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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 June 30, 2019

OR

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

For the Transition Period from to

Commission File Number 001-36189

Tandem Diabetes Care, Inc.

(Exact name of registrant as specified in its charter)

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

(858) 366-6900

Registrant's telephone number, including area code

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

Title of Each Class	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 ☒ 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	☒	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 July 26, 2019, there were 58,652,286 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)

	June 30, 2019 (Unaudited)	December 31, 2018 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 38,157	$ 41,826
Short-term investments	93,231	87,201
Accounts receivable, net	48,438	35,193
Inventories, net	27,341	19,896
Prepaid and other current assets	5,989	3,769
Total current assets	213,156	187,885
Property and equipment, net	22,750	17,151
Operating lease right-of-use assets	17,665	—
Patents, net	967	1,130
Other long-term assets	543	128
Total assets	$ 255,081	$ 206,294
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,268	$ 6,824
Accrued expense	5,786	3,930
Employee-related liabilities	23,896	24,030
Deferred revenue	7,139	4,600
Common stock warrants	25,616	17,926
Operating lease liabilities	5,341	—
Other current liabilities	7,168	8,978
Total current liabilities	84,214	66,288
Deferred rent - long-term	—	3,799
Operating lease liabilities - long-term	16,608	—
Other long-term liabilities	8,914	4,932
Total liabilities	109,736	75,019
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common stock, $0.001 par value; 200,000 shares authorized as of June 30, 2019 and December 31, 2018. 58,589 and 57,554 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively.	58	57
Additional paid-in capital	769,704	731,306
Accumulated other comprehensive income (loss)	162	(13)
Accumulated deficit	(624,579)	(600,075)
Total stockholders' equity	145,345	131,275
Total liabilities and stockholders' equity	$ 255,081	$ 206,294

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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Sales	$ 93,255	$ 34,126	$ 159,250	$ 61,402
Cost of sales	43,351	19,039	75,993	34,912
Gross profit	49,904	15,087	83,257	26,490
Operating expenses:				
Selling, general and administrative	40,565	22,628	75,524	43,541
Research and development	11,204	6,456	20,594	12,431
Total operating expenses	51,769	29,084	96,118	55,972
Operating loss	(1,865)	(13,997)	(12,861)	(29,482)
Other income (expense), net:				
Interest and other income	786	299	1,543	390
Interest and other expense	(9)	(3,112)	(16)	(6,184)
Change in fair value of stock warrants	(424)	(42,549)	(13,170)	(56,777)
Total other income (expense), net	353	(45,362)	(11,643)	(62,571)
Net loss	$ (1,512)	$ (59,359)	$ (24,504)	$ (92,053)
Other comprehensive loss:				
Unrealized gain on short-term investments	$ 101	$ 6	$ 151	$ 6
Foreign currency translation	20	—	24	—
Comprehensive loss	$ (1,391)	$ (59,353)	$ (24,329)	$ (92,047)
Net loss per share, basic and diluted	$ (0.03)	$ (1.17)	$ (0.42)	$ (2.32)
Weighted average shares used to compute basic and diluted net loss per share	58,219	50,948	57,996	39,594

See accompanying notes to unaudited condensed consolidated financial statements.

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

Three Months Ended June 30, 2019

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2019	57,982	$ 58	$ 743,930	$ 41	$ (623,067)	$ 120,962
Exercise of stock options	364	—	5,579	—	—	5,579
Exercise of common stock warrants	75	—	262	—	—	262
Issuance of common stock for Employee Stock Purchase Plan	168	—	2,951	—	—	2,951
Fair value of common stock warrants at time of exercise	—	—	4,569	—	—	4,569
Stock-based compensation	—	—	12,413	—	—	12,413
Foreign currency translation	—	—	—	20	—	20
Unrealized gain on short-term investments	—	—	—	101	—	101
Net loss	—	—	—	—	(1,512)	(1,512)
Balance at June 30, 2019	58,589	$ 58	$ 769,704	$ 162	$ (624,579)	$ 145,345

Six Months Ended June 30, 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	774	1	7,477	—	—	7,478
Exercise of common stock warrants	93	—	326	—	—	326
Issuance of common stock for Employee Stock Purchase Plan	168	—	2,951	—	—	2,951
Fair value of common stock warrants at time of exercise	—	—	5,479	—	—	5,479
Stock-based compensation	—	—	22,165	—	—	22,165
Foreign currency translation	—	—	—	24	—	24
Unrealized gain on short-term investments	—	—	—	151	—	151
Net loss	—	—	—	—	(24,504)	(24,504)
Balance at June 30, 2019	58,589	$ 58	$ 769,704	$ 162	$ (624,579)	$ 145,345

Three Months Ended June 30, 2018

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2018	46,636	$ 47	$ 521,958	$ —	$ (510,158)	$ 11,847
Issuance of common stock in public offering, net of underwriter's discount and offering costs	—	—	(20)	—	—	(20)
Exercise of stock options	1	—	7	—	—	7
Exercise of common stock warrants	6,549	6	22,383	—	—	22,389
Fair value of common stock warrants at time of exercise	—	—	48,320	—	—	48,320
Stock-based compensation	—	—	2,815	—	—	2,815
Unrealized gain on short-term investments	—	—	—	6	—	6
Net loss	—	—	—	—	(59,359)	(59,359)
Balance at June 30, 2018	53,186	$ 53	$ 595,463	$ 6	$ (569,517)	$ 26,005

Six Months Ended June 30, 2018

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
Balance at December 31, 2017	10,119	$ 10	$ 448,455	$ —	$ (477,614)	$ (29,149)
Adjustment to retained earnings from adoption of ASC 606	—	—	—	—	150	150
Issuance of common stock in public offering, net of underwriter's discount and offering costs	34,500	35	63,975	—	—	64,010
Exercise of stock options	1	—	7	—	—	7
Exercise of common stock warrants	8,486	8	29,159	—	—	29,167
Fair value of common stock warrants at time of exercise	—	—	49,919	—	—	49,919
Stock-based compensation	80	—	3,948	—	—	3,948
Unrealized gain on short-term investments	—	—	—	6	—	6
Net loss	—	—	—	—	(92,053)	(92,053)
Balance at June 30, 2018	53,186	$ 53	$ 595,463	$ 6	$ (569,517)	$ 26,005

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30,	
	2019	**2018**
Operating activities		
Net loss	$ (24,504)	$ (92,053)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,946	2,898
Interest expense related to amortization of debt discount and debt issuance costs	—	1,387
Provision for allowance for doubtful accounts	797	745
Provision for inventories reserve	1,018	184
Change in fair value of common stock warrants	13,170	56,777
Amortization of premium (discount) on short-term investments	(166)	298
Stock-based compensation expense	22,156	3,890
Other	26	151
Changes in operating assets and liabilities:		
Accounts receivable, net	(13,988)	6,135
Inventories, net	(8,454)	1,958
Prepaid and other current assets	(2,533)	(821)
Other long-term assets	(415)	(43)
Accounts payable	2,206	(1,733)
Accrued expense	1,851	1,446
Employee-related liabilities	(140)	(848)
Deferred revenue	2,539	439
Other current liabilities	(1,050)	(49)
Deferred rent	—	(359)
Other long-term liabilities	3,985	603
Net cash used in operating activities	(556)	(18,995)
Investing activities		
Purchases of short-term investments	(74,164)	(40,500)
Proceeds from maturities and sales of short-term investments	68,450	4,250
Purchase of property and equipment	(8,169)	(1,087)
Net cash used in investing activities	(13,883)	(37,337)
Financing activities		
Proceeds from public offering, net of offering costs	—	64,008
Proceeds from exercise of common stock warrants	326	29,164
Proceeds from issuance of common stock under Company stock plans	10,429	8
Net cash provided by financing activities	10,755	93,180
Effect of foreign exchange rate changes on cash	15	—
Net (decrease) increase in cash and cash equivalents and restricted cash	(3,669)	36,848
Cash and cash equivalents and restricted cash at beginning of period	41,826	23,700
Cash and cash equivalents and restricted cash at end of period	$ 38,157	$ 60,548
Supplemental disclosures of cash flow information		
Interest paid	$ —	$ 4,784
Supplemental schedule of noncash investing and financing activities		
Right-of-use assets obtained in exchange for operating lease obligations	$ 11,445	$ —
Debt discount included in other long-term liabilities	$ —	$ 4,964
Property and equipment included in accounts payable	$ 239	$ 92

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 focused on 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.

The Company manufactures and sells insulin pump products that are designed to address large and differentiated needs of the insulin-dependent diabetes market. The Company's manufacturing and sales activities primarily focus on the t:slim X2 Insulin Delivery System (t:slim X2), the Company's flagship pump platform that is capable of remote feature updates and 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 Tandem Device Updater, a Mac and PC-compatible tool for the remote update of Tandem 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 selling 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 began commercial sales of its first product, t:slim, in August 2012 and subsequently commercialized t:flex in May 2015, t:slim G4 in September 2015 and t:slim X2 in October 2016. The t:slim X2 hardware platform now represents 100% of new pump shipments, but the Company continues to provide ongoing service and support to existing t:slim, t:slim G4 and t:flex customers. In September 2017, the Company received approval by the United States Food and Drug Administration (FDA) for the integration of t:slim X2 with the Dexcom Mobile G5 CGM. In June 2018, the Company received FDA approval for t:slim X2 with Basal-IQ technology, the Company's first-generation Automated Insulin Delivery (AID) algorithm, and the first insulin pump designated as compatible with integrated CGM (iCGM) devices. The Company commenced commercial sales of this product integrated with the Dexcom G6 CGM in August 2018.

During the third quarter of 2018, the Company commenced sales of the t:slim X2 in select geographies outside the United States, including Australia, Italy, New Zealand, Scandinavia (Denmark, Norway and Sweden), South Africa, Spain, and the United Kingdom. Direct sales efforts in Canada began in the fourth quarter of 2018. During the second quarter of 2019, we began selling our t:slim X2 with Basal-IQ technology in select geographies outside the United States.

As of June 30, 2019, the Company had $131.4 million in cash, cash equivalents and short-term investments. The Company has incurred operating losses since its inception and had an accumulated deficit of $624.6 million as of June 30, 2019, which included a net loss of $24.5 million for the six months ended June 30, 2019. 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, 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 third party intellectual property rights.

The Company has funded its operations primarily through 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 its capital stock, or it may elect to borrow capital under new credit lines 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

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, 2018 (Annual Report), from which the balance sheet information herein was derived. These unaudited condensed consolidated financial statements exclude disclosures required by U.S. GAAP for complete financial statements.

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.

2. Summary of Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies during the six months ended June 30, 2019, as compared with those disclosed in the Annual Report other than adoption of the new lease accounting standard effective January 1, 2019 (See Note 6, "Leases").

Use of Estimates

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions 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's current product offering consists primarily of insulin pumps, disposable cartridges and infusion sets for the storage and delivery of insulin. The Company has viewed its operations and managed its business as one segment as 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 doubtful accounts for potential credit losses. Provisions are made based on historical experience, assessment of specific risk, review of outstanding invoices, 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 expense, 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 June 30, 2019 approximated its carrying value, based on the borrowing rates that were available for loans with similar terms. The estimated fair value of certain of the Company's common stock warrants was determined using the Black-Scholes pricing model as of June 30, 2019 and December 31, 2018 (see Note 5, "Fair Value Measurements").

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 product to insulin-dependent diabetes customers.

In January 2018, the Company adopted the Revenue from Contracts with Customers Standard which superseded existing revenue guidance under U.S. GAAP and International Financial Reporting Standards. Pursuant to the Revenue from Contracts with Customers Standard's core principle, subsequent to January 1, 2018, 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. The Company elected to implement this new standard utilizing the modified retrospective method. Under this approach, the Company applied the new standard to all new contracts initiated on or after the effective date and, for contracts which had remaining obligations as of the effective date, the Company recorded an adjustment to the opening balance of accumulated deficit. The accounting for the significant majority of the Company's revenues was not impacted by the new guidance. As a result, on January 1, 2018, the Company recorded a net reduction to accumulated deficit in the amount of $149,000, reflecting the impact of the accounting change.

Prior to the implementation of this new standard, revenue was recognized when persuasive evidence of an arrangement existed, delivery had occurred and title passed, the price was fixed or determinable, and collectability was reasonably assured.

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, while access to the complementary products, such as the t:connect cloud-based data management application and the Tandem Device Updater, are considered performance obligations satisfied over the typical four-year warranty period of the insulin pumps. There is no standalone value for these complementary products. Therefore, the Company determines their value by applying the expected cost-plus margin approach and then allocates the residual to the insulin pumps. At June 30, 2019 and December 31, 2018, $6.3 million and $3.8 million, respectively, were recorded as deferred revenue for these performance obligations that are satisfied over time.

Additionally, the Company offers a 30-day right of return to its customers from the date of shipment of any 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 product 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 on the Company's balance sheets for product return allowance was $0.2 million and $0.3 million at June 30, 2019 and December 31, 2018, respectively. Actual product returns have not differed materially from estimated amounts reserved 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. Warranty costs are estimated based on the current expected product replacement cost and expected replacement rates based on historical experience. The Company evaluates the reserve quarterly and makes adjustments when appropriate. Changes to the actual replacement rates or the expected product replacement cost could have a material impact on the Company's estimated warranty reserve.

As of June 30, 2019 and December 31, 2018, the warranty reserve was $14.3 million and $9.1 million, respectively. The following table provides a reconciliation of the change in product warranty liabilities from December 31, 2018 through June 30, 2019 (in thousands):

Balance at December 31, 2018	$	9,138
Provision for warranties issued during the period		8,723
Settlements made during the period		(4,611)
Increases in warranty estimates		1,008
Balance at June 30, 2019	$	14,258

Current portion	$	5,344
Non-current portion		8,914
Total	$	14,258

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 a Black-Scholes option-pricing model on the date of grant. The Black-Scholes option-pricing model requires the use of subjective assumptions about a number of key variables, including stock price volatility, expected term, and risk-free interest rate. 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 options outstanding under the Company's other equity incentive plans. For warrants that are recorded as a liability in the accompanying balance sheet, 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 such securities are dilutive to loss per share for the period, an adjustment to net loss used in the calculation is required 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 all periods presented, 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Warrants to purchase common stock	611	628	611	628
Options to purchase common stock	6,790	2,166	6,216	1,852
ESPP	23	1	12	1
	7,424	2,795	6,839	2,481

Recent Accounting Pronouncements

In June 2016, the FASB issued 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. This 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 current, other-than-temporary-impairment model. The standard is effective for public business entities for annual periods beginning after December 15, 2019, and interim periods within those years. The Company plans to implement the new standard in the first quarter of 2020, and is in the process of reviewing its credit loss models to assess the impact of the adoption of the standard on its consolidated financial statements.

In August 2018, the FASB issued Accounting Standards Update 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. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The Company is in the process of determining the impact of the adoption of the standard on its consolidated financial statements as well as whether to early adopt the new standard.

In August 2018, the FASB issued ASU 2018-15, *Customer's Accounting for* Implementation *Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract*, that changes the accounting for implementation costs incurred in a cloud computing arrangement that is a service contract. The update aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The implementation costs should be presented as a prepaid asset on the balance sheet and expensed over the term of the hosting arrangement. The standard is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2019. 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, principally 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 June 30, 2019 and December 31, 2018 (in thousands):

At June 30, 2019	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale securities:					
Commercial paper	Less than 1	$ 23,591	$ 15	$ —	$ 23,606
Government sponsored enterprise	Less than 1	2,750	1	—	$ 2,751
U.S. Treasury securities	Less than 1	9,693	21	—	9,714
Corporate debt securities	Less than 1	57,059	101	—	57,160
Total		$ 93,093	$ 138	$ —	$ 93,231

At December 31, 2018	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale securities:					
Commercial paper	Less than 1	$ 53,559	$ —	$ (22)	$ 53,537
U.S. Treasury securities	Less than 1	17,937	—	(2)	17,935
Corporate debt securities	Less than 1	15,718	12	(1)	15,729
Total		$ 87,214	$ 12	$ (25)	$ 87,201

4. Inventories

Inventories consisted of the following as of June 30, 2019 and December 31, 2018 (in thousands):

	June 30, 2019	December 31, 2018
Raw materials	$ 10,311	$ 6,622
Work-in-process	5,300	2,710
Finished goods	11,730	10,564
Total	$ 27,341	$ 19,896

5. Fair Value Measurements

Authoritative guidance on fair value measurements defines fair value and provides a consistent framework for both measuring fair value as well as 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 provides 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 June 30, 2019 and December 31, 2018, 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 June 30, 2019		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash equivalents [1]	$ 35,771	$ 35,771	$ —	$ —
Commercial paper	23,606	—	23,606	—
Government sponsored enterprise	2,751	—	2,751	—
U.S. Treasury securities	9,714	9,714	—	—
Corporate debt securities	57,160	—	57,160	—
Total assets	$ 129,002	$ 45,485	$ 83,517	$ —
Liabilities				
Common stock warrants	$ 25,616	$ —	$ —	$ 25,616
Total liabilities	$ 25,616	$ —	$ —	$ 25,616

		Fair Value Measurements at December 31, 2018		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash equivalents [1]	$ 37,373	$ 37,373	$ —	$ —
Commercial paper	53,537	—	53,537	—
U.S. Treasury securities	17,935	17,935	—	—
Corporate debt securities	15,729	—	15,729	—
Total assets	$ 124,574	$ 55,308	$ 69,266	$ —
Liabilities				
Common stock warrants	$ 17,926	$ —	$ —	$ 17,926
Total liabilities	$ 17,926	$ —	$ —	$ 17,926

(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. There were no transfers between Level 1 and Level 2 assets during the six months ended June 30, 2019 and 2018.

The Company's Level 3 liabilities at June 30, 2019 and December 31, 2018 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 $3.3 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. Inputs used in the pricing model include the market price of the Company's common stock and estimates of stock price volatility, expected warrant life and risk-free interest rate. The Company develops its estimates based on publicly available historical data. The assumptions used to estimate the fair values of the common stock warrants at June 30, 2019 and December 31, 2018 are presented below:

	Series A Warrants	
	June 30, 2019	December 31, 2018
Risk-free interest rate	1.7%	3.0%
Expected dividend yield	0.0%	0.0%
Expected volatility	81.2%	78.3%
Expected term (in years)	3.3	3.8

The following table presents a summary of changes in the fair value of the Company's Level 3 financial liabilities for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,	
	2019	2018
Balance at beginning of period	$ 17,926	$ 5,432
Increase in fair value included in change in fair value of common stock warrants	13,170	56,777
Decrease in fair value from warrants exercised during the period	(5,480)	(49,918)
Balance at end of period	$ 25,616	$ 12,291

During the six months ended June 30, 2019, the Company issued 93,270 shares of common stock upon the exercise of Series A warrants. During the six months ended June 30, 2018, the Company issued 8,485,871 shares of common stock upon the exercise of certain warrants issued in the October 2017 Financing, and 13,450 warrants expired unexercised. As of June 30, 2019, there were Series A warrants outstanding to purchase 417,515 shares of common stock (see Note 8, "Stockholders' Equity").

6. Leases

In February 2016, the FASB issued ASU 2016-02, *Leases* (ASU 2016-02). ASU 2016-02 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 twelve months. It also changed the definition of a lease and expanded the disclosure requirements of lease arrangements. In July 2018, the FASB added a transition option for implementation that allowed companies to continue to use the legacy guidance in ASC 840, *Leases*, including its disclosure requirements, in the comparative periods presented in the year of adoption. The new accounting standard must be adopted using the modified retrospective approach and was effective for the Company starting in the first quarter of fiscal 2019. The Company elected the transition option and certain practical expedients, and recognized a cumulative-effect transition adjustment for the recognition of right-of-use leased assets and corresponding operating lease liabilities of $12.4 million on the consolidated balance sheet upon adoption of this standard 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 this standard.

The Company's leases consist primarily of operating leases for general office space, laboratory, manufacturing, and warehouse facilities, and equipment. Leases with an initial term of 12 months or less are not recorded on the balance sheet. 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 located at 10935 Vista Sorrento Parkway, San Diego, California (the Vista Sorrento Parkway Lease). The initial lease term commenced in March 2019 and expires in September 2022. During the second quarter of 2019, the lease term was extended through December 2022. The Company has a one-time option to extend the term of the Vista Sorrento Parkway Lease for a period of five 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 commencement, and $0.2 million in the second quarter of 2019 related to the extension, of the Vista Sorrento Parkway Lease.

In March 2019, the Company entered into a lease agreement for approximately 40,490 square feet of space located at 6495 Marindustry Place, San Diego, California to house additional operations functions, including warehousing and shipping (the Marindustry Place Lease). The initial lease term commenced in May 2019 and expires in April 2026. The Company has a one-time option to extend the term of the Marindustry Place Lease for a period of no less than three years and no more than five years. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of $3.4 million on the consolidated balance sheet in the second quarter of 2019 related to the Marindustry Place Lease.

In May 2019, the Company entered into an amendment to the Vista Sorrento Parkway Lease (the Amendment) to expand the leased premises at 10935 Vista Sorrento Parkway, San Diego, California by approximately 33,681 square feet of additional general administrative office space (the Expansion Space). The initial lease term for the Expansion Space commenced in May 2019 and expires in December 2022. The Company has a one-time option to extend the lease term of the Expansion Space for a period of five years. The Company recognized right-of-use leased assets and corresponding operating lease liabilities of $4.3 million on the consolidated balance sheet in the second quarter of 2019 related to the Amendment.

Future minimum lease payments under non-cancellable operating leases as of June 30, 2019 were as follows (in thousands):

Years Ending December 31,		
2019 (remaining)	$	2,005
2020		6,816
2021		7,085
2022		5,874
2023		1,991
Thereafter		1,578
Total future minimum lease payments		25,349
Less: amount representing interest		(3,400)
Present value of future minimum lease payments		21,949
Less: current portion of operating lease liabilities		(5,341)
Operating lease liabilities - long-term	$	16,608

7. Term Loan Agreement

In August 2018, the Company fully repaid the term loan made by Capital Royalty Partners II, L.P. and its affiliated funds (CRG) pursuant to the Amended and Restated Term Loan Agreement (Term Loan Agreement). The balance of the outstanding debt at the time of repayment and at June 30, 2018 was $82.7 million. The repayment included approximately $1.1 million in accrued interest and $5.0 million in associated financing fees that became due. As a result of the repayment, the Company did not have any borrowings outstanding under the Term Loan Agreement as of June 30, 2019 or December 31, 2018.

Under the Term Loan Agreement, interest was payable at the Company's option, (i) in cash at a rate of 11.5% per annum, or (ii) at a rate of 9.5% of the 11.5% per annum in cash and 2.0% of the 11.5% per annum (PIK Loan) to be added to the principal of the loan and subject to accruing interest.

The Company entered into a series of amendments to the Term Loan Agreement between 2016 and 2018, which included the addition of a financing fee payable at the maturity of the Company's loans, the issuance of 193,788 ten-year warrants to CRG to purchase shares of the Company's common stock at an exercise price of $23.50 per share and certain other minimum financing covenants. The financing fee was applicable to the entire aggregate principal amount of borrowings outstanding, including total PIK Loans issued. As of June 30, 2019, the warrants to purchase 193,788 shares of the Company's common stock at an exercise price of $23.50 per share remained outstanding.

8. Stockholders' Equity

Public Offerings

In the first quarter of 2018, the Company completed a public offering of 34,500,000 shares of common stock at a public offering price of $2.00 per share. The gross proceeds to the Company from the offering were approximately $69.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

In the third quarter of 2018, the Company completed a public offering of 4,035,085 shares of common stock at a public offering price of $28.50 per share. The gross proceeds to the Company from the offering were $115.0 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

Shares Reserved for Future Issuance

The following shares of the Company's common stock were reserved for future issuance as of June 30, 2019 (in thousands):

Shares underlying outstanding warrants	710
Shares underlying outstanding stock options	7,618
Shares authorized for future equity award grants	3,453
Shares authorized for issuance as ESPP awards	1,852
	13,633

The Company issued 74,985 and 93,270 shares of its common stock upon the exercise of warrants during the three and six months ended June 30, 2019, respectively. The Company issued 8,603,321 shares of its common stock upon the exercise of warrants during the year ended December 31, 2018.

In June 2019 and 2018, the Company received approval from its stockholders to increase the number of shares of common stock reserved under the 2013 Plan by 5,000,000 and 5,500,000 shares, respectively. The Company issued 364,818 and 773,782 shares of its common stock upon the exercise of stock options during the three and six months ended June 30, 2019, respectively. The Company issued 136,042 shares of its common stock upon the exercise of stock options during the year ended December 31, 2018.

The ESPP enables eligible employees to purchase shares of common stock using their after-tax payroll deductions, subject to certain conditions. Historically, offerings under the ESPP consisted of a two-year offering period with four six-month purchase periods which begin in May and November of each year. The Company previously suspended the ESPP in May 2017 due to a lack of available shares. In June 2018, the Company received approval from its stockholders to increase the number of shares reserved for issuance under the ESPP by 2,000,000 shares. A new offering commenced under the ESPP on June 15, 2018, and the first purchase date was November 15, 2018. There were 168,165 shares of common stock purchased under the ESPP in the six months ended June 30, 2019. There were 80,581 shares of common stock purchased under the ESPP during the year ended December 31, 2018.

Stock-Based Compensation

In June 2019, the Company granted options to purchase 1,644,715 shares of common stock, which were originally awarded between February 2019 and June 2019, 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 the 2013 Plan. In total, the Company granted options to purchase 2,679,535 shares of common stock under the 2013 Plan during the six months ended June 30, 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 vesting monthly over the following three years.

In June 2018, the Company granted options to purchase 811,800 shares of common stock under the 2013 Plan, which were originally awarded on December 1, 2017, subject to and conditioned upon the approval by its stockholders of an increase in the number of shares authorized under the 2013 Plan. In addition, in June 2018, the Company granted options to purchase 3,339,300 shares of common stock under the 2013 Plan. 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 50% of the underlying shares on the first anniversary of the award, with the balance vesting monthly over the following year.

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

	Stock Options			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Weighted average grant date fair value (per share)	$ 41.38	$ 11.97	$ 39.11	$ 11.89
Risk-free interest rate	1.9%	2.8%	2.5%	2.8%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	71.8%	71.5%	71.8%	71.4%
Expected term (in years)	6.0	5.6	6.0	5.7

	ESPP			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Weighted average grant date fair value (per share)	$ 33.49	$ 9.62	$ 33.49	$ 9.62
Risk-free interest rate	2.3%	2.4%	2.3%	2.4%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	75.9%	77.0%	75.9%	77.0%
Expected term (in years)	1.3	1.3	1.3	1.3

ESPP valuations using the Black-Scholes option-pricing model 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Cost of sales	$ 1,379	$ 180	$ 2,427	$ 345
Selling, general & administrative	8,950	2,100	15,950	3,012
Research and development	2,084	418	3,779	533
Total	$ 12,413	$ 2,698	$ 22,156	$ 3,890

The total stock-based compensation expense capitalized as part of the cost of the Company's inventories was $0.4 million and $0.4 million as of June 30, 2019 and December 31, 2018, respectively.

9. Commitments and Contingencies

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 meaningful estimate of the reasonably possible loss (or range) of loss that could result from an adverse outcome. As of June 30, 2019 and December 31, 2018, 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 June 30, 2019, or this 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 and financing plans, product launches, 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. 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. 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 exclusively focus on our flagship pump platform, the t:slim X2 Insulin Delivery System, or t:slim X2, and our complementary product offerings. The simple-to-use t:slim X2 is based on our proprietary technology platform and is the smallest durable insulin pump available. It is the only pump currently available in the United States that is capable of remote feature updates, which positions us well to address the evolving needs and preferences of differentiated segments of the insulin-dependent diabetes market. By delivering innovative hardware and software solutions, as well as best-in-class customer support, we aim to improve and simplify the lives of people with diabetes and their healthcare providers.

We have commercially launched six insulin pumps in the United States since inception, all of which have been developed using our proprietary technology platform. Three of these pumps have featured continuous glucose monitoring technology, or CGM. In the past four years, we have shipped approximately 114,000 pumps, more than 17,000 of which were in international markets, which is representative of our estimated global installed customer base on the typical four-year reimbursement cycle.

During the third quarter of 2018, we began selling our t:slim X2 with G5 in Australia, Italy, New Zealand, Scandinavia (Denmark, Norway and Sweden), South Africa, Spain, and the United Kingdom. Direct sales efforts in Canada began in the fourth quarter of 2018. During the second quarter of 2019, we began selling our t:slim X2 with Basal-IQ technology in select geographies outside the United States.

We have discontinued sales of our original t:slim, t:flex and t:slim G4 pumps, and our t:slim X2 hardware platform now represents 100% of new pump shipments. However, we continue to provide ongoing service and support for our earlier products.

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

In the United States, our insulin pumps are compatible with the Tandem Device Updater, a revolutionary tool that allows pump users to update their pumps' software quickly and easily from a personal computer. The Tandem Device Updater provides our in-warranty domestic customers potential access to new and enhanced features and functionality faster than the industry has been able to in the past. The first use of our Tandem Device Updater was for deployment of the latest t:slim software to in-warranty t:slim pumps purchased before April 2015. Since that time, we set a new standard of care in our industry by offering all existing in-warranty t:slim X2 customers in the United States two significant software updates: (i) integration with the Dexcom G5 Mobile CGM system in September 2017 and (ii) an upgrade to our new Basal-IQ technology and integration with Dexcom's G6 CGM in August 2018. Our Tandem Device Updater positions us to bring future innovations including our Automated Insulin Delivery (AID) algorithms to t:slim X2 customers, independent of the typical four-year insurance pump reimbursement cycle. Though we have not utilized our Tandem Device Updater to perform software updates for devices outside the United States, we are currently developing that capability and intend to do so in the future.

For the six months ended June 30, 2019, and 2018, our consolidated sales were $159.3 million, and $61.4 million, respectively. For the six months ended June 30, 2019, and 2018, our net loss was $24.5 million, and $92.1 million, respectively. Worldwide pump sales accounted for 70% and 63% of our total sales, respectively, for the six months ended June 30, 2019 and 2018, while pump-related supplies and accessories accounted for the remainder in each year. Our accumulated deficit as of June 30, 2019 and December 31, 2018 was $624.6 million and $600.1 million, respectively. These amounts included $182.8 million and $147.4 million of non-cash stock-based compensation charges and non-cash changes in the fair value of common stock warrants as of June 30, 2019 and December 31, 2018, respectively.

In the United States, we have rapidly increased sales since our commercial launch 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. More recently, our sales have further increased following the scaled launch of t:slim X2 in geographies outside 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 both domestically and outside the United States. 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 United States Food and Drug Administration, or the FDA, and as we develop the capability to utilize the Tandem Device Updater to provide remote updates outside the United States. 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 customer support infrastructure, both of which benefit 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.

Products Under Development

Our products under development support our strategy of focusing on both consumer and clinical needs, and include new AID systems, a next-generation hardware platform, and connected (mobile) health offerings. We intend to leverage our consumer-focused approach and proprietary technology platform to continue to develop products that have the features and functionalities that will allow us to meet the needs of people in differentiated segments of the insulin-dependent diabetes market, including the following:

- *t:slim X2 with Control IQ* – Our second-generation AID system is expected to integrate our t:slim X2 with the technology that we licensed from TypeZero Technologies, LLC, or TypeZero, and Dexcom's G6 CGM sensor. The integrated CGM, or iCGM, designation for the system also provides the opportunity for integration development efforts with future iCGM sensors that may become available in the market. With our implementation of TypeZero's inControl AID algorithms, our product is intended to both increase and decrease basal insulin based on a user's predicted blood glucose levels from a compatible iCGM sensor, as well as deliver automated correction boluses. In conjunction with Dexcom and TypeZero, which was acquired by Dexcom in August 2018, we have integrated our technologies into the U.S. portion of the Clinical Acceptance of the Artificial Pancreas, or DCLP3, portion of the International Diabetes Closed Loop, or the IDCL, trial. The 6-month study was completed in April 2019. In June 2019, positive results from this study were announced with significant time-in-range improvements. Subsequently, we filed a regulatory submission with the FDA for our t:slim X2 insulin pump with Control-IQ technology. Subject to FDA approval, our goal is to commence commercial sales of our t:slim X2 with Control-IQ technology in the United States in the fourth quarter of 2019. In addition, our t:slim X2 with Control-IQ technology has also been evaluated in several early pediatric studies and we are currently supporting a pivotal study among pediatric patients with type 1 diabetes that commenced in the first half of 2019.

- *t:sport Insulin Delivery System* – Expected to be 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. t:sport is expected to utilize a pumping mechanism that differs from our current Micro-Delivery technology.

- *Connected (Mobile) Health Offerings* - We are currently developing a mobile application that is being designed to utilize the capability of the Bluetooth radio integrated with the t:slim X2 to wirelessly upload pump data to t:connect, receive notification of pump alerts and alarms, integrate other health-related information from third party sources, and support future pump-control capabilities for our products under development. Subject to FDA approval, we intend to launch the first generation of our mobile application with a subset of these features in the United States in 2019.

Pump Shipments

Since inception, we have derived nearly all of our sales from the shipment of insulin pumps and associated supplies 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 units shipped per quarter to be an important metric for managing our business.

In the second quarter of 2019, we shipped 21,258 insulin pumps worldwide compared to 5,447 insulin pumps shipped in the second quarter of 2018. In the United States we have shipped more than 96,000 pumps within the four-year period ended June 30, 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(1) - 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(2)	4,042	4,582	3,896	4,418	16,938
2017(2)	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	N/A	N/A	22,468

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

	Pump Units Shipped for Each of the Three Months Ended in Respective Years(1) - 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	N/A	N/A	13,522

(1) The pump units shipped do not reflect returns or exchanges of pump products that occur in the ordinary course of business.

(2) 2016 and 2017 U.S. shipments do not include approximately 3,300 pump trade-ins fulfilled under the Technology Upgrade Program related to our commercial launch of t:slim X2.

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, and the commercial launch of our products in geographies outside the United States.

We believe that our financial condition and operating results, as well as the decision-making process of our 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;
- 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;
- timing of holidays and summer vacations which may vary by geography;
- the buying patterns of our distributors and other customers;
- the timing of the commercialization of new products by us or our competitors;
- 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
- anticipated and actual regulatory approvals of our products and competitive products.

In particular, we believe the following specific factors have, and could continue to, materially impact our business going forward:

- continued increase in demand following the commercial launch of t:slim X2 and the demonstrated success of our Tandem Device Updater, which we expect will positively impact our sales;
- 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 attract customers of Animas Corporation, or Animas, following the announcement by Johnson & Johnson that it discontinued the operations of Animas and will discontinue availability of Animas pump supplies in late 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, and
- expansion and new product launches in select international geographies.

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 to improve our operating margins, including costs associated with our commercial launch in certain international markets. In the fourth quarter of 2018, we achieved profitability for the first time. However, we may be unable to sustain profitability in the near term. 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, increasing gross profits from additional sales of infusion sets, maximizing manufacturing efficiencies on increased production volumes; and leveraging the investments made in our sales, clinical, marketing and customer support organizations.

Components of Results of Operations

Sales

We offer products for people with insulin-dependent diabetes. We commenced commercial sales of our original t:slim insulin pump platform in the United States in the third quarter of 2012 and continued to launch various iterations of that platform during the following years. In October 2016, we began shipping our flagship pump platform, the t:slim X2 insulin pump. The t:slim X2 hardware platform, which includes 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. 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.

In the third quarter of 2018, we commenced commercial sales of t:slim X2 with G5 in select international geographies. 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. In other international markets, we expect that most of our commercial sales will initially be to independent distributors who will perform all sales, customer support and training in their respective markets. 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 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, and expect to continue to experience, pump shipments being weighted heavily towards the second half of the year, with the highest percentage of pump shipments expected in the fourth quarter of the year due to the nature of the reimbursement environment. Consistent with our historical seasonality, we also expect domestic pump shipments from the fourth quarter to the following first quarter to decrease significantly. Internationally, we do not expect this same impact from seasonality. We also believe the opportunity to transition former Animas customers during 2019 has, and will continue to, impact our quarterly sales trends worldwide.

In addition, our quarterly sales have 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. For instance, customers may defer a purchasing decision if they believe that 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 decision or take additional time to consider the anticipated or new approval or product launch in their purchasing decision. However, we are not able to quantify the extent of the impact of these or similar events on future purchasing decisions.

Cost of Sales

We manufacture our pumps and disposable cartridges at our manufacturing facility in San Diego, California. 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, freight, reserves for expected warranty costs, scrap and 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.

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 over the long-term, 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 proprietary technology platform and manufacturing infrastructure, and will be able to further reduce costs with increased automation, process improvements and raw materials cost reductions. Pumps have, and are expected to continue to have, a higher gross margin than our pump-related supplies. Therefore, the percentage of pump sales relative to total sales will have a significant impact on gross margin. We also expect our warranty costs per unit to decrease as we release additional product features and functionality utilizing the Tandem Device Updater. However, our overall gross margin may fluctuate in future quarterly periods as a result of numerous factors aside from those associated with production volumes and product mix. In addition, as demand for our products increases, we may make additional investments in manufacturing capacity or increase our reliance on third parties for manufacturing-related services, which could have a negative impact on gross margin.

Other factors impacting our overall gross margin may include, the changing percentage of products sold to distributors versus directly to individual customers, varying levels of reimbursement among third-party payors and in 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, warranty and training 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, or 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. As of June 30, 2019, our field sales and clinical organization consisted of approximately 70 territories, and we began the process of expanding to approximately 80 territories to support an expected increase in demand in the second half of 2019. Territories in the United States are maintained by sales representatives and field clinical specialists, and supported by managed care liaisons, additional sales management and other customer support personnel. Our operations in Canada are supported by a direct sales force of approximately 10 field representatives. 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 in 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 a significant increase in our stock price over the previous year. We expect higher non-cash stock-based compensation expense will be sustained in future quarters. Our 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, or 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, as well as continue to reflect a notable increase in non-cash stock-based compensation expense due to the valuation of certain employee stock option grants and a significant increase in our stock price over the previous year.

Other Income and Expense

Other income and expense primarily consist of changes in the fair value of certain warrants issued in our public offering of common stock in October 2017. In 2018, it also included interest expense and amortization of debt discount and issuance costs associated with our Amended and Restated Term Loan Agreement, or the Term Loan Agreement, with Capital Royalty Partners II, L.P. and its affiliated funds, or CRG. In August 2018, we fully repaid amounts due under the Term Loan Agreement. Prior to that, there was $82.7 million of outstanding principal under the Term Loan Agreement, which accrued interest at a rate of 11.5% per annum. As a result of the full repayment, we did not incur any interest expense or costs associated with the Term Loan Agreement subsequent to the third quarter of 2018. Other income also includes 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 June 30, 2019	Three Months Ended June 30, 2018	Six Months Ended June 30, 2019	Six Months Ended June 30, 2018
Sales:				
Domestic	$ 70,371	$ 34,126	$ 125,025	$ 61,402
International	22,884	—	34,225	—
Total sales	93,255	34,126	159,250	61,402
Cost of sales	43,351	19,039	75,993	34,912
Gross profit	49,904	15,087	83,257	26,490
Gross margin	54%	44%	52%	43%
Operating expenses:				
Selling, general and administrative	40,565	22,628	75,524	43,541
Research and development	11,204	6,456	20,594	12,431
Total operating expenses	51,769	29,084	96,118	55,972
Operating loss	(1,865)	(13,997)	(12,861)	(29,482)
Other income (expense), net:				
Interest and other income	786	299	1,543	390
Interest and other expense	(9)	(3,112)	(16)	(6,184)
Change in fair value of stock warrants	(424)	(42,549)	(13,170)	(56,777)
Total other income (expense), net	353	(45,362)	(11,643)	(62,571)
Net loss	$ (1,512)	$ (59,359)	$ (24,504)	$ (92,053)

Comparison of the Three Months Ended June 30, 2019 and 2018

Sales. For the three months ended June 30, 2019, sales were $93.3 million, which included $22.9 million of international sales. Sales were $34.1 million for the same period in 2018, when we did not yet have any international sales.

The total sales increase of $59.1 million was primarily driven by a 290% increase in worldwide pump shipments to 21,258 in the second quarter of 2019 compared to 5,447 in the second quarter of 2018. Worldwide pump shipments were positively impacted by strong demand for our products following the August 2018 domestic launch of t:slim X2 with Basal-IQ technology, and the commencement of commercial sales of t:slim X2 with G5 in select international geographies in the third quarter of 2018, as well as the fulfillment of certain international pump demand from backlog that began in 2018 due to supply constraints. Additionally, sales from pump-related supplies increased 113% primarily due to an overall increase in our installed base of customers reordering supplies.

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

	Three Months Ended June 30, 2019	Three Months Ended June 30, 2018
Pump	$ 48,806	$ 21,230
Infusion sets	14,735	8,754
Cartridges	6,710	4,036
Other	120	106
Total Domestic Sales	$ 70,371	$ 34,126

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

	Three Months Ended June 30,	
	2019	2018
Pump	$ 16,955	$ —
Infusion sets	3,484	—
Cartridges	2,290	—
Other	155	—
Total International Sales	$ 22,884	$ —

Sales to distributors accounted for 74% and 77% of our total domestic sales for the three months ended June 30, 2019 and 2018, respectively. Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor. Sales to international distributors accounted for the vast majority of our total international sales.

Cost of Sales and Gross Profit. Our cost of sales for the three months ended June 30, 2019 was $43.4 million resulting in gross profit of $49.9 million, compared to $19.0 million in cost of sales for the same period in 2018 resulting in gross profit of $15.1 million. The gross margin for the three months ended June 30, 2019 was 54% compared to 44% in the same period in 2018.

The increase in our gross profit for the three months ended June 30, 2019 was primarily the result of a 290% increase in pump shipments. Gross profit and gross margin also increased as a result of per unit manufacturing cost improvements from higher production volumes and overall manufacturing efficiencies gained from our new manufacturing facility which became fully operational at the beginning of 2018. Additionally, we recognized a notable increase in non-cash stock-based compensation expense allocated to cost of sales of $1.4 million in the three months ended June 30, 2019 compared to $0.3 million in the same period in 2018, due to the valuation of certain 2018 and 2019 employee stock option grants and a significant increase in our stock price. As a whole, 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 79% to $40.6 million for the three months ended June 30, 2019 from $22.6 million for the same period in 2018. Employee-related expenses for our SG&A functions comprise the majority of SG&A expenses. The increase compared to 2018 was primarily the result of an $8.3 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, as well as an increase of $6.9 million in non-cash stock-based compensation. The increase in stock-based compensation expense for the three months ended June 30, 2019 to $9.0 million is primarily due to the valuation of certain 2018 and 2019 employee stock option grants and a significant increase in our stock price. This higher level of expense is expected to continue in future quarters.

Research and Development Expenses. R&D expenses increased 74% to $11.2 million for the three months ended June 30, 2019 from $6.5 million for the same period in 2018. The increase in R&D expenses was primarily the result of an increase in non-cash stock-based compensation allocated to R&D of $1.7 million, as well as an increase of $1.7 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts. The increase in stock-based compensation expense for the three months ended June 30, 2019 to $2.1 million is primarily due to the valuation of certain 2018 and 2019 employee stock option grants and a significant increase in our stock price. This higher level of expense is expected to continue in future quarters.

Other Income and Expense. Total other income for the three months ended June 30, 2019 was $0.4 million compared to total other expense of $45.4 million in the same period in 2018. Other expense for the three months ended June 30, 2019 primarily consisted of a $0.4 million revaluation loss from the change in the fair value of the Series A warrants. Other expense for the three months ended June 30, 2018 primarily consisted of a $42.5 million revaluation loss from the change in the fair value of certain warrants due to the significant appreciation of our stock price during the second quarter of 2018, and $3.1 million of interest expense associated with the Term Loan Agreement which was fully repaid in August 2018. Interest and other income consisted primarily of interest earned on our cash equivalents and short-term investments, for which our average invested balances were significantly higher during the second quarter of 2019 compared to the second quarter of 2018.

Comparison of the Six Months Ended June 30, 2019 and 2018

Sales. For the six months ended June 30, 2019, sales were $159.3 million, which included $34.2 million of international sales. Sales were $61.4 million for the same period in 2018, when we did not yet have any international sales.

The total sales increase of $97.8 million was primarily driven by a 264% increase in worldwide pump shipments to 35,990 in the first six months of 2019, compared to 9,891 in the first six months of 2018. Worldwide pump shipments were positively impacted by strong demand for our products following the August 2018 domestic launch of t:slim X2 with Basal-IQ technology, and the commencement of commercial sales of t:slim X2 with G5 in select international geographies in the third quarter of 2018, as well as the fulfillment of certain international pump demand from backlog that existed at the end of 2018 due to supply constraints. Additionally, sales from pump-related supplies increased 105% primarily due to an overall increase in our installed base of customers reordering supplies.

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

	Six Months Ended June 30,	
	2019	2018
Pump	$ 85,709	$ 38,323
Infusion sets	26,689	15,647
Cartridges	12,381	7,226
Other	246	206
Total Domestic sales	$ 125,025	$ 61,402

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

	Six Months Ended June 30,	
	2019	2018
Pump	$ 26,161	$ —
Infusion sets	4,781	—
Cartridges	3,112	—
Other	171	—
Total International sales	$ 34,225	$ —

Sales to distributors accounted for 74% and 78% of our total domestic sales for the six months ended June 30, 2019 and 2018, respectively. Our percentage of sales to distributors versus individual customers is principally determined by the mix of customers ordering our products within the period and whether or not we have a contractual arrangement with their underlying third-party insurance payor. Sales to international distributors accounted for the vast majority of our total international sales.

Cost of Sales and Gross Profit. Our cost of sales for the six months ended June 30, 2019 was $76.0 million resulting in gross profit of $83.3 million, compared to $34.9 million in cost of sales for the same period in 2018 resulting in gross profit of $26.5 million. The gross margin for the six months ended June 30, 2019 was 52% compared to 43% in the same period in 2018.

The increase in our gross profit for the six months ended June 30, 2019 was primarily the result of a 264% increase in pump shipments. Gross profit and gross margin also increased as a result of per unit manufacturing cost improvements from higher production volumes and overall manufacturing efficiencies gained from our new manufacturing facility which became fully operational at the beginning of 2018. Additionally, we recognized a notable increase in non-cash stock-based compensation expense allocated to cost of sales of $2.4 million in the six months ended June 30, 2019 compared to $0.4 million in the same period in 2018, due to the valuation of certain 2018 and 2019 employee stock option grants and a significant increase in our stock price. As a whole, 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 73% to $75.5 million for the six months ended June 30, 2019 from $43.5 million for the same period in 2018. Employee-related expenses for our SG&A functions comprise the majority of SG&A expenses. The increase compared to 2018 was primarily the result of a $14.3 million increase in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our sales growth and growing installed customer base, as well as an increase of $12.9 million in non-cash stock-based compensation. The increase in stock-based compensation expense for the six months ended June 30, 2019 to $16.0 million is primarily due to the valuation of certain 2018 and 2019 employee stock option grants and a significant increase in our stock price. This higher level of expense is expected to continue in the future.

Research and Development Expenses. R&D expenses increased 66% to $20.6 million for the six months ended June 30, 2019 from $12.4 million for the same period in 2018. The increase in R&D expenses was primarily the result of an increase in non-cash stock-based compensation allocated to R&D of $3.2 million, as well as an increase of $3.2 million in salaries, incentive compensation and other employee benefits due to an increase in personnel to support our product development efforts. The increase in stock-based compensation expense for the six months ended June 30, 2019 to $3.8 million is primarily due to the valuation of certain 2018 and 2019 employee stock option grants and a significant increase in our stock price. This higher level of expense is expected to continue in the future.

Other Income and Expense. Total other expense for the six months ended June 30, 2019 and 2018 was $11.6 million and $62.6 million, respectively. Other expense for the six months ended June 30, 2019 primarily consisted of a $13.2 million revaluation loss from the change in the fair value of the Series A warrants due to the significant appreciation of our stock price during the first six months of 2019. Other expense for the six months ended June 30, 2018 primarily consisted of a $56.8 million revaluation loss from the change in the fair value of certain warrants, and $6.2 million of interest expense associated with the Term Loan Agreement which was fully repaid in August 2018. Interest and other income consisted primarily of interest earned on our cash equivalents and short-term investments, for which our average invested balances were significantly higher during the first six months of 2019 compared to the first six months of 2018.

Liquidity and Capital Resources

As of June 30, 2019, we had $131.4 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 private and public offerings of equity securities, debt financing, and cash collected from product sales. Since the beginning of 2018, we completed the following financing activities:

- In February 2018, we completed a registered public offering of 34,500,000 shares of common stock at a public offering price of $2.00 per share. The gross proceeds from the offering were approximately $69.0 million, before deducting underwriting discounts and commissions and other offering expenses.

- In August 2018, we completed a registered public offering of 4,035,085 shares of common stock at a public offering price of $28.50 per share. The gross proceeds from the offering were approximately $115.0 million, before deducting underwriting discounts and commissions and other offering expenses.

- Between January 2018 and June 2019, we received proceeds of $29.9 million from the exercise of 8,829,035 outstanding warrants which were originally registered in a public offering of common stock in October 2017. As of June 30, 2019, there were warrants to purchase 417,515 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 acquisition of intellectual property, expenditures related to increases in our manufacturing capacity and improvements to our manufacturing efficiency, overall facility expansion, and other working capital needs. Additionally, we have used cash to pay the interest expense associated with our Term Loan Agreement. The outstanding balance associated with the Term Loan Agreement was fully repaid in August 2018, which will result in no interest expense or other costs associated with the Term Loan Agreement in future periods.

We expect our sales performance and the resulting operating income or loss, as well as the status of each of our new product development programs, will significantly impact our cash flow from operations, liquidity position and cash management decisions.

The following table shows a summary of our cash flows for the six months ended June 30, 2019 and 2018:

	Six Months Ended June 30,	
(in thousands)	**2019**	**2018**
Net cash provided by (used in):		
Operating activities	$ (556)	$ (18,995)
Investing activities	(13,883)	(37,337)
Financing activities	10,755	93,180
Effect of foreign exchange rate changes on cash	$ 15	$ —
Total	$ (3,669)	$ 36,848

Operating activities. Net cash used in operating activities was $0.6 million for the six months ended June 30, 2019, compared to $19.0 million for the same period in 2018. The decrease in net cash used in operating activities was primarily associated with a reduction in net loss when adjusted for non-cash expenses, particularly the change in the fair value of common stock warrants and stock-based compensation expense, offset by net changes in working capital. Our operating loss for the six months ended June 30, 2018 included $6.2 million in interest expense. Working capital changes in 2019 primarily consisted of increases in accounts receivable, inventories, and prepaid and other current assets, offset by an increase in other long-term liabilities related to accrued warranty. Accounts receivable increased to $48.4 million at June 30, 2019 from $35.2 million at December 31, 2018, as a result of higher sales in the second quarter of 2019 as compared to the fourth quarter of 2018. Inventories increased to $27.3 million at June 30, 2019 from $19.9 million at December 31, 2018, as a result of our strategic plan to rebuild inventory levels following the strong sales demand in the fourth quarter of 2018.

Investing activities. Net cash used by investing activities was $13.9 million for the six months ended June 30, 2019, which was primarily related to purchases of short-term investments of $74.2 million, offset by $68.5 million in proceeds from maturities and sales of short-term investments, and $8.2 million in purchases of property and equipment. Net cash used in investing activities was $37.3 million for the six months ended June 30, 2018, which was primarily related to purchases of short-term investments of $40.5 million offset by $4.3 million in proceeds from maturities and sales of short-term investments.

Financing activities. Net cash provided by financing activities was $10.8 million for the six months ended June 30, 2019, which primarily consisted of $10.4 million in proceeds from the issuance of common stock under Company stock plans. Net cash provided by financing activities was $93.2 million for the six months ended June 30, 2018, which consisted primarily of net proceeds of approximately $64.0 million from the public offering of our common stock in February 2018, as well as proceeds of $29.2 million from the exercise of Series A and Series B warrants issued in connection with our public offering of common stock in October 2017.

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 and amount of any additional financings, including the exercise of the remaining Series A warrants and proceeds from the issuance of equity awards pursuant to employee stock plans;
- fluctuations in gross margins and operating margins; and
- fluctuations in working capital, including changes in accounts receivable, inventories, accounts payable, employee related liabilities, and operating lease liabilities.

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;
- acquisition of equipment and other fixed assets;
- additional facilities leases and manufacturing equipment to support business growth and increase manufacturing capacity; and
- payments under our 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 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 capital stock, or we may elect to borrow amounts under new credit lines 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. 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, and uncertainties regarding the regulatory environment.

Indebtedness

Repayment of Term Loan Agreement

In August 2018, we fully repaid our term loan with CRG pursuant to the Term Loan Agreement. The balance of the outstanding debt at the time of repayment was $82.7 million. The repayment included approximately $1.1 million in accrued interest and $5.0 million in associated financing fees that became due. Therefore, we did not have any borrowings outstanding under the Term Loan Agreement as of June 30, 2019 and December 31, 2018. At the time of repayment, the remaining $5.3 million debt discount balance associated with the financing fees and certain debt issuance costs was accelerated and recognized as a loss on extinguishment of debt during the third quarter of 2018.

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. The preparation of these consolidated financial statements requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about our financial condition and results of operations that are not readily apparent from other sources. Actual results may differ 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, 2018, or the Annual Report, other than adoption of the new lease accounting standard. Refer to Note 6, “Leases” in the Notes to Unaudited Condensed Consolidated Financial Statements for further details.

Off-Balance Sheet Arrangements

As of June 30, 2019, 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, government-sponsored enterprise securities and U.S. government treasury securities. Some of the financial instruments in which we invest have market risk associated with them, 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 potentially subject us to credit risk, in that the value of the instrument may fluctuate based on the issuer's ability to pay.

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

Because of the short-term maturities of our financial instruments, we do not believe that an increase or decrease in market interest rates would have any significant impact on the realized value of our investment portfolio. If a 10% change in interest rates were to have occurred on June 30, 2019, 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 the United States are currently made to independent distributors under agreements denominated in U.S. dollars. Accordingly, we have assessed that 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 exchange risk associated with currency exposure related to existing assets and liabilities, committed transactions and forecasted future cash flows. In certain circumstances, we may seek to manage such foreign exchange risk by using derivative instruments such as foreign exchange forward contracts to hedge our risk. In general, we may hedge material foreign 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 and Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the Securities and Exchange Commission, or the 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 June 30, 2019, 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 June 30, 2019.

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 June 30, 2019 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we are involved in various 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 consider carefully 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 1A of the 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 profitability.*

Since our inception in January 2006, we have incurred a significant net loss. As of June 30, 2019, we had an accumulated deficit of $624.6 million. To date, we have financed our operations primarily through public and private offerings of our equity securities, debt financing, and cash collected from sales of our products. We have devoted substantially all of our resources to the 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 commercial product, the t:slim Insulin Delivery System, or t:slim, in the third quarter of 2012. In October 2016, we launched t:slim X2, our flagship pump platform, and in August 2017, we commenced commercial sales of t:slim X2 with Dexcom G5 Mobile CGM integration. The t:slim X2 hardware platform now represents nearly 100% of new pump shipments. In June 2018, we received FDA approval to sell our new t:slim X2 with Basal-IQ technology, which is integrated with Dexcom G6 CGM, and commenced sales and shipments of the t:slim X2 with Basal-IQ technology in the United States during the third quarter of 2018. Outside the United States, we have been selling our t:slim X2 with G5 integration in select markets since the third quarter of 2018 and in the second quarter of 2019 we commenced sales and shipments of our t:slim X2 with Basal-IQ technology in a subset of those markets.

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, 2018 and 2017, our gross profit was $89.8 million and $44.1 million, respectively. Although we have achieved a positive overall gross margin, we still operate at a significant net loss and expect that we will 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 research and development activities, create additional efficiencies in our manufacturing processes, 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, and the timing of regulatory approval of our products and the products of our competitors. Any additional operating losses will have an adverse effect on our stockholders' equity, and we cannot assure you that we will ever be able to achieve or 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 plc, or Medtronic;
- the potential that breakthroughs for the monitoring, treatment or prevention of diabetes may render our insulin pumps obsolete or less desirable;
- adverse regulatory or legal actions relating to our insulin pump products or similar products or technologies;
- 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; and
- claims that any of our insulin pump products, or any component thereof or related supplies or systems, 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, which under some circumstances are subject to termination by Dexcom, with or without cause, on relatively short notice. Sales of our products may also be negatively impacted in the event of any regulatory or legal actions relating to Dexcom's CGM products, 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 Dexcom's CGM products are not viewed as superior to competing CGM products in markets where our products are sold.

Furthermore, sales of our products may be adversely impacted by negative perceptions regarding our financial stability relative to that of our competitors, and our ability to sustain our business operations on a long-term basis. These perceptions may cause people with insulin-dependent diabetes, their caregivers and healthcare providers, as well as independent distributors and third-party payors, to question our ability to continue to sell our products, provide customer service, support our commercial organization, and fulfill our strategic objectives. These concerns may arise from a number of factors, including our recent and projected financial results, changes in and volatility of our stock price, the competitive environment in our industry, and uncertainties regarding the regulatory environment. Any such concerns, whether actual or perceived, could cause consumers to delay the purchase of our products or purchase competitive products.

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.

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 24/7 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 the products of our competitors, the failure to secure regulatory clearance or approvals in a timely manner or at all, or for other reasons. The failure to retain a high percentage of our customers and increase sales to these customers consistent with our forecasts would have a material adverse effect on our business, financial condition and operating results.

We operate in a very competitive industry and if we fail to compete successfully against our existing or potential competitors, 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, or MDI, therapy.

Our primary competitors are major medical device companies that are either publicly traded companies or divisions or subsidiaries of publicly traded companies. For instance, Medtronic MiniMed, a division of Medtronic, has been the market leader for many years and has the majority share of the traditional insulin pump market in the United States. However, the market for insulin pumps continues to experience significant changes. For instance, in October 2017, Johnson & Johnson announced its plans to discontinue the operations of Animas and to exit the insulin pump business entirely. Animas designated Medtronic as a preferred partner to facilitate the transition of their respective insulin pump customers. In addition, over the past several years Eli Lilly & Co. announced that it was developing an insulin pump and Becton Dickinson announced that it plans to launch an insulin pump designed for persons with type 2 diabetes. 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 and regulatory uncertainty;
- 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;
- products supported by long-term clinical data;
- 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 research and development, 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, Medtronic offers a traditional insulin pump with a hybrid closed-loop AID functionality and a new CGM system and Insulet offers an insulin pump with a tubeless delivery system that does not utilize an infusion set. These specific features may make the competitive products more desirable to customers and healthcare providers, which could negatively impact sales of our products.

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 Laboratories launched a new blood glucose monitoring system in the United States which competes with the Dexcom technology, and another CGM product with CE mark approval was approved in the second quarter of 2018 for sale in the United States. Competitive pressures within our industry 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, 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, positive lifestyle impact, 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 insulin pump products or similar products or technologies generally;
- 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, even if we are able to convince people with insulin-dependent diabetes, their caregivers or healthcare providers that our products compare favorably to the products and treatment alternatives offered by our competitors, negative perceptions regarding our financial stability relative to that of our competitors, and our ability to sustain our business operations on a long-term basis, could cause consumers to delay the purchase of our products or to purchase competitive products.

Furthermore, the rapid evolution of technology and treatment options within our industry may cause consumers to delay the purchase of our products in anticipation of advancements or breakthroughs, or the perception that advancements or breakthroughs could occur, in our products or the products offered by our competitors. It is also possible that consumers interested in purchasing any of our future products currently under development may delay the purchase of one of our current products.

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

Our ability to achieve profitability will depend, in part, on our ability to reduce the per unit cost of our products by increasing production volume and manufacturing efficiency, and by reducing raw material and component costs, labor, product-training, warranty and manufacturing overhead costs per unit.*

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, warranty, scrap and excess and obsolete inventories. It also includes manufacturing overhead costs, including expenses relating to quality assurance, inventories procurement and control, facilities, equipment, information technology and operations management. If we are unable to sustain or reduce 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, and improved warranty performance, 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, or result in our sales growing at a slower rate than we expect, 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 productivity following the relocation of our manufacturing operations to our Barnes Canyon facility or as we undertake other actions to expand our manufacturing capacity. Furthermore, while we currently believe our proprietary technology platform will allow us to efficiently design and develop new products, changes in the market that require us to modify or replace our existing platform will reduce the efficiencies gained through our platform and could increase our per unit costs or prevent those costs from declining. 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.

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.

We have derived nearly all of our revenue from sales of insulin pumps, and related insulin cartridges and infusion sets, and expect to continue to do so in the foreseeable future. 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, or CMS, which administers the U.S. Medicare program. Medicare periodically reviews its reimbursement practices for diabetes-related products. Medicare previously implemented a competitive bidding process for blood glucose strip reimbursement, which resulted in a significant reduction in the reimbursement rate for those products. In 2017, Medicare announced, and then shortly thereafter suspended, a competitive bidding process for insulin pumps. As a result, there is uncertainty as to the future Medicare reimbursement rate for our products. 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. We expect this decision will prevent a majority of UnitedHealthcare members from purchasing an insulin pump from us for the foreseeable future. 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 approximately 184 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 adding 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 do not have 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 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.

We expect to derive nearly all of our revenue from the sale of our t:slim X2 insulin pump, and the related insulin cartridges and infusion sets, unless and until we receive regulatory clearance or approval for other products currently under development. As a result, 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 fail to achieve their objectives, 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 increased the number of sales, marketing, clinical and customer service personnel employed by us since the initial commercial launch of t:slim 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 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. 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, 2018, sales to approximately 64 independent distributors represented approximately 79% of our sales. While our goal in the United States is to reduce the percentage of our sales to independent distributors over time as we enter into contracts with additional third-party payors, 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 even increase in the near term, particularly in light of our plans to primarily rely 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 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, 2018, our two largest independent distributors in the United States collectively comprised approximately 35% of our sales, and our nine independent international distributors collectively comprised approximately 5% of our 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, or other arrangements pursuant to which independent distributors may purchase product from us, the terms of the arrangements could result in our product margins to be 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, or 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. In particular, we are relying on data from the U.S. portion of the Clinical Acceptance of the Artificial Pancreas (DCLP3) portion of the IDCL Trial, to support our development of t:slim X2 with Control IQ technology. We may also rely on data from other portions of the larger IDCL Trial to support additional regulatory submissions. The IDCL Trial is being conducted entirely by third parties over which we have little or no control or influence. In the event that the ongoing aspects of the IDCL Trial are not performed on a timely basis, or if the quality or accuracy of the data obtained from the IDCL Trial is compromised due to the failure to adhere to clinical protocols or regulatory requirements or for other reasons, our development activities for t:slim X2 with Control IQ technology may be negatively impacted.

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, especially with respect to the ongoing portions of the IDCL Trial that we intend to rely upon for the development of t:slim X2 with Control IQ technology. 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 and the announcement by Johnson & Johnson that it is discontinuing the operations of Animas and exiting the insulin pump business, 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. 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 facing growth 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.

The Technology Upgrade Program resulted in accounting complexities that may lead to confusion when comparing our historical and future financial results.

While our Technology Upgrade Program expired on September 30, 2017, it resulted in a number of accounting complexities that will continue to make comparisons of our historical and future financial results more difficult. In particular, during the term of the Technology Upgrade Program, U.S. GAAP prevented us from recognizing, at the time of sale, up to 100% of the sales and cost of sales associated with the sale of our insulin pumps to eligible customers. Instead, depending on the type of pump sold, we were required to defer some or all of the sales and cost of sales until a later date. In light of the expiration of the Program, we are no longer subject to these accounting deferrals. However, in evaluating our 2017 financial results through December 31, 2017, as a result of the Technology Upgrade Program we recorded incremental net sales of $5.0 million that were previously deferred, with a corresponding increase of $3.1 million in gross profit. It is possible that we may offer other consumer-directed programs in the future, which may result in similar or additional accounting complexities.

Despite our efforts to explain the required accounting treatment for the Technology Upgrade Program, it is possible that there may be confusion when comparing our historical and future financial results, which may cause investors to avoid investing in our common stock and adversely impact our stock price.

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; and
- potential damage to or destruction of our manufacturing equipment or manufacturing facility.

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 external third-parties to perform contracted manufacturing services for us and we will 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.

If we 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, or their inability to provide us with an adequate supply of components or products, 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. For example, we have implemented a business strategy intended to increase our future sales of infusion sets, and any increase in the sales of our infusion sets could strain the ability of our suppliers to deliver products in a manner that meets our various requirements.

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 or damage to their manufacturing equipment or facilities. 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. Furthermore, negative perceptions among our suppliers regarding our financial stability, and our ability to sustain our business operations on a long-term basis, may cause one or more of our suppliers to terminate their relationship with us, or claim that our financial condition causes them to demand different payment terms.

We generally use a small number of suppliers for our components and products. Depending on a limited number of suppliers exposes us to risks, including limited control over cost, 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 is 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. 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.

We may also have difficulty obtaining similar 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 new 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.

We believe the transition period for our direct customers and distributors in the United States to utilize their inventories on hand before transitioning to t:lock is substantially complete. In addition, we are initially offering standard Luer-lok cartridges and infusion sets in select international markets, and expect to transition to our t:lock connector in international markets during 2019. Accordingly, we may continue offering both styles of cartridges and infusion sets to facilitate the transition of customer supplies through 2019, although there may be circumstances that require additional time for some direct customers and distributors to complete the transition. Our supplier of infusion sets must manufacture a variety of lengths and styles of infusion sets with t:lock that match our cartridges. Failure to do so, or to do so at the necessary production volumes, may result in our inability to convert customers to t:lock when anticipated, which would negatively impact our ability to achieve our financial projections. 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 t:lock was designed based on customer feedback, and all standard Luer-lok infusion sets that we currently offer are also available with t:lock, 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 t:lock 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 t:lock 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, research and development activities, customer and technical support, and management and administrative functions. In addition, the majority of our inventories of component supplies and finished goods is stored at one facility in San Diego. We also store finished goods at certain third-party warehouses in California and Texas for the fulfillment of certain customer orders. 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 operations to our new facility.*

At the beginning of 2018, we completed the transition of our manufacturing operations to our Barnes Canyon facility that we expect will allow for future product manufacturing expansion. However, we may not experience the anticipated operating efficiencies at the new facility, or we may experience efficiencies to a lesser extent than projected. 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 September 2017, following a site inspection of our Barnes Canyon facility, the FDA issued a Form 483, List of Inspectional Observations, containing two observations. Following our receipt of the Form 483, we began implementing corrective and preventive actions to fully address the FDA observations, and in October 2017, we provided a written response to the FDA. In December 2017, we received a letter from the FDA stating that our initial written response did not fully address the FDA observations, and that the FDA would address the observations during its next regularly scheduled inspection of our facilities. If the FDA is not satisfied, it may issue a warning letter to us or may take other actions, any of which could have a material adverse effect on our business. On August 15, 2018, we closed the voluntary recall initiated on April 12, 2018 for 55 t:slim G4 pumps.

We expect that the management and support of our new manufacturing facility 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 from the new facility. 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 offerings through our research and development efforts, 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 offerings 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.

The safety and efficacy of our products is not supported by long-term clinical data, which could limit sales, and our products could cause unforeseen negative effects.

Our t:slim X2 insulin pump received pre-market clearance under Section 510(k) of the U.S. Federal Food, Drug, and Cosmetic Act, or FDCA. The 510(k) clearance process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes and does not always require long-term clinical studies. t:slim X2 with G5 integration and t:slim X2 with Basal-IQ technology received FDA approval under a Premarket Approval, or PMA, application. However, currently there are only limited published studies to evaluate the safety or effectiveness of our PMA-approved products in a controlled setting. As a result, we currently lack the breadth of published long-term clinical data supporting the safety and efficacy of our products and the benefits they offer. For these reasons, 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.

We may enter into collaborations, in-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, in-licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products and to pursue new markets, or we may amend or modify similar agreements that we already have in place. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities. We may not identify or complete any such transactions or arrangements 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 transaction or arrangement that we do identify and complete. In particular, these collaborations may not result in the development of products that achieve commercial success or result in positive financial results and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators 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, 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 of intellectual property developed during the collaboration. 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 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 currently run until June 2020 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 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, our administrative offices 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.

Any significant disruptions to our information technology systems, or failures of our pumps' software to perform as we anticipate, could have an adverse effect on our business, financial condition and operating results.*

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage 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 earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses, and computer system or data network failures, any of which could adversely impact the availability, confidentiality and integrity of information assets contained in those systems. In addition, our currently-marketed insulin pumps and our products currently under development contain software which could be subject to computer virus, hacker attacks or other 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. We may also face new risks relating to our information technology systems as we begin to commercialize our products outside 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, all of which could have a material adverse effect on our business, financial condition and operating results.

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. Many of these individuals have been employed by us for many years, have played integral roles in the growth of our business, and will continue to provide value to us. In our industry, it is common to attract and retain executive talent and other employees with compensation packages that include a significant equity component. At this time, a substantial number of our outstanding equity awards issued prior to 2017, which generally were issued in the form of stock options, are significantly out of the money and unlikely to be exercised in the future. 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. 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.

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, including the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, and related regulations, Canada's Personal Information Protection and Electronic Documents Act, referred to as PIPEDA, and the EU General Data Protection Regulation, commonly known as GDPR. 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.

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, or GDPR, 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. We believe we are in substantial compliance with applicable laws, however, 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 begin to commercialize our products worldwide. As we continue to expand, our business will need to adapt to meet these and other similar legal requirements.

We are seeking approval to commercialize 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 U.S. 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, or natural disasters.

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 have no current commitments with respect to any acquisition. 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 to raise additional funds in the future and if we are unable to raise additional funds when necessary, we may not be able to achieve our strategic objectives.*

At June 30, 2019, we had $131.4 million in cash, cash equivalents and short-term investments. Our management expects the continued growth of our business, including the expansion of our customer service infrastructure to support our growing base of customers, our plans to expand commercial sales of our products outside the United States, the growth of our manufacturing and warehousing operations and additional research and development 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 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 the hiring of additional personnel, purchasing manufacturing equipment and other measures 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; and
- unanticipated general and administrative expenses.

As a result of these and other factors we may in the future seek additional capital from public or private offerings of our capital stock, 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 product in geographies outside 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;
- 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.

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 June 30, 2019, our patent portfolio consisted of approximately 74 issued U.S. patents and 69 pending U.S. patent applications. Of these, our issued U.S. patents expire between approximately 2021 and 2036. We also have and are seeking patent protection for our proprietary technologies in other countries throughout the world. In addition, we have 11 U.S. trademark registrations and 15 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. 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 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. We received approval of our PMA for t:slim G4 in September 2015 and of our PMA supplement for the t:slim X2 with G5 integration in August 2017. More recently, in June 2018, we received approval of our PMA for the t:slim X2 with Basal-IQ technology. 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.

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. We anticipate that certain of our products currently under development will require the more costly, lengthy and uncertain PMA approval process.

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. For example, based on feedback from the FDA, in February 2019 we received approval of a de novo 510(k) application to down-classify the t:slim X2 to a Class II device, under the new insulin pump classification referred to as ACE pumps, and we intend to separately file a PMA for our implementation of the Control-IQ technology. Ultimately, the FDA may not support our new regulatory filing strategy.

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. 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, 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 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 are required to comply with the FDA's Quality System Regulation, or the 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. If we or our suppliers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us. Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results.

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 MDR 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 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 or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, 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;
- 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 protected health information, such as HIPAA and the Health Information Technology for Economic and Clinical Health.

Further, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, or, collectively, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. An individual or entity can now be found guilty under the PPACA without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that claims submitted in violation of the Anti-Kickback Statute automatically constitute false claims for purposes of the False Claims Act. 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. 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.

To enforce compliance with the federal laws, the U.S. Department of Justice, or the DOJ, 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 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 imposes, 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, although this tax has been suspended for calendar years 2016, 2017, 2018 and 2019. It is unclear at this time if the moratorium will be further extended. We do not believe that our products are 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 IRS, and the IRS may disagree with our analysis. Absent further legislative action, the medical device excise tax applies to sales of taxable medical devices beginning on January 1, 2020, and future products that we manufacture, produce or import may be subject to this tax (unless the retail exemption or other applicable exemption applies). The financial impact this tax may have on our business is unclear and there can be no assurance that our business will not be materially adversely affected by it. Additionally, Congress could terminate the moratorium or further change the law related to the medical device tax in a manner that could adversely affect us.

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.

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, or the TCJA, which significantly reforms the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, 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, 2018, we had federal net operating loss, or NOL, carryforwards of approximately $352.7 million, not considering the limitation discussed below. The federal tax loss carryforwards begin to expire in 2026, unless previously utilized. In addition, if there is an "ownership change" with respect to our company, as defined under Section 382 of the Code the utilization of our NOL carryforwards may be subject to substantial limitations imposed by the Code, and similar state provisions. 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.

Although we have not yet completed an update of our Section 382 analysis subsequent to December 31, 2017, offerings of our securities following that date may have caused an ownership change or could increase the likelihood that we undergo an ownership change for purposes of Section 382 of the Code in the future. Based on preliminary results of the Section 382 analysis, the Company anticipates that an ownership change may have occurred in 2018 and that the resulting limitation would significantly reduce the Company's ability to utilize its net operating loss and credit carryovers before they expire. 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 such NOL carryforwards to expire unused, in each case reducing or eliminating the benefit of such NOL carryforwards.

With respect to our NOLs generated in 2018 and thereafter, the TCJA may reduce the tax benefit of our NOLs. Under the TCJA, 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 TCJA, 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 TCJA.

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.

The requirements of being a public company have increased our costs and will continue to strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Exchange Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NASDAQ Global Market and other applicable securities rules and regulations. Compliance with these rules and regulations has increased our legal and financial compliance costs, made some activities more difficult, time-consuming or costly, and increased demand on our systems and resources.

The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to meet these additional requirements, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired additional employees to help us comply with these requirements, in the future we may need to hire more employees or utilize external consultants in order to further support our efforts, which will increase our expenses.

Regulations related to "conflict minerals" may cause us to incur additional expenses and could limit the supply and increase the cost of certain metals used in manufacturing our products.

The SEC adopted a rule requiring disclosures by public companies of specified minerals, known as conflict minerals, that are necessary to the functionality or production of products manufactured or contracted to be manufactured. The rule requires companies to perform due diligence, disclose and annually report to the SEC whether or not such minerals originate from the Democratic Republic of Congo or an adjoining country. The rule could affect sourcing at competitive prices and availability in sufficient quantities of certain minerals used in the manufacture of our products, which could increase our expenses. In addition, there may be material costs associated with complying with the disclosure requirements, such as costs related to determining the source of certain minerals used in our products, as well as costs of possible changes to products, processes, or sources of supply as a consequence of such verification activities.

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. 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 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. **Mine Safety Disclosures**

Not applicable.

Item 5. **Other Information**

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference				Provided Herewith
		Form	File No.	Date of First Filing	Exhibit Number	
10.1	First Amendment to Lease Agreement, dated May 17, 2019, by and between Tandem Diabetes Care, Inc. and TREA PACIFIC PLAZA, LLC					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

** 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: August 1, 2019

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)

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)

FIRST AMENDMENT TO OFFICE LEASE

This FIRST AMENDMENT TO OFFICE LEASE ("Amendment") is made as of May 15, 2019 ("Effective Date"), by and between TRBA PACIFIC PLAZA, LLC, a Delaware limited liability company ("Landlord"), and TANDEM DIABETES CARE, INC., a Delaware corporation ("Tenant").

RECITALS :

A. Landlord and Tenant are parties to that certain Office Lease dated as of January 10, 2019 (the "Original Lease"), pursuant to which, Tenant currently leases from Landlord certain premises consisting of approximately 25,332 rentable square feet (the "Current Premises"), commonly known as Suite 200 within the building located at 10935 Vista Sorrento Parkway, San Diego, California (the "Building"), which is part of the project commonly known as Pacific Plaza at Torrey Hills (the "Project"), as more particularly described in the Original Lease,

B. The Term of the Original Lease is scheduled to expire by its tenns on September 29, 2022 (the "Expiration Date"),

C. The parties desire to amend the Original Lease in order to provide, among other things, for Tenant to expand the Current Premises, upon the terms and conditions set forth below.

D. Capitalized terms tiot defined herein have the meanings given to such tenns in the Original Lease.

WITNESSETH:

NOW, THEREFORE, in consideration of the above Recitals and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Expansion of Current Premises. Tenant hereby leases from Landlord, and Landlord hereby leases to Tenant, that certain premises commonly known as Suite 120 and Suite 150 on the first (ls floor of the Building, consisting of 5,477 rentable square feet (4,988 USP), and 3,329 rentable square feet (3,032 USF), respectively, and collectively 8,806 rentable square feet (8,020 USF) in the aggregate (the "First Floor Expansion Space"), and Suite 300 on the third (3'") floor of the Building, consisting of approximately 24,875 rentable square feet (22,940 USF)(the "Third, Floor Expansion Space"), for an aggregate of an additional 33,681 rentable square feet (30,960 USF)(collectively, the "Expansion Space"). The Expansion Space is depicted on Exhibit A attached hereto. Exhibit A attached hereto identifying the Expansion Space is hereby incorporated into and made a part of the Original Lease, as amended by this Amendment (the "Amended Lease"), and from and after the date hereof, all references in the Amended Lease to the defined term "Premises" shall mean and refer to the Current Premises plus the Expansion Space, consisting of approximately 59,013 rentable square feet in the aggregate. Tenant's use and occupancy of the Expansion Space shall be in accordance with all of the terms and conditions of the Amended Lease.

2. First Floor Expansion Space. The term as to the First Floor Expansion Space (the "First Floor Expansion Space Tenn") shall commence on the Effective Date of this Amendment (also, the "First Floor Expansion Space Commencement Date" or "FFESCD"), and shall expire co-terminously with Tenant's lease of the Current Premises and the Third Floor Expansion Space on the Third, Floor Expansion Space Expiration Date (as de.fined below), Tenant shall be given exclusive possession of the First Floor Expansion Space upon full execution of this Amendment.

3. Third Floor Expansion Space. The term as to the Third Floor Expansion Space ("Third Floor Expansion Space Term) shall commence on the date that certain Tenant Improvements (as

defined below) for the Third Floor Expansion Space are completed by Tenant ("Third Floor Expansion Space Commencement Date" or "TFESCD"), but in no event later than January 1, 2020, and shall expire on the last day of the thirty-seventh (37 full calendar month following the Third Floor Expansion Space Commencement Date ("Third Floor Expansion Space Expiration Date" or "TFESED"). The parties estimate the TFESCD will be December 1, 2019.

4. Expansion Space Base Rent.

(a) Effective as of the First Floor Expansion Space Commencement Date and continuing throughout the First Floor Expansion Space Term, Tenant shall pay monthly installments of Base Rent for the First Floor Expansion Space consisting of approximately 8,806 rentable square feet in the aggregate (not inclusive of the Current Premises or third Floor Expansion Space) to Landlord in accordance with the following schedule:

Period/Months	Base Rent
FFESCD-12	$33,462.80*
13 -24	$34,466.84
25 -36	$35,500.68
37-TFESED	$36,565.70

(b) Effective as of the Third Floor Expansion Space Commencement Date and continuing throughout the Third Floor Expansion Space Term, Tenant shall pay monthly installments of Base Rent for the Titird Floor Expansion Space consisting of approximately 24,875 rentable square feet (not inclusive of the Current Premises or First Floor Expansion Space) to Landlord in accordance with the following schedule;

Period/Months	Base Rent
TFESCD-12	$94,525.00*
13 -24	$97,360.75
25 - 36	$100,281.57
37-TFESED	$103,290.00

*Notwithstanding the foregoing, provided Tenant is not in default under the Amended Lease beyond any applicable notice and cure period, Landlord hereby agrees to abate Tenant's obligation to pay (a) the monthly installment of Base Rent for the First Floor Expansion Space commencing on FFESCD and ending on June 25, 2019, inclusive, and (b) the monthly installment of Base Rent for the Third Floor Expansion Space commencing on TFESCD and for forty-five (45) days following the TFESCD, inclusive (such total amount of abated Monthly Base Rent being hereinafter referred, to as the "Abated Amount"). During such abatement period, Tenant will still "be responsible for the payment of all other monetary obligations under the Amended Lease.

5. Term for Current Premises. Effective as of the Effective Date of this Amendment, the Term for the Current Premises shall be extended to expire upon the Third Floor Expansion Space Expiration Date.

6. Current Premises Base Rent. Tenant shall continue to pay monthly installments of Base Rent and all other monetary obligations for the Current Premises continuing through the Current Premises Expiration Date pursuant to the terms of the Original Lease. Effective as of the expiration of the Tenn for the Current Premises (i.e., month 42 of the original Term), the Monthly Base Rent for the Current Premises shall continue at the rate payable for month 42 as stated in the Original Lease through month 48 measured from the original Term Commencement Date. Should for any reason the Third Floor Expansion Space Expiration Date fall beyond month 48 as measured from the original Tenn Commencement Date, then commencing as of the 1st day of month 49 as measured

from the original Term Commencement Date, Monthly Base Rent for the Current Premises shall be increased to $104,066.56 per month through the Third Floor Expansion Space Expiration Date.

7. Additional Security Deposit. Landlord currently holds a Security Deposit under the Original Lease in the amount of One Hundred One Thousand Thirty-Five and 50/100 Dollars ($101,035.50) (the "Existing Security Deposit"). Concurrently with the full execution o f this Amendment, Tenant shall deposit with Landlord an additional security deposit in the amount of One Hundred Thirty-Five Thousand Seven Hundred Eighty-Two and 25/100 Dollars ($135,782.25) (the "Additional Security Deposit"), which when added to the Existing Security Deposit shall equal Two Hundred Thirty-Six Thousand Eight Hundred Seventeen and 75/100 Dollars ($236,817.75) (the "New Security Deposit"). All references to "Security Deposit" in the Amended Lease shall be deemed to refer to the New Security Deposit and shall be governed by Paragraph 2(c) of the Amended Lease. Accordingly, upon full execution of fuis Amendment, Tenant shall deliver the following amounts to Landlord:

(a)	One month installment of Base Rent for First Floor Expansion Space:	$33,462.80
(b)	One month installment of Base Rent for Third Floor Expansion Space:	$94,525.00
(c)	Additional Security Deposit:	$135,782.25
	Total due upon execution of the Amendment:	$263,770.05

8. Tenant's Proportionate Share. Effective as of the First Floor Expansion Space Commencement Date, Effective as of the Third Floor Expansion Space Commencement Date, Tenant's Proportionate Share for the Current Premises and the First Floor Expansion Space shall be 15.49% based on the Premises (inclusive of the First Floor Expansion Space) consisting of approximately 34,138 rentable square feet in the aggregate and the Project consisting of approximately 220,348 rentable square feet. Effective as of the Third Floor Expansion Commencement Date, Tenant's Proportionate Share for the Current Premises and- the Expansion Space shall be 26.78% based on the Premises (inclusive of all of the Expansion Space) consisting of approximately 59,013 in the aggregate and the Project consisting of approximately 220,348 rentable square feet.

9. Condition of the Current Premises. Tenant is currently in possession of the Current Premises and acknowledges that Landlord. shall not be obligated to refurbish or improve the Current Premises or to otherwise fund improvements for the Current Premises in any manner whatsoever in conjunction with this Amendment Tenant further acknowledges that except_as expressly provided in the Original Lease and this Amendment, neither Landlord nor any agent of Landlord has made any representation or warranty regarding the condition of the Current Premises, the improvements, refurbishments, or alterations therein, the Building or the Project, or with respect to the functionality thereof or the suitability of any of the foregoing for the conduct of Tenant's business and that all representations and warranties of Landlord, if any, are as set forth in the Original Lease and this Amendment.

10. Condition of First Floor Expansion Space. Tenant acknowledges that the First Floor Expansion Space is newly completed and never occupied spec space. Landlord shall deliver the First Floor Expansion Space to Tenant in broom-clean condition and free of debris, with the existing Building standard plumbing, lighting, roof, electrical, fire sprinkler, life and safety, and HVAC systems serving and within the Premises (collectively, the "Operating Systems") in good operating condition and recently serviced, including balancing the HVAC. In addition, to the best of Landlord's knowledge, the First Floor Expansion Space is in a condition that met current codes and conditions at time of construction thereof and will meet such codes and conditions on the FFESCD, subject to grandfathered rights, if and to the extent required by applicable governmental authorities. If a non-compliance with such warranty exists as of the Effective Date or if one of such Operating Systems or elements should malfunction or fail within the warranty period below, as Tenant's sole remedy for Landlord's breach of this warranty, Landlord shall, as Landlord's sole obligation, promptly after receipt of written notice from Tenant setting forth with specificity the nature and extent of such non-compliance, malfunction or failure, repair same at Landlord's expense; provided, however, Landlord

shall have no liability hereunder for repairs or replacements to the extent necessitated by the acts or omissions of Tenant mid/or any of Tenant's agents. The warranty period shall be nine (9) months after delivery of the First Floor Expansion Space to Tenant. Tenant acknowledges that except as expressly provided in this Amendment, neither Landlord nor any agent of Landlord has made any other representation or warranty regarding the condition of the First Floor Expansion Space, the improvements, refurbishments, or alterations therein, the Building, or with respect to the functionality thereof or the suitability of any of the foregoing for the conduct of Tenant's b11Siness and that all representations and warranties of Landlord, if any, are as set forth in this Amendment and Tenant shall accept the First Floor Expansion Space in its present AS-IS condition, subject only to the foregoing representations by Landlord.

11. Condition of Third Floor Expansion Space; Tenant Improvements. Tenant acknowledges that the Third Floor Expansion Space is in shell condition without distribution of utilities or HVAC or any tenant improvements. Landlord will deliver the Third Floor Expansion Space to Tenant upon the Effective Date of this Lease in broom-clean condition and free of debris, with the base shell and core improvements of the Building in place and operational, subject to Tenant's improvement of the Third Floor Expansion Space with lobby and common corridors to Building standard specifications, demising walls, HVAC, electricity and life safety system distribution to Tenant's Premises configuration. Landlord shall provide to Tenant an allowance of Two Hundred Ninety Eight Thousand, Seven Hundred and Fifty and No/100 Dollars ($298,750.00) (the "Allowance") to be used by Tenant to design, plan, engineer, commence, and complete interior improvements to the Third Floor Expansion Space including lobby and common corridors as well as the design and installation of Building signage permitted under the Original Lease (collectively, the "Tenant Improvements") in accordance with and subject to the terms and conditions of Exhibit B attached hereto. Landlord shall disburse the Allowance as provided in the Work Letter. Tenant acknowledges that except as expressly provided in this Amendment, neither Landlord nor any agent of Landlord has made any other representation or warranty regarding the condition of the Third Floor Expansion Space, the improvements, refurbishments, or alterations therein, the Building, or with respect to the functionality thereof or the suitability of any of the foregoing for the conduct of Tenant's business and that Tenant shall accept the Third Floor Expansion Space in its present AS-IS condition, subject only to the foregoing representations by Landlord.

12. Right of First Offer. Tenant shall have the right of first offer to lease Suite 100 on the first (1 floor) of the Building in accordance with the terms and conditions of Rider No. 1 attached to this Amendment.

13. Accessibility. Pursuant to Section 1938 of the California Civil Code, Landlord hereby advises Tenant that as of the date of this Amendment neither the Current premises, the Expansion Space, the Building nor the Project have undergone inspection by a Certified Access Specialist. Further, pursuant to Section 1938 of the California Civil Code, Landlord notifies Tenant of the following: "A Certified Access Specialist (CASp) can inspect the Premises and determine whether the Premises comply with all of the applicable construction-related accessibility standards under state law. Although California state law does not require a CASp inspection of the Premises, the commercial Property owner or lessor may not prohibit the lessee or tenant from obtaining a CASp inspection of the Premises for the occupancy or potential occupancy of the lessee or tenant, if requested by the lessee or tenant. The parties shall mutually agree on the arrangements for the time and manner of any such CASp inspection, the payment of the costs and fees for the CASp inspection and the cost of making any repairs necessary to correct violations of construction-related accessibility standards within the Premises." Therefore and notwithstanding anything to the contrary contained in the Amended Lease, Landlord and Tenant agree that (a) Tenant may, at its option and at its sole cost, cause a CASp to inspect the Premises and determine whether the Premises complies with all of the applicable construction-related accessibility standards under California law, (b) the parties shall mutually coordinate and ;easonably approve of the timing of any such CASp inspection so that Landlord may, at its option, have a representative present during such inspection, and (c) if Tenant requires the CASp inspection under this Paragraph, Tenant shall be solely responsible for the cost of any repairs necessary to correct violations of construction-related accessibility standards within the Premises, the Expansion Space, in the Building, or at the Project, revealed solely as a result of such CASp inspection, any and all such alterations and repairs within the Premises to be performed by Tenant in accordance with Article 4 of the Original Lease; provided Tenant shall have no obligation

to remove any repairs or alterations made pursuant to a CASp inspection under this Paragraph 13.

14. Utilities. Paragraph 7(b)(iv) of the Original Lease is hereby amended to read in full as follows:

"(iv) Heating, ventilation and air conditioning service provided by Landlord to Tenant during hours other ihan Business Hours and as early as 5:00 am. PST daily, upon the prior request of Tenant given at any time to Landlord, and Tenant shall pay to Landlord, not more frequently than monthly, for overtime HVAC on an hourly basis (1 hour minimum,Mondays through. Saturdays, and 4 hour minimum on Sundays), $45.00 per hour per floor throughout the Term; and"

15. Parking. As provided in the Original Lease, Tenant shall have the right to use an additional 3.75 unreserved parking stalls per 1,000 usable square feet in the Expansion Space (i.e., an additional 116 unreserved parking stalls). Tenant's additional parking spaces shall be located in one of the two (2) parking structures in the Project. Tenant's parking rights shall be governed by the Amended Lease.

16. Broker. Tenant warrants that it has had no dealings with any real estate broker or agent in connection with the negotiation of this Amendment, excepting only RE:Align, Inc. (the "Broker") and that it knows of no other real estate broker or agent acting on behalf of Tenant who is or might be thereby entitled to a commission in connection with this Amendment. Each party agrees to indemnify and defend the other party against and hold the other party harmless from any and all claims, demands, losses, liabilities, lawsuits, judgments, and costs and expenses (including without limitation reasonable attorneys' fees) with respect to any leasing commission or equivalent compensation alleged to be owing on account of the indemnifying party's dealings with any real estate broker or agent other than the Broker. Landlord shall pay any brokerage commissions payable to the Broker in coIWection with the execution of this Amendment pursuant, to a separate agreement between Landlord and the Broker. Nothing set forth herein or otherwise under this Amendment shall be deemed to require that Tenant retain any specific broker to act on Tenant's behalf or for its benefit, including the Broker, in connection with any further or future negotiations with Landlord under this Amendment, including as to any renewals or extensions of the Lease Tenn, or expansions of the Premises, and Tenant hereby disclaims any such retention or relationship absent further notice-by Tenant thereof to Landlord in each such instance.

17. Security Documents. Landlord represents and warrants that no Security Documents exist as of the Effective Date of this Amendment.

18. Signage. Landlord confirms that Tenant is entitled to the Building Sign specified in Paragraph 7(h) of the Original Lease upon the execution of this Amendment.

19. Extension Option. Tenant shall continue to have the Extension Option set forth in Rider No. 1 attached to the Original Lease; provided, however, Tenant may exercise such Exterudon Option for a period of only 4 years (vs. *5* years), but as to all of the Tenant Premises collectively in any event.

20. Authority. Each party warrants to the other that the person signing this Amendment on its behalf is fully authorized to do so and, by so doing, to bind such party.

21. Successors and Assigns. This Amendment shall extend to, be binding upon, and inure to the benefit of, the respective successors and permitted assigns and beneficiaries of the parties hereto.

22. No Other Modification. Landlord and Tenant agree that except as otherwise specifically modified in this Amendment, the Original Lease has not been modified, supplemented, amended, or otherwise changed in any way and the Original Lease remains in full force and effect between the parties hereto as modified by this Amendment. To the extent of any inconsistency between the terms and conditions of the Original Lease and the terms and conditions of this Amendment, the terms and
conditions of this Amendment shall apply and govern the parties. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which, together, shall constitute

one and the same Amendment. For purposes of this Amendment, signatures by facsimile or electronic PDF shall be binding to the same extent as original signatures.

[SIGNATURES ON FOLLOWING PAGES]

IN WITNESS WHEREOF, the parties hereto have executed this Amendment as of the day and year first above written.

LANDLORD:

TREAPACIFICPLAZA, LLC,
a Delaware limited liability company

By: Teachers Insurance and Annuity Association of America, a New York corporation, for the benefit of its Real Estate Account, its sole member

By: /s/ Erik Sobek
Print Name: Erik Sobek
Title: Senior Director

TENANT:

Tandem Diabetes Care, Inc.,
a Delaware corporation

By: /s/ David B. Berger
Print Name: David B. Berger
Title: EVP, Chief Legal & Compliance Officer & Secretary

By: /s/ Jim Leal
Print Name: Jim Leal
Title: Sr. Vice President, Operations

EXHIBIT A EXPANSION SPACE

(Suites 120, 150 and 300)

10935 VISTA SORRENTO PARKWAY

SUITE 150
- 3,329 RSF
- Spec Suite
  Double door entrance off lobby

SUITE 120
- 5,477 RSF
- Spec Suite

10935 VISTA SORRENTO PARKWAY

SUITE 300
- 24,875 RSF
- Full floor available
- Entrance off elevator lobby

EXHIBIT B

WORK LETTER
[TENANT BUILD W/ALLOWANCE]

1. **TENANT IMPROVEMENTS**. As used in the Amended Lease and this Work Letter, the term " **Tenant Improvements**" or "**Tenant Improvement Work**" or "**Tenant's Work**" means those items of general tenant improvement construction for the Third Floor Expansion Space shown on the Final Plans (described in Section 4 below), more particularly described in Section 5 below. Tenant intends to complete the Tenant Improvements on or before December 1, 2019.

2 . **WORK SCHEDULE**. Prior to commencing construction, Tenant will deliver to Landlord, for Landlord's review and approval, a schedule (" **Work Schedule**"), which will set forth the timetable for the planning and completion of the installation of the Tenant Improvements.

3 . **CONSTRUCTION REPRESENTATIVES**. Landlord hereby appoints the following person(s) as Landlord's representative ("**Landlord's Representative**") to act for Landlord in all matters covered by this Work Letter: Evan Cassalato at Cruzan - CM Management Services. evan@cruzan.co

Tenant hereby appoints the following person(s) as Tenant's representative (" **Tenant's Representative**") to act for Tenant in all matters covered by this Work Letter: Danielle Schuh - DSchuh@tandemdiabetes.com.

All communications with respect to the matters covered by this Work Letter are to be made to Landlord's Representative or Tenant's Representative, as the case may be, in writing in compliance with the notice provisions of the Original Lease. Either party may change its representative under this Work Letter at any time by written notice to the other party in compliance with the notice provisions of the Original Lease.

4. **TENANT IMPROVEMENT PLANS**

(a) **Preparation of Space Plans**. In accordance with the Work Schedule, Landlord agrees to meet with Tenant's architect and/or space planner for the purpose of promptly reviewing preliminary space plans for the layout of the Premises prepared by Tenant ("**Space Plans**"). Landlord shall provide Tenant and its design professionals with as-built plans and specifications for the base Building and Building systems promptly following the Effective Date (collectively, the "**Base Building Plans**"). The Space Plans are to be sufficient to convey the architectural design of the Premises and layout of the Tenant Improvements therein and are to be submitted to Landlord in accordance with the Work Schedule for Landlord's approval, including as to floor space configuration and implementation of Building Standard improvements and finishes or better as utilized in Suite 150 of the Premises as to all lobby and common corridors, ceiling tiles, lights (based on the portion of Suite 150 with drop ceilings), doors, hardware, glass (sidelight or full glass) and kitchen finishes as the "Minimum Specifications and Finishes". Attached hereto as Exhibit B-1 is a detailed specification sheet for the Minimum Specifications and Finishes. Landlord agrees not to withhold its approval as to elements of Tenant's Space Plans to the extent conforming to or exceeding Landlord's Minimum Specifications and Finishes. If Landlord reasonably disapproves any aspect of the Space Plans other than as to specifications and finishes which meet Landlord's Minimum Specifications and Finishes, Landlord will advise Tenant in writing of such disapproval and the reasons therefor in accordance with the Work Schedule. Tenant will then submit to Landlord for Landlord's approval, in accordance with the Work Schedule, a redesign of the Space Plans incorporating the revisions reasonably required by Landlord. Landlord shall advise Tenant within five (5) business days after Landlord's receipt of the Space Plans if the same are unsatisfactory or incomplete in any respect. Landlord's notice of disapproval of the Space Plans, if any, shall describe the basis for Landlord's disapproval (based upon a commercially reasonable standard) in reasonable detail, as well as the changes which Landlord requires in order to approve the Space Plans and the Space Plans shall not be disapproved where and to the extent conforming to or exceeding Landlord's Minimum Specifications and Finishes. If Tenant is so advised, Tenant shall promptly cause the Space Plans to be revised to Landlord's reasonable satisfaction. The foregoing Space Plans procedure, and the submissions/approvals related thereto, shall be followed until the Space Plans are approved by Landlord, however, after the initial review, Landlord shall respond within three (3) business days to any revisions, and any failure of Landlord to respond within the foregoing time periods shall constitute Landlord's approval of the Space Plans in form most recently provided by Tenant to Landlord (collectively, the " **Landlord Approval Process**").

(b) **Preparation of Final Plans**. Based on the approved Space Plans, and in accordance with the Work Schedule, Tenant's architect will prepare complete architectural plans, drawings and specifications and complete engineered mechanical, structural and electrical working drawings for all of the Tenant Improvements for the Premises (collectively, the "**Final Plans**"). The Final

Plans will show (a) the subdivision (including partitions and walls), layout, lighting, finish and decoration work (including carpeting and other floor coverings) for the Third Floor Expansion Space; (b) all internal and external communications and utility facilities which will require conduiting or other improvements from the base Building shell work and/or within common areas; and (c) all other specifications for the Tenant Improvements. The Final Plans will be submitted to Landlord for signature to confirm that they are consistent with the Space Plans. If Landlord reasonably disapproves any aspect of the Final Plans based on any inconsistency with the Space Plans, Landlord agrees to advise Tenant in writing of such disapproval and the reasons therefor within the time frame set forth in the Work Schedule and, in all events, consistent with the Landlord Approval Process (as the same shall be applied to the approval of the Final Plans). In accordance with the Work Schedule and the Landlord Approval Process, as applicable, Tenant will then cause Tenant's architect to redesign the Final Plans incorporating the revisions reasonably requested by Landlord so as to address any inconsistency with the Space Plans or other design issues.

(c) **Requirements of Tenant's Final Plans**. Tenant's Final Plans will include locations and complete dimensions, and the Tenant Improvements, as shown on the Final Plans, will: (i) be compatible with the Building shell and with the design, construction and equipment of the Building; (ii) if not comprised of the Building standards set forth in the written description thereof (the "**Standards**"), then compatible with and of at least equal quality as the Standards and approved by Landlord; (iii) comply with all applicable laws, ordinances, rules and regulations of all governmental authorities having jurisdiction, and all applicable insurance regulations; (iv) not require Building service beyond the level normally provided to other tenants in the Building and will not overload the Building floors; and (v) be of a nature and quality consistent with the overall objectives of Landlord for the Building, as determined by Landlord in its reasonable but subjective discretion.

(d) **Submittal of Final Plans**. Once approved by Landlord and Tenant, Tenant's architect will submit the Final Plans to the appropriate governmental agencies for plan checking and the issuance of a building permit. Tenant's architect, with Landlord's cooperation, will make any changes to the Final Plans which are requested by the applicable governmental authorities to obtain the building permit. After approval of the Final Plans no further changes may be made without the prior written approval of both Landlord and Tenant, and then only after agreement by Tenant to pay any excess costs resulting from the design and/or construction of such changes, if any. Notwithstanding the foregoing, the cost to make any changes to the Final Plans resulting from defects in the construction of the Building, or for pre-existing violations of applicable law applicable to the Building (collectively, "**Existing Building Defects or Violations**") shall be borne solely by Landlord and shall not reduce the Allowance available to Tenant.

(e) **Changes to Shell of Building**. If the Final Plans or any amendment thereof or supplement thereto shall require changes in the Building shell, the increased cost of the Building shell work caused by such changes will be paid for by Tenant or charged against the "Allowance" described in Section 5 below, excluding any changes due to Existing Building Defects or Violations which shall be borne solely by Landlord and shall not reduce the Allowance available to Tenant.

(f) **Work Cost Estimate and Statement**. Prior to the commencement of construction of any of the Tenant Improvements shown on the Final Plans, Tenant will submit to Landlord a written estimate of the cost to complete the Tenant Improvement Work, which written estimate will be based on the Final Plans taking into account any modifications which may be required to reflect changes in the Final Plans required by the City or County in which the Premises are located (the "**Work Cost Estimate**"). Landlord will either approve the Work Cost Estimate or disapprove specific items that are inconsistent with the Final Plans and submit to Tenant revisions to the Final Plans to reflect deletions of and/or substitutions for such disapproved items. Submission and approval of the Work Cost Estimate will proceed in accordance with the Work Schedule and the Landlord Approval Process (as the same shall be applied to the approval of the Work Cost Estimate, provided that Landlord's review shall be limited to identifying specific items in the Work Cost Estimate that are inconsistent with the Final Plans). Upon Landlord's approval of the Work Cost Estimate (such approved Work Cost Estimate to be hereinafter known as the "**Work Cost Statement**"), Tenant will have the right to purchase materials and to commence the construction of the items included in the Work Cost Statement pursuant to Section 6 hereof. If the total costs reflected in the Work Cost Statement exceed the Allowance described in Section 5 below, Tenant agrees to pay such excess.

(g) **Defects in Design Documents**. Tenant and Tenant's architect and space planner and other design professionals ("**Tenant's Design Team**") shall be entitled to rely on the accuracy and correctness of the Base Building Plans to the extent and in the degree customary in the design and construction industry for projects in the same locality as the Project and similar in size and scope to the design of the Tenant Improvements. In the event the Space Plan or the Final Plan (collectively, the "**Tenant Improvement Construction Documents**") become materially inaccurate as a result of Tenant's Design Team's reliance on the Base Building Plans, and such Base Building Plans are determined to be materially inconsistent with the Building as constructed, then, Landlord shall be responsible for the actual cost to Tenant to effect the correction to the Tenant Improvement Construction Documents to alleviate such deficiency and Landlord shall pay the actual cost to correct such Tenant Improvement Construction Documents (as such cost shall be verified to Landlord's reasonable satisfaction), or to perform at Landlord's expense in accordance with the corrected Tenant Improvement Construction Documents, the re-construction of the materially adversely affected portions of the Tenant Improvements.

5. **PAYMENT FOR THE TENANT IMPROVEMENTS**

(a) **Allowance**. Landlord hereby grants to Tenant the Allowance described in Paragraph 11 of the Amendment to which this Work Letter is attached. The Allowance is to be used only for:

(i) Payment of the cost of preparing the Space Plans and the Final Plans, including mechanical, electrical, plumbing and structural drawings and of all other aspects necessary to complete the Final Plans. The Allowance will not be used for the payment of extraordinary design work requested by Tenant that is not consistent with the scope of the Standards (i.e., above-standard design work) or for payments to any other consultants, designers or architects other than Tenant's architect.

(ii) The payment of plan check, permit and license fees relating to construction of the Tenant Improvements and preparation of bid packages in connection with the selection of contractors, subcontractors and vendors for the Tenant Improvement work.

(iii) Construction of the Tenant Improvements, including, without limitation, the following:

(aa) Installation within the Third Floor Expansion Space of all partitioning, doors, floor coverings, ceilings, wall coverings and painting, millwork and similar items;

(bb) All electrical wiring, lighting fixtures, outlets and switches, and other electrical work necessary for the Third Floor Expansion Space;

(cc) The furnishing and installation of all duct work, terminal boxes, diffusers and accessories necessary for the heating, ventilation and air conditioning systems within the Third Floor Expansion Space, including the cost of meter and key control for after-hour air conditioning;

(dd) Any additional improvements to the Third Floor Expansion Space required for Tenant's use of the Third Floor Expansion Space including, but not limited to, odor control, special heating, ventilation and air conditioning, noise or vibration control or other special systems or improvements;

(ee) All fire and life safety control systems such as fire walls, sprinklers, halon, fire alarms, including piping, wiring and accessories, necessary for the Third Floor Expansion Space;

(ff) All plumbing, fixtures, pipes and accessories necessary for the Third Floor Expansion Space;

(gg) Testing and inspection costs;

(hh) Design and installation of Tenant's Building signage; and

(ii) Fees and costs attributable to general conditions associated with the construction of the Tenant Improvements plus a two percent (2%) construction administration fee based on total Tenant Improvement hard construction costs ("**Construction Administration Fee**") to cover the services of Landlord's tenant improvement coordinator, such Construction Administration Fee to Landlord not to exceed $35,000 in the aggregate.

(b) **Excess Costs**. The cost of each item referenced in Section 5(a) above shall be charged against the Allowance. If the work cost exceeds the Allowance, Tenant shall be solely responsible for payment of all excess costs, including the Construction Administration Fee (as and when performance of such changes actually occurs), which fee shall be paid to Landlord within five (5) business days after invoice therefor; provided, however, that Landlord will first apply toward any such costs any remaining balance of the Allowance. In no event will the Allowance be used to pay for Tenant's furniture, artifacts, equipment, telephone systems or any other item of personal property which is not affixed to the Third Floor Expansion Space.

(c) **Changes**. Any changes to the Final Plans will be approved by Landlord and Tenant in the manner set forth in Section 4 above. Tenant shall be solely responsible for any additional costs associated with such changes including the Construction Administration Fee (as and when performance of such changes actually occurs), which fee shall be paid to Landlord within five (5) business days after invoice therefor; provided, however, that Landlord will first apply toward any such costs any remaining balance of the Allowance. Landlord will have the right to decline Tenant's request for a change to the Final Plans if such changes are inconsistent with the provisions of Section 4 above. Notwithstanding the foregoing, any changes due to Existing Building Defects or Violations shall be borne solely by Landlord and shall not reduce the Allowance available to Tenant.

(d) **Governmental Cost Increases**. If increases in the cost of the Tenant Improvements as set forth in the Work Cost Statement are due to requirements of any governmental agency (excluding any changes due to Existing Building Defects or Violations which shall be borne solely by Landlord and shall not reduce the Allowance available to Tenant), Tenant shall be solely responsible for such additional costs including the Construction Administration Fee (as and when performance of such changes actually occurs), which fee shall be paid to Landlord within five (5) business days after invoice therefor; provided, however, that Landlord will first apply toward any such increase any remaining balance of the Allowance.

(e) **Unused Allowance Amounts**. Any unused portion of the Allowance upon completion of the Tenant Improvements will not be refunded to Tenant or be available to Tenant as a credit against any obligations of Tenant under the Lease.

(f) **Disbursement of the Allowance**. Provided Tenant is not in default following the giving of notice and passage of any applicable cure period under the Amended Lease or this Work Letter which is then continuing, Landlord shall disburse the Allowance to Tenant not less frequently than monthly to reimburse Tenant for the actual construction costs which Tenant incurs in connection with the construction of the Tenant Improvements upon completion of the Tenant Improvements included in such disbursement request and satisfaction of the following conditions:

(i) Tenant has delivered to Landlord a draw request ("**Draw Request**") in the form attached as Exhibit B-1 with respect to the Improvements specifying that the requisite portion of Tenant's Work has been completed, together with invoices, receipts and bills evidencing the costs and expenses set forth in such Draw Request and evidence of payment by Tenant for all costs which are payable in connection with such Tenant's Work covered by the Draw Request. The Draw Request shall constitute a representation by Tenant that, to Tenant's actual knowledge, the Tenant's Work identified therein has been completed in a good and workmanlike manner and in accordance with the Final Plans and the Work Schedule;

(ii) The architect for the Tenant Improvements has certified to Landlord that the Tenant Improvements have been completed to the level indicated in the Draw Request in accordance with the Final Plans;

(iii) Tenant has delivered to Landlord properly executed mechanics lien releases from all of Tenant's contractors, agents and suppliers in compliance with California Civil Code Sections 8120 through 8138, which lien releases shall be conditional with respect to the then-requested payment amounts and unconditional with respect to payment amounts previously disbursed by Landlord;

(iv) Landlord or Landlord's architect or construction representative has inspected the Tenant Improvements and determined that the portion of Tenant's Work covered by the Draw Request has been completed in a good and workmanlike manner;

(v) With respect to the final disbursement of the Allowance, which shall include all retention amounts owed to Tenant's general contractor (" **Final Disbursement**"), not less than thirty-five (35) days shall have elapsed following the filing of a valid notice of completion by Tenant for the Tenant Improvements;

(vi) With respect to the Final Disbursement, Tenant has delivered to Landlord: (i) properly executed mechanics lien releases from all of Tenant's contractors, agents and suppliers in compliance with both California Civil Code Sections 8120 through 8138, which lien releases shall be conditional with respect to the then-requested payment amounts and unconditional with respect to payment amounts previously disbursed by Landlord; (ii) an application and certificate for payment (AIA form G702-1992 or equivalent) signed by Tenant's architect/space planner; (iii) original stamped building permit plans; (iv) copy of the building permit; (v) original stamped building permit inspection card with all final sign-offs; (vi) a reproducible copy (in a form approved by Landlord) of the "as-built" drawings of the Tenant Improvements; (vii) air balance reports; (viii) excess energy use calculations; (ix) one year warranty letters from Tenant's general contractors; (x) manufacturer's warranties and operating instructions; (xi) final punchlist completed and signed off by Tenant's architect/space planner; and (xii) an acceptance of the Third Floor Expansion Space signed by Tenant; and

(x) With respect to the final disbursement, Tenant has delivered to Landlord evidence satisfactory to Landlord that all construction costs for which Tenant is responsible under this Work Letter in excess of the Allowance have been paid for by Tenant.

6 . **CONSTRUCTION OF TENANT IMPROVEMENTS**. Following Landlord's approval of the Final Plans and the Work Cost Statement described in Section 4(f) above, Tenant's contractor (selected or pre-approved as provided in Section 8(n)) will commence and diligently proceed with the construction of the Tenant Improvements. Tenant shall use commercially reasonable efforts to cause its contractor to complete the Tenant Improvements in a good and workmanlike manner in accordance with the Final Plans and the Work Schedule. Tenant agrees to use commercially reasonable efforts to cause construction of the Tenant Improvements to commence promptly following the issuance of a building permit for the Tenant Improvements. Landlord shall

have the right to enter upon the Third Floor Expansion Space to inspect Tenant's construction activities following reasonable advance notice Tenant.

7. **DELIVERY OF POSSESSION; TERM AND RENT COMMENCEMENT DATE**

(a) **Delivery of Possession**. Landlord agrees to deliver possession of the Third Floor Expansion Space (currently vacant) to Tenant promptly following execution of this Amendment by the parties in the condition required under the Amended Lease.

(b) **Third Floor Expansion Space Commencement Date**. The Third Floor Expansion Space Commencement Date and Tenant's obligation to pay rent with respect to the Third Floor Expansion Space will commence upon the earlier of (i) substantial completion of the Tenant Improvements (as defined below in Section 7(c)) below or (ii) January 1, 2020 (the "**TFESCD**").

(c) **Substantial Completion; Punch-List**. For purposes of Section 8(b) above, the Tenant Improvements will be deemed to be "substantially completed" when Tenant's contractor certifies in writing to Landlord and Tenant that Tenant has substantially performed all of the Tenant Improvement Work required to be performed by Tenant under this Work Letter, other than decoration and minor "punch-list" type items and adjustments which do not materially interfere with Tenant's use of the Third Floor Expansion Space; and Tenant has obtained a temporary certificate of occupancy or other required equivalent approval from the local governmental authority permitting occupancy of the Third Floor Expansion Space. Within ten (10) days after receipt of such certificates, Tenant and Landlord will conduct a walk-through inspection of the Third Floor Expansion Space and Landlord shall provide to Tenant a written punch-list specifying those decoration and other punch-list items which require completion in accordance with the Final Plans, which items Tenant will thereafter diligently complete.

8. **MISCELLANEOUS CONSTRUCTION COVENANTS**

(a) **No Liens**. Tenant shall not allow the Tenant Improvements or the Building or any portion thereof to be subjected to any mechanic's, materialmen's or other liens or encumbrances arising out of the construction of the Tenant Improvements.

(b) **Diligent Construction**. Tenant will promptly, diligently and continuously pursue construction of the Tenant Improvements to completion in compliance in all material respects with the Final Plans, the Work Schedule and this Work Letter. Landlord and Tenant shall cooperate with one another during the performance of Tenant's Work to effectuate such work in a timely and compatible manner.

(c) **Compliance with Laws**. Tenant will construct the Tenant Improvements in a safe and lawful manner. Tenant shall, at its sole cost and expense, comply with all applicable laws and all regulations and requirements of, and all licenses and permits issued by, all municipal or other governmental bodies with jurisdiction which pertain to the installation of the Tenant Improvements. Copies of all filed documents and all permits and licenses shall be provided to Landlord. Any portion of the Tenant Improvements which is not acceptable to any applicable governmental body, agency or department, or is not in compliance with the Final Plans, shall be promptly repaired or replaced by Tenant at Tenant's expense excluding any changes due to Existing Building Defects or Violations which shall be borne solely by Landlord and shall not reduce the Allowance available to Tenant. Notwithstanding any failure by Landlord to object to any such Tenant Improvements, Landlord shall have no responsibility therefor.

(d) **Indemnification**. Subject to the terms of the Original Lease regarding insurance and waiver of subrogation by the parties, Tenant hereby indemnifies and agrees to defend and hold Landlord, the Third Floor Expansion Space and the Building harmless from and against any and all suits, claims, actions, losses, costs or expenses of any nature whatsoever, together with reasonable attorneys' fees for counsel of Landlord's choice, arising out of or in connection with the Tenant Improvements or the performance of Tenant's Work; provided however all such claims shall be limited to claims for worker's compensation, personal injury or property damage, and any materialmen's and mechanic's liens and shall exclude any such claims arising out of the negligence or misconduct of Landlord or its agents, including Landlord's Representative.

(e) **Insurance**. Construction of the Tenant Improvements shall not proceed without Tenant first requiring that its general contractor maintain workers' compensation and commercial general liability insurance and property damage insurance as well as "All Risks" builders' risk insurance, with minimum coverage of $2,000,000 or such other amount as may be approved by Landlord in writing and issued by an insurance company reasonably satisfactory to Landlord. Not less than ten (10) days before commencing the construction of the Tenant Improvements, certificates of such insurance shall be furnished to Landlord. All such policies shall provide that thirty (30) days prior notice must be given to Landlord before modification, termination or cancellation. All insurance policies maintained by Tenant's contractor pursuant to this Work Letter shall name Tenant, Landlord and any lender with an interest in the Third Floor Expansion Space as additional insureds.

(f) **Construction Defects**. Landlord shall have no responsibility for the Tenant Improvements and Tenant will remedy, at Tenant's own expense, and be responsible for any and all defects in the Tenant Improvements (excluding any Existing Building Defects or Violations, the cost of which shall be borne solely by Landlord) that may appear during or after the completion thereof whether the same shall affect the Tenant Improvements in particular or any parts of the Third Floor Expansion Space in general. Tenant shall be responsible for correcting any defect in any portion of the Tenant Improvements constructed by Tenant or Tenant's contractor or subcontractors (other than arising due to any Existing Building Defects or Violations which shall remain Landlord's responsibility at its sole cost), or by reason of inadequate cleanup due to, and following completion of, the Tenant Improvements.

(g) **Additional Services**. If the construction of the Tenant Improvements shall require that additional services or facilities (including, but not limited to, hoisting, cleanup or other cleaning services, trash removal, field supervision, or ordering of materials) be provided by Landlord, then Tenant shall pay Landlord for such items at Landlord's actual cost without markup. Electrical power and heating, ventilation and air conditioning shall be available to Tenant during normal business hours for construction purposes at no charge to Tenant.

(h) **Coordination of Labor**. All of Tenant's contractors, subcontractors, employees, servants and agents must work in harmony with and shall not interfere with any labor employed by Landlord, or Landlord's contractors or by any other tenant or its contractors with respect to the any portion of the Property. Nothing in this Work Letter shall, however, require Tenant to use union labor.

(i) **Work in Adjacent Areas** . Any work to be performed in areas adjacent to the Third Floor Expansion Space shall be performed only after obtaining Landlord's express written permission, which shall not be unreasonably withheld, conditioned or delayed, and shall be done only if an agent or employee of Landlord is present.

(j) **HVAC Systems** . Tenant agrees to be entirely responsible for the maintenance or the balancing of any heating, ventilating or air conditioning system installed by Tenant and/or maintenance of the electrical or plumbing work installed by Tenant and/or for maintenance of lighting fixtures, partitions, doors, hardware or any other installations made by Tenant.

(k) **Coordination with Lease**. Nothing herein contained shall be construed as (i) constituting Tenant as Landlord's agent for any purpose whatsoever, or (ii) a waiver by Landlord or Tenant of any of the terms or provisions of the Amended Lease. Any default by Tenant following the giving of notice and the passage of any applicable cure period with respect to any portion of this Work Letter shall be deemed a breach of the Amended Lease for which Landlord shall have all the rights and remedies as in the case of a breach of said Lease.

(l) **Approval of Plans**. Landlord will not check Tenant drawings for building code compliance. Approval of the Final Plans by Landlord is not a representation that the drawings are in compliance with the requirements of governing authorities, and it shall be Tenant's responsibility to meet and comply with all federal, state, and local code requirements. Approval of the Final Plans does not constitute assumption of responsibility by Landlord or its architect for their accuracy, sufficiency or efficiency, and Tenant shall be solely responsible for such matters. In all matters requiring the approval of Landlord under this Work Letter, such approval shall not be unreasonably withheld, conditioned, or delayed.

(m) **Tenant's Deliveries**. Tenant shall deliver to Landlord, at least five (5) business days prior to the commencement of construction of Tenant's Work, the following information:

(i) The names, addresses, telephone numbers, and primary contacts for the general, mechanical and electrical contractors Tenant intends to engage in the performance of Tenant's Work; and

(ii) The date on which Tenant's Work will commence, together with the estimated dates of completion of Tenant's construction and fixturing work (which information may be included in the Work Schedule for purposes of compliance herewith).

(n) **Qualification of Contractors**. Once the Final Plans have been proposed and approved, Tenant shall select and retain a general contractor, major subcontractors and vendors (such as HVAC engineers) from a list of preferred contractors, subcontractors and vendors provided by Landlord in connection with all aspects of the design and construction of the Tenant Improvement Work in accordance with the Final Plans. All contractors, subcontractors and vendors engaged by Tenant shall be bondable and licensed, possessing good labor relations, capable of performing quality workmanship and working in harmony with Landlord' s general contractor and other contractors on the job, if any, all as determined by Landlord. All Tenant Improvement Work shall be coordinated with any ongoing general construction work on the Site or in the Building, if any. Landlord hereby approves JB Pacific as Tenant's general contractor, and Studio Varone Architecture as Tenant's architect.

(o) **Warranties**. Tenant shall cause its general contractor to provide warranties for not less than one (1) year (or such shorter time as may be customary and available without additional expense to Tenant) against defects in workmanship, materials and equipment, which warranties shall run to the benefit of Landlord or shall be assignable to Landlord to the extent that Landlord is obligated to maintain any of the improvements covered by such warranties.

(p) **Landlord's Performance of Work**. Within twenty (20) days after receipt of Landlord's notice of Tenant's failure to perform its obligations under this Work Letter, if Tenant shall fail to commence to cure such failure, Landlord shall have the right, but not the obligation, to perform, on behalf of and for the account of Tenant, subject to reimbursement of the cost thereof by Tenant, any and all of Tenant's Work which Landlord determines, in its reasonable discretion, should be performed immediately and on an emergency basis for the best interest of the Third Floor Expansion Space including, without limitation, work which pertains to structural components, mechanical, sprinkler and general utility systems, roofing and removal of unduly accumulated construction material and debris; provided, however, Landlord shall give Tenant at least twenty (20) days prior notice to the performance of any of Tenant's Work.

(q) **As-Built Drawings**. Tenant shall cause "As-Built Drawings" (excluding furniture, fixtures and equipment) to be delivered to Landlord and/or Landlord's representative no later than sixty (60) days after the completion of Tenant's Work. In the event these drawings are not received by such date, Landlord may, at its election, cause said drawings to be obtained and Tenant shall pay to Landlord, as additional rent, the cost of producing these drawings.

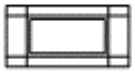
9. **FREIGHT/CONSTRUCTION ELEVATOR**. Landlord will, consistent with its obligation to other tenants in the Building, if appropriate and necessary, make the freight/construction elevator reasonably available to Tenant in connection with the construction of the Tenant Improvements. Tenant agrees to pay for any after-hours staffing of the freight/construction elevator, if needed.

EXHIBIT B-1

MINIMUM SPECIFICATIONS AND FINISHES
Pac Plaza Building Standards

Lighting

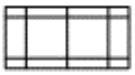
F-1 LIGHTING FIXTURE:	LINEAR LED PENDANT
BUILDING STANDARD	
MANUFACTURER	PINNACLE LIGHTING
MODEL	EDGE EVOLUTION EX3 (DIRECT / SATINE LENS) 35K / 384 LM SINGLE CIRCUIT DIMMING
DIMENSIONS	3.5" X 5.5" X 8'-0"
FINISH	WHITE (MATTE)
SUPPORT	AIRCRAFT CABLE (SILVER)



F-2 LIGHTING FIXTURE:	LED DIRECT / INDIRECT LIGHTING FIXTURE
BUILDING STANDARD	
MANUFACTURER	LITHONIA LIGHTING
MODEL	AVANTE
DIMENSIONS	2'-0" x 4'-0"
TRIM & FINISH	WHITE

F-3 LIGHTING FIXTURE:	LED PENDANT
BUILDING STANDARD	
MANUFACTURER	BASELITE LIGHTING
MODEL	TR1/PR/61 LED 50 DIMMING BALLAST
DIMENSIONS	12" X 15"
FINISH	BLACK
SHADE	CLEAR
SUPPORT	CABLE (BLACK)

Acoustical Ceiling Grid & Tile



SUSPENDED ACOUSTICAL CEILING GRID & TILE	
BUILDING STANDARD	
MANUFACTURER	ARMSTRONG
GRID	SUPRA FINE XL 9/16 GRID
CEILING TILE	ARMSTRONG DUNE
TEGULAR	
CEILING HEIGHT	10'-0" A.F.F.

Fixtures, Finishes, and Equipment (Break Area)

CABINETS:

CB	MANUFACTURER:	FORMICA / PURE WHITE / MATTE 949-58
	CABINET PULLS:	MOCKET DP3B / 4" / MATTE BLACK

COUNTERS:

CT	MANUFACTURER:	CAESARSTONE / PURE WHITE / 1141

APPLIANCES:

DW	DISHWASHER ASKO 30 SERIES DBI633IS 32 3/4"H X 23 7/8"W X 22 7/8"D	
R1	REFRIGERATOR:	WHIRLPOOL / #WRF535SWBM / STAINLESS STEEL
S1	SINK:	KOHLER / VAULT UNDERMOUNT SINK / K-3894-2 / STAINLESS
	FAUCET:	DELTA / TRINSIC / 9159-BL-DST / MATTE BLACK
	GARBAGE DISPOSAL:	BUILDING STANDARD
	INSTA HOT:	ELECTRIC TANKLESS WATER HEATER MANUFACTURER: CHRONOMITE SERIES INSTANT FLOW SR STANDARD FLOW DIMENSIONS: 6 $\frac{1}{4}$" X 9 $\frac{1}{2}$" X 2 $\frac{3}{4}$"

CARPET TILE
BUILDING STANDARD OPTIONS OR EQUAL
TYPICAL BUILDING STANDARD OPTIONS:
- INTERFACE AERIAL SQUARES COLLECTION AE310
- INTERFACE AERIAL PLANKS COLLECTION AE311
- INTERFACE BIKE PATH PLANKS COLLECTION BP410

Doors, Frames, Hardware
FRAMES: Western Integrated or Equal Anodized Aluminum Frames
DOORS: PG Primed Solid Core MDO (Medium Density Overlay), AWI 5-Ply - Bonded Edges
HINGES: Hager 4-1/2" x 4-1/2" BB1279
LOCKS: Sargent Mortise 8200 Series

DRAW REQUEST FOR TENANT IMPROVEMENT ALLOWANCE

The following is the form that shall be used by _____ ("Tenant") as the Draw Request for the Tenant Improvement Allowance funds to be provided by _____ ("Landlord") pursuant to that certain lease between Landlord and Tenant for the premises at _____, CA, (the "Premises"):

_____

_____

_____

_____

Attn: _____

In accordance with the Lease dated as of _____ __, 2019, between Tenant and Landlord, Tenant requests, pursuant to Paragraph 5(f) of Exhibit B to the Lease, disbursement of a portion of the Allowance in the amount of $_____. Submittal of this Draw Request constitutes a representation by the undersigned that Tenant has completed Tenant's Work in the Premises at a cost equal to or greater than $_____ in a good, code compliant, and workmanlike manner and in accordance with the Final Permitted Plans for such Tenant's Work and that such Tenant's Work is free of liens.

TOTAL DRAW REQUEST $_____.

In accordance with the Paragraph 5(f) of Exhibit B to the Lease, Landlord is to disburse the Allowance upon Tenant's submittal of this Draw Request and satisfaction of the other requirements for disbursement of the Allowance as described therein.

TENANT:

_____,
a _____

By:
Name:
Title:

Date: _____

EXHIBIT C

TENANT'S COMMENCEMENT LETTER

To: TREA PACIFIC PLAZA, LLC, a Delaware limited liability company ("Landlord")

Date: _____

Tenant's Commencement Letter

_____

The undersigned, as the Tenant under that certain Lease dated as of January 10, 2019, as amended by First Amendment dated as of April __, 2019 (as amended, the "Lease"), between TREA PACIFIC PLAZA, LLC, a Delaware limited liability company, as Landlord, and the undersigned, as Tenant, as amended, hereby certifies that:

1. The undersigned has accepted possession and entered into occupancy of the Third Floor Expansion Space described in the Lease.

2. The Third Floor Expansion Space Commencement Date is _____.

3. The Third Floor Expansion Space Expiration Date of the Lease is _____.

4. The Lease is in full force and effect and has not been further modified or amended.

5. Landlord has performed all of its obligations to improve the Third Floor Expansion Space for occupancy by the undersigned.

Very truly yours,

TANDEM DIABETES CARE, INC.,

a Delaware corporation

By:

Name:

Title:

RIDER NO. 1 TO AMENDMENT

RIGHT OF FIRST OFFER

This Rider No. 1 is made and entered into by and between TREA PACIFIC PLAZA, LLC, a Delaware limited liability company ("**Landlord**"), and TANDEM DIABETES CARE, INC., a Delaware corporation ("**Tenant**"), as of the day and year of the Amendment between Landlord and Tenant to which this Rider is attached. Landlord and Tenant hereby agree that, notwithstanding anything contained in the Original Lease to the contrary, the provisions set forth below shall be deemed to be part of the Amended Lease and shall supersede any inconsistent provisions of the Original Lease. All references in the Original Lease and in this Rider to the "Lease" shall be construed to mean the Amended Lease (and all exhibits and Riders attached thereto), as amended and supplemented by this Rider. All capitalized terms not defined in this Rider shall have the same meaning as set forth in the Amended Lease.

1. **Grant of Option; Conditions**. Subject to the terms and conditions of this Rider No. 1, Tenant shall have a one-time right of first offer to lease (the "**Right of First Offer**") Suite 100 on the first (1st) floor in the Building ("**ROFO Space**"). Tenant's Right of First Offer shall be exercised as follows: at any time after Landlord has determined that the existing tenant in the ROFO Space as of the Effective Date of the Amendment to which this Rider is attached (Cisco) will not extend or renew the term of its lease for such ROFO Space (but prior to leasing such ROFO Space to a party other than the existing tenant), Landlord shall deliver written notice to Tenant (the "**ROFO Notice**") of the terms under which Landlord is prepared to lease the ROFO Space to Tenant including rental rate and length of term, which terms shall reflect the then fair market rental rate (hereinafter defined) for such ROFO Space. Tenant may lease such ROFO Space in its entirety only, under such terms, by delivering written notice of exercise to Landlord (the "**Notice of Exercise**") within thirty (30) days after the date of the ROFO Notice, except that Tenant shall have no such Right of First Offer and Landlord need not provide Tenant with a ROFO Notice, if:

a. Tenant is in default under the Amended Lease beyond any applicable cure periods at the time that Landlord would otherwise deliver the ROFO Notice; or

b. the existing tenant in the ROFO Space has notified Landlord that they intend to renew or extend its lease for such ROFO Space.

2. Terms for ROFO Space.

a. The term for the ROFO Space shall commence upon the commencement date stated in the ROFO Notice and thereupon such ROFO Space shall be considered a part of the Premises, provided that all of the terms stated in the ROFO Notice shall govern Tenant's leasing of the ROFO Space and only to the extent that they do not conflict with the ROFO Notice, the terms and conditions of this Lease shall apply to the ROFO Space. The term for the ROFO Space shall expire per the terms of the ROFO Notice, notwithstanding that the expiration date stated in the ROFO Notice may not be coterminous with the then expiration date for the Premises Term.

b. Tenant shall pay Base Rent and Additional Rent for the ROFO Space in accordance with the terms and conditions of the ROFO Notice or as otherwise agreed by Landlord and Tenant.

c. The ROFO Space (including improvements and personalty, if any) shall be accepted by Tenant in its condition and as-built configuration existing on the earlier of the date Tenant takes possession of the ROFO Space or as of the date the term for such ROFO Space commences, unless the ROFO Notice specifies any work to be performed by Landlord in the ROFO Space, in which case Landlord shall perform such work in the ROFO Space. If Landlord is delayed delivering possession of the ROFO Space due to the holdover or unlawful possession of such space by any party, Landlord shall use reasonable efforts to obtain possession of the space, and the commencement of the term for the ROFO Space shall be postponed until the date Landlord delivers possession of the ROFO Space to Tenant free from occupancy by any party subject to such outside date therefor as the parties shall agree upon.

3. Termination of Right of First Offer. The rights of Tenant hereunder with respect to the ROFO Space shall terminate on the earlier to occur of: (i) Tenant's failure to exercise its Right of First Offer within the thirty (30) day period provided in Section 1 above; and (ii) the date Landlord would have provided Tenant a ROFO Notice if one or more of the conditions set forth in Section 1(a) and 1(b) above then exists; provided that (i) Landlord shall have contemporaneously provided written notice of the existence of such condition to Tenant, and (ii) if the condition described in Section 1(b) above is the basis for Landlord's failure to send the ROFO Notice, and Landlord and the tenant described in Section 1(b) above do not enter into a binding extension, renewal, or lease of the ROFO Space, then Tenant's Right of First Offer with respect to the ROFO Space shall again apply.

4 . ROFO Amendment. If Tenant exercises its Right of First Offer, Landlord shall prepare an amendment (the "**ROFO Amendment**") adding the ROFO Space to the Premises on the terms set forth in the ROFO Notice and reflecting the changes in the Base Rent, Rentable Square Footage of the Premises, Tenant's Proportionate Share and other appropriate terms. A copy of the ROFO Amendment shall be sent to Tenant promptly after Landlord's receipt of the Notice of Exercise executed by Tenant, and Tenant shall execute and return the ROFO Amendment to Landlord within fifteen (15) days thereafter provided such ROFO Amendment reflects the terms set forth in this Rider.

5 . Subordination. Notwithstanding anything herein to the contrary, Tenant's Right of First Offer is subject and subordinate to any renewal of Landlord's lease with the existing tenant of the ROFO Space, Cisco, pursuant to any option or agreement between Landlord and Cisco to stay in the Building.

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: August 1, 2019

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: August 1, 2019

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 June 30, 2019, 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: August 1, 2019

/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 June 30, 2019, 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: August 1, 2019

/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.