on such other terms that are consistent with the above referenced material transfer agreement.

4.6. [***]. If at any time during the term of this Agreement TypeZero [***], or any combination thereof when viewed as whole-and in light of potential market opportunity) for a grant of a license under the Licensed IP Rights to any Third Party that are [***], TypeZero shall also [***] to Tandem, and if Tandem [***], the parties shall amend this Section 4 to reflect such terms, such amendment to be effective as of the date TypeZero and Tandem both sign the same.

4.7. Sale of Company. During the term of this Agreement, and subject in all events to confidentiality obligations and the attorney-client privilege (which TypeZero expressly reserves) and contractual obligations to the contrary (such as "no shop" provisions and the like), should TypeZero intend to accept an offer from any potential buyer for the sale of all or part of TypeZero's business (whether by asset sale, merger, reorganization, change of control, operation of law or otherwise) (a "Third Party Offer"), TypeZero shall notify Tandem of such state of affairs; provided, however, that TypeZero need not identify the potential buyer or otherwise provide to Tandem the terms and conditions of such Third Party Offer. TypeZero will consider in good faith any proposed counter-offer from Tandem to the Third Party Offer and any modifications thereof; provided, however, that Tandem shall have no obligation to make any offer to acquire all or any part of TypeZero's business.

5. ROYALTY REPORTS AND ACCOUNTING

5.1. Royalty Reports. Within [***] after the end of each calendar [***] during the term of this Agreement following first to occur of the First Commercial Sale of a Product, Tandem shall furnish to TypeZero a [***] written report showing in reasonably specific detail (a) the calculation of Net Sales during such calendar quarter; (b) the calculation of the royalties, if any, that shall have accrued based upon such Net Sales; (c) the withholding taxes, if any, required by law to be deducted with respect to such sales; and (d) the exchange rates, if any, used in determining the amount of United States dollars. With respect to sales of Products invoiced in United States dollars, the gross sales, Net Sales and royalties payable shall be expressed in United States dollars. With respect to Net Sales invoiced in a currency other than United States dollars, all such amounts shall be expressed both in the currency in which the distribution is invoiced and in the United States dollar equivalent. The United States dollar equivalent shall be calculated using the average of the exchange rate (local currency per US$1) published in The Wall Street Journal, Western Edition, under the heading "Currency Trading" on the last business day of each month during the applicable calendar quarter.

5.2. Audits.

5.2.1. Upon the written request of TypeZero and not more than [***], Tandem shall permit an independent certified public accounting firm of nationally recognized standing selected by TypeZero and reasonably acceptable to Tandem, [***], to have access during normal business hours to such of the financial records of Tandem as may be reasonably necessary to verify the accuracy of the payment reports hereunder for the [***] immediately prior to the date of such request (other than records for which TypeZero has already conducted an audit under this Section.

5.2.2. If such accounting firm concludes that additional amounts were owed during the audited period, Tandem shall pay such additional amounts within [***] after the date TypeZero delivers to Tandem such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by TypeZero; provided, however, if the audit discloses that the royalties payable by Tandem for such period are more than [***] of the royalties actually paid for such period, then Tandem shall pay the reasonable fees and expenses charged by such accounting firm.

5.2.3. TypeZero shall cause its accounting firm to retain all financial information subject to review under this Section 5.2 in strict confidence; provided, however, that Tandem shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Tandem regarding such financial information. The accounting firm shall disclose to TypeZero only whether the reports are correct or not and the amount of any discrepancy. No other information shall be shared. TypeZero shall treat all such financial information as Tandem's Confidential Information.

6. PAYMENTS

6.1. Payment Terms. Royalties shown to have accrued by each royalty report provided for under Section 5 shall be due on the date such royalty report is due. Payment of royalties in whole or in part may be made in advance of such due date.

6.2. Exchange Control. If at any time legal restrictions prevent the prompt remittance of part or all royalties with respect to any country in the Territory where the Product is sold, Tandem shall have the right, in its sole discretion, to make such payments by depositing the amount thereof in local currency to TypeZero's account in a bank or other depository institution in such country. If the royalty rate specified in this Agreement should exceed the permissible rate established in any country, the royalty rate for sales in such country shall be adjusted to the highest legally permissible or government-approved rate.

6.3. Withholding Taxes. Tandem shall be entitled to deduct the amount of any withholding taxes, value-added taxes or other taxes, levies or charges with respect to such amounts, other than United States taxes, payable by Tandem, its Affiliates or sublicensees, or any taxes required to be withheld by Tandem, its Affiliates or sublicensees, to the extent Tandem, its Affiliates or sublicensees pay to the appropriate governmental authority on behalf of TypeZero such taxes, levies or charges. Tandem shall use reasonable efforts to minimize any such taxes, levies or charges required to be withheld on behalf of TypeZero by Tandem, its Affiliates or sublicensees. Tandem promptly shall deliver to TypeZero proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto.

7. CONFIDENTIALITY

7.1. Confidential Information. During the term of this Agreement, and for a period of [***] following the expiration or earlier termination hereof, each party shall maintain in confidence all information of the other party that is disclosed by the other party and identified as, acknowledged to be, or reasonably should be considered confidential at the time of disclosure (the "Confidential Information"), and shall not use, disclose or grant the use of the Confidential Information except on a need-to-know basis to those directors, officers, affiliates, employees, permitted licensees, permitted assignees and agents, consultants, clinical investigators or contractors, to the extent such disclosure is reasonably necessary in connection with performing its obligations or exercising its rights under this Agreement. To the extent that disclosure is authorized by this Agreement, prior to disclosure, each party hereto shall obtain agreement of any such Person to hold in confidence and not make use of the Confidential Information for any purpose other than those permitted by this Agreement. Each party shall notify the other promptly upon discovery of any unauthorized use or disclosure of the other party's Confidential Information.

7.2. Permitted Disclosures. The confidentiality obligations contained in Section 7.1 shall not apply to the extent that (a) any receiving party (the "Recipient") is required (i) to disclose information by law, regulation or order of a governmental agency or a court of competent jurisdiction, or (ii) to disclose information to any governmental agency for purposes of obtaining approval to test or market a product, provided in either case that the Recipient shall provide written notice thereof to the other party and sufficient opportunity to object to any such disclosure or to request confidential treatment thereof; or (b) the Recipient can demonstrate that (i) the disclosed information was public knowledge at the time of such disclosure to the Recipient, or thereafter became public knowledge, other than as a result of actions of the Recipient in violation hereof; (ii) the disclosed information was rightfully known by the Recipient (as shown by its written records) prior to the date of disclosure to the Recipient by the other party hereunder; (iii) the disclosed information was disclosed to the Recipient on an unrestricted basis from a source unrelated to any party to this Agreement and not under a duty of confidentiality to the other party; or (iv) the disclosed information was independently developed by the Recipient without use of the Confidential Information disclosed by the other party. Notwithstanding any other provision of this Agreement, Tandem may disclose Confidential Information of the TypeZero relating to information developed pursuant to this Agreement to any Person with whom Tandem has, or is proposing to enter into, a business relationship, as long as such Person has entered into a confidentiality agreement with Tandem. All Confidential Information of both parties shall be returned or, at the disclosing party's option destroyed, by within a prompt and commercially reasonable time after this Agreement terminates for any reason; provided, however, that a Recipient (A) may retain one (1) copy for its legal archival purposes, (B) will not be required to remove electronic files, and (C) will not be required to return or destroy records that it is required to maintain under applicable laws, rules, or regulations, including, without limitation, records in a Party's quality systems relating to Products.

7.3. Terms of this Agreement. Except as otherwise provided in Section 7.2, TypeZero and Tandem shall not disclose any terms or conditions of this Agreement to any Third Party without the prior consent of the other party. Notwithstanding the foregoing, prior to execution of this Agreement, Tandem and TypeZero have agreed upon the substance of information that can be used to describe the terms of this transaction, and Tandem and TypeZero may disclose such information, as modified by mutual agreement from time to time, without the other party's consent.

8. TERMINATION

8.1. Expiration. Subject to Sections 8.2 and 8.3 below, this Agreement shall expire on [***]. Upon such expiration of this Agreement, Tandem shall have a fully paid-up, non-exclusive license under the Licensed Know-How Rights to conduct research and to develop, make, have made, use, sell, offer for sale and import Products in the Territory for use in the Field.

8.2. Termination by Tandem. Tandem may terminate this Agreement, in its sole discretion, upon [***] prior written notice to TypeZero; provided, however, that any amounts paid by Tandem to TypeZero pursuant to Section 4 of this Agreement or otherwise shall be nonrefundable.

8.3. Termination for Cause. Except as otherwise provided in Section 9, TypeZero may terminate this Agreement upon or after the breach of any material provision of this Agreement by Tandem if Tandem has not cured such breach within [***] after receipt of express written notice thereof by TypeZero; provided, however, if any default is not capable of being cured within such [***] period and Tandem is diligently undertaking to cure such default as soon as commercially feasible (but not more than [***] thereafter under the circumstances, TypeZero shall have no right to terminate this Agreement. If TypeZero terminates this Agreement, any amounts paid by Tandem to TypeZero pursuant to Section 4 of this Agreement or otherwise shall be nonrefundable.

8.4. Effect of Expiration or Termination. Expiration or termination of this Agreement shall not relieve the parties of any obligation accruing prior to such expiration or termination, and the provisions of Sections [***] and [***] shall survive the expiration or termination of this Agreement.

9. FORCE MAJEURE

Neither party shall be held liable or responsible to the other party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected party including but not limited to fire, floods, embargoes, war, acts of war (whether war be declared or not), acts of terrorism, insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other party.

10. MISCELLANEOUS

10.1. Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the parties hereto to the other party shall be in writing, delivered by any lawful means to such other party at its address indicated below, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

If to TypeZero: TypeZero Technologies LLC
212 East Main Street, Suite 202
Charlottesville, VA 22902
Attention: Chad Rogers, President and CEO

With a copy to: Kevin L. Passarello
Buchanan Ingersoll & Rooney, PC
1700 K Street, NW, Suite 300
Washington, DC 20006

If to Tandem: Tandem Diabetes Care, Inc.
11045 Roselle Street
San Diego, California 92121
Attention: Chief Executive Officer

With a copy to: Tandem Diabetes Care, Inc.
11045 Roselle Street
San Diego, California 92121
Attention: General Counsel

10.2. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of [***], without regard to the conflicts of law principles thereof.

10.3. Assignment. Neither party shall assign its rights or obligations under this Agreement without the prior written consent of the other party; provided, however, that a party may, without such consent, assign this Agreement and its rights and obligations hereunder (a) to any Affiliate, or (b) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement.

10.4. Waivers and Amendments. No change, modification, extension, termination or waiver of this Agreement, or any of the provisions herein contained, shall be valid unless made in writing and signed by duly authorized representatives of the parties hereto.

10.5. Entire Agreement. This Agreement embodies the entire agreement between the parties and supersedes any prior representations, understandings and agreements between the parties regarding the subject matter hereof. There are no representations, understandings or agreements, oral or written, between the parties regarding the subject matter hereof that are not fully expressed herein.

10.6. Bankruptcy. The foregoing license is and shall be deemed to be, for purposes of 11 U.S.C. Section 365(n), a license of "Intellectual Property Rights" as defined thereunder, and if TypeZero is under any proceeding under the United States Bankruptcy Code and the trustee in bankruptcy of TypeZero, or TypeZero as a debtor in possession, elects to reject the foregoing license, Tandem may, pursuant to 11 U.S.C. Section 365(n)(1) and (2), retain any and all of Tandem's rights under such license to the maximum extent permitted by law.

10.7. Severability. Any of the provisions of this Agreement that are determined to be invalid or unenforceable in any jurisdiction shall be ineffective to the extent of such invalidity or unenforceability in such jurisdiction, without rendering invalid or unenforceable the remaining provisions hereof and without affecting the validity or enforceability of any of the terms of this Agreement in any other jurisdiction.

10.8. Waiver. The waiver by either party hereto of any right hereunder or the failure to perform or of a breach by the other party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other party whether of a similar nature or otherwise.

10.9. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have executed this Agreement effective as of the Effective Date.

TYPEZERO TECHNOLOGIES, LLC

By: /s/ Chad Rogers

Name: Chad Rogers

Title: CEO

Date: 7/14/2016

TANDEM DIABETES CARE, INC.

By: /s/ Kim D. Blickenstaff

Name: Kim D. Blickenstaff

Title CEO

Date: 7/14/2016

EXHIBIT A

[***]

Tandem Diabetes Care, Inc.
2020 Sr. Management Cash Bonus Plan

The Tandem Diabetes Care, Inc. 2020 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 reward highly skilled individuals, including executive officers, with the background and experience required for the Company's future growth and success by providing meaningful cash incentive payments to plan participants who are in a position to contribute significantly to Company success.

- Align the interests of plan participants with those of the Company's stockholders by tying a meaningful portion of their total compensation opportunity to the achievement of specific Company performance objectives, such as an annual revenue target.

- Together with base salary, long-term equity incentives and other components of compensation, create an appropriate balance of cash versus non-cash, and guaranteed versus at risk compensation opportunities.

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 2020 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, 2020 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, 2020, an individual is promoted or hired and becomes an eligible participant under the Bonus Plan at any time during the 2020 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. Cash incentives may be earned under the Bonus Plan based on the achievement of financial performance objectives, product development milestones, and customer-related objectives. The financial performance objectives are comprised of two parts and will collectively represent 80% of the overall Target Bonus Amount. The product development milestones and customer-related objectives will each represent 10% of the overall Target Bonus Amount, which together with the financial performance objectives, represent 100% of the overall Target Bonus Amount.

Financial Performance Objectives

The portion of the cash bonuses that relate to the Company financial objectives may be earned based on the Company's actual revenue for fiscal year 2020 as compared to a pre-established 2020 revenue target (the "***Revenue Target***"), provided that the Company also achieves at least a minimum adjusted EBITDA (further adjusted for the change in fair value of common stock warrants and non-cash stock based compensation expense, as well as any accrued payment pursuant to the Bonus Plan) margin percentage (the "**Minimum Operating Percentage Target**"). Subject to the foregoing, the Company 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 2019 revenue, which places the Company's revenue for 2020 at 75% of the Revenue Target (the ***"Minimum Revenue Target"***), must be achieved for any bonus to be earned under the financial performance objectives portion of the Bonus Plan.

- If the Company's actual revenues are between this Minimum Revenue Target and the Revenue Target, the goal achievement for the financial performance objectives will be calculated proportionately in a straight-line from 0% to 100%. If the Company's actual revenues exceed the Revenue Target, the goal achievement for the financial performance objectives will be calculated proportionately as a percentage of the Revenue Target.

Product Development Objectives

The portion of the cash bonuses that relates to our product development milestones generally requires that we submit certain products under development for regulatory clearance and the manufacturing readiness of those products. Subject to the Committee's final discretion, an individual product development milestone must be achieved within a required time period for the applicable portion of the Bonus Plan to be achieved. Overall goal achievement of our product development milestones will be based on the portion of the product development milestones that we actually achieve during 2020.

Customer-Related Objectives

The portion of the cash bonuses that relates to the Company key customer-related objectives generally requires the Company to achieve a minimum annual metric related to customer support and services, and achieve a minimum annual percentage of current domestic customers eligible for insurance reimbursement to purchase a new insulin pump. Overall goal achievement is subject to the Compensation Committee's final discretion, and determination of the Company's customer related objectives will be based on the level of achievement by the Company during fiscal year 2020.

Potential Incremental Bonus

If the Company's actual revenues are above 105% of the Revenue Target, and the Minimum Operating Percentage Target is achieved, then the Bonus Plan has two levels of potential incremental overall goal achievement:

- If the Company's actual revenues are above 105% of the Revenue Target and up to 115% of the Revenue Target, the percentage of overall goal achievement with respect to the Company financial objectives under the Bonus Plan will first be calculated as described above, and then the overall goal achievement under the Bonus Plan will be multiplied by an amount equal to 100% plus one times each percent of revenue achievement above 105% of the Revenue Target and up to 115% of the Revenue Target, and the cash bonus will be calculated based on this modified level of goal achievement; or

- If the Company's actual revenues are above 115% of the Revenue Target, the percentage of overall goal achievement with respect to the Company financial objectives under the Bonus Plan will first be calculated as described above, and then the overall goal achievement under the Bonus Plan will be multiplied by an amount equal to 100% plus two times each percent of revenue achievement above 105% of the Revenue Target, and the cash bonus will be calculated based on this modified level of goal achievement.

- If revenue is greater than 105% but does not meet a secondary minimum adjusted EBITDA margin percentage target, then the financial achievement will be calculated as percent to plan.

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 components and product development components of the Bonus Plan may be earned independent of one another. If the Company does not achieve any portion of any of the financial performance components or the product development components of the Bonus Plan, no payouts will be made unless the Board or the 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 Compensation Committee and the Board of Directors 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

Payment of bonuses will be made as soon as practical after the end of the plan year, but not later than March 15, 2021. 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Tandem Diabetes Care, Inc.

By: /s/ John F. Sheridan

John F. Sheridan
President, Chief Executive Officer

Dated: April 30, 2020

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

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

    b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the

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

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

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

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

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

Tandem Diabetes Care, Inc.

By: /s/ Leigh A. Vosseller

Leigh A. Vosseller

Executive Vice President, Chief Financial Officer and Treasurer

Dated: April 30, 2020

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, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John F. Sheridan, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Dated: April 30, 2020

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

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

Exhibit 32.2

CERTIFICATION
PURSUANT TO U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Tandem Diabetes Care, Inc. (the "Company") for the period ended March 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leigh A. Vosseller, Executive Vice President, Chief Financial Officer and Treasurer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

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

Dated: April 30, 2020

/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. § 1350, and is not being filed for purposes of Section 18 of the Exchange Act, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.