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 September 30, 2018

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	Name of Exchange on Which Registered
Common Stock, par value $0.001 per share	**The NASDAQ Stock Market LLC**

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 October 24, 2018, there were 57,369,283 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)

	September 30, 2018 (Unaudited)	December 31, 2017 (Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 32,327	$ 13,700
Short-term investments	81,254	479
Accounts receivable, net	21,689	20,793
Inventory, net	24,366	26,993
Prepaid and other current assets	3,035	2,191
Total current assets	162,671	64,156
Property and equipment, net	17,582	19,631
Patents, net	1,212	1,457
Restricted cash—long term	-	10,000
Other long-term assets	141	102
Total assets	$ 181,606	$ 95,346
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 6,198	$ 5,150
Accrued expense	3,931	2,832
Employee-related liabilities	17,229	14,488
Deferred revenue	3,703	2,526
Common stock warrants	20,643	5,432
Other current liabilities	6,846	5,657
Total current liabilities	58,550	36,085
Notes payable—long-term	-	76,541
Deferred rent—long-term	4,028	4,687
Other long-term liabilities	3,599	7,181
Total liabilities	66,177	124,494
Commitments and contingencies (Note 8)		
Stockholders' equity (deficit):		
Common stock, $0.001 par value; 200,000 and 100,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively. 57,364 and 10,119 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively.	57	10
Additional paid-in capital	719,148	448,455
Accumulated other comprehensive loss	(13)	—
Accumulated deficit	(603,763)	(477,613)
Total stockholders' equity (deficit)	115,429	(29,148)
Total liabilities and stockholders' equity (deficit)	$ 181,606	$ 95,346

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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Sales	$ 46,264	$ 27,003	$ 107,667	$ 67,306
Cost of sales	24,468	15,131	59,381	40,680
Gross profit	21,796	11,872	48,286	26,626
Operating expenses:				
Selling, general and administrative	29,506	20,125	73,048	65,077
Research and development	7,999	4,914	20,430	14,910
Total operating expenses	37,505	25,039	93,478	79,987
Operating loss	(15,709)	(13,167)	(45,192)	(53,361)
Other income (expense), net:				
Interest and other income	443	60	833	179
Interest and other expense	(1,401)	(2,928)	(7,585)	(8,445)
Loss on extinguishment of debt	(5,313)	—	(5,313)	—
Change in fair value of stock warrants	(12,265)	—	(69,042)	—
Total other expense, net	(18,536)	(2,868)	(81,107)	(8,266)
Net loss	$ (34,245)	$ (16,035)	$ (126,299)	$ (61,627)
Other comprehensive loss:				
Unrealized gain (loss) on short-term investments	$ (19)	$ —	$ (13)	$ 1
Comprehensive loss	$ (34,264)	$ (16,035)	$ (126,312)	$ (61,626)
Net loss per share, basic and diluted	$ (0.62)	$ (3.09)	$ (2.81)	$ (13.79)
Weighted average shares used to compute basic and diluted net loss per share	55,615	5,190	44,993	4,468

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Nine Months Ended September 30,	
	2018	**2017**
Operating activities		
Net loss	$ (126,299)	$ (61,627)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	4,353	4,737
Interest expense related to amortization of debt discount and debt issuance costs	1,721	1,338
Provision for allowance for doubtful accounts	1,017	664
Provision for inventory reserve	397	316
Payment in kind interest accrual of notes payable	—	1,236
Change in fair value of common stock warrants	69,042	—
Amortization of premium (discount) on short-term investments	783	(16)
Stock-based compensation expense	13,427	10,502
Loss on extinguishment of debt	5,313	—
Other	155	69
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,913)	(73)
Inventory, net	2,752	(9,038)
Prepaid and other current assets	(823)	1,133
Other long-term assets	(39)	(53)
Accounts payable	1,083	522
Accrued expense	1,098	907
Employee-related liabilities	2,741	797
Deferred revenue	1,178	(4,137)
Other current liabilities	1,100	(601)
Deferred rent	(571)	(425)
Other long-term liabilities	1,033	(746)
Net cash used in operating activities	(22,452)	(54,495)
Investing activities		
Purchase of short-term investments	(100,550)	—
Proceeds from sales and maturities of short-term investments	18,500	8,500
Purchase of property and equipment	(2,098)	(4,299)
Net cash provided by (used in) investing activities	(84,148)	4,201
Financing activities		
Principal payments on notes payable	(87,711)	—
Proceeds from public offering, net of offering costs	172,929	25,125
Proceeds from exercise of warrants	29,536	—
Proceeds from common stock issued under employee benefit plans	473	570
Net cash provided by financing activities	115,227	25,695
Net increase (decrease) in cash and cash equivalents and restricted cash	8,627	(24,599)
Cash and cash equivalents and restricted cash at beginning of period	23,700	46,678
Cash and cash equivalents and restricted cash at end of period	$ 32,327	$ 22,079
Supplemental disclosures of cash flow information		
Interest paid	$ 5,841	$ 5,871
Supplemental schedule of noncash investing and financing activities		
Lease incentive - lessor-paid tenant improvements	$ —	$ 3,037
Debt discount included in other long-term liabilities	$ —	$ 6,720
Common stock warrants issued in connection with term loan	$ —	$ 3,331
Property and equipment included in accounts payable	$ 57	$ 72

See accompanying 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 next-generation flagship product that is updatable and designed to display continuous glucose monitoring (CGM), sensor information directly on the pump Home Screen. 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'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 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 will continue to provide ongoing service and support to existing t:slim, t:slim G4 and t:flex customers. In June 2018, the Company received approval by the United States Food and Drug Administration (FDA) for t:slim X2 with Basal-IQ technology, the Company's first generation Automated Insulin Delivery (AID) algorithm, and commenced commercial sales of this product in August 2018.

In August 2018, the Company commenced sales of the t:slim X2 in select geographies outside the United States.

In July 2016, the Company launched a Technology Upgrade Program that provided eligible t:slim and t:slim G4 customers a path to obtain the t:slim X2 hardware platform. Participating customers had the right to exchange their original t:slim and t:slim G4 for a t:slim X2 under a variable pricing structure. The Technology Upgrade Program expired on September 30, 2017.

The Company has incurred operating losses since its inception and, as reflected in the accompanying financial statements, the Company had an accumulated deficit of $603.8 million as of September 30, 2018, which included a net loss of $126.3 million for the nine months ended September 30, 2018. Management expects operating losses and negative cash flows to continue for at least the next 12 months.

As of September 30, 2018, the Company had $113.6 million in cash and cash equivalents and short-term investments in marketable securities. Management believes that the cash and investments on hand will be sufficient to satisfy its liquidity requirements for at least the next 12 months.

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, increase gross profits from higher sales of infusion sets, 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 equity and debt financing. The Company may in the future seek additional capital from public or private offerings of its capital stock, or it may elect to borrow additional amounts 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 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 funded its operations primarily through private and public equity and debt financing. The Company may in the future seek additional capital from public or private offerings of its capital stock, or it may elect to borrow amounts 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 financing will be available on acceptable terms, or at all.

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 financial statements and accompanying footnotes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2017 (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.

Reclassifications

Certain reclassifications of prior year amounts have been made to conform to the current year presentation.

2. Summary of Significant Accounting Policies

There have been no material changes in our significant accounting policies during the nine months ended September 30, 2018, as compared with those disclosed in the Annual Report other than adoption of the new revenue recognition standard (Revenue from Contracts with Customers Standard).

Use of Estimates

The preparation of the financial statements in conformity with U.S. GAAP requires management to make informed 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 financial statements and accompanying footnotes as of the date of the financial statements. Actual results could materially differ from those estimates and assumptions.

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.

Restricted Cash

The Company recorded $10.0 million of restricted cash as of December 31, 2017, for the minimum cash balance requirement in connection with the Amended and Restated Term Loan Agreement (Term Loan Agreement) with Capital Royalty Partners II, L.P. and its affiliated funds (CRG) (see Note 6, Term Loan Agreement). Due to the full repayment of the term loan in August 2018, no restricted cash balance existed at September 30, 2018. In January 2018, the Company adopted new guidance from the Financial Accounting Standards Board (FASB) that clarified how entities should classify certain cash receipts and cash payments on the statement of cash flows. As a result, the restricted cash balance that existed in prior periods is included as a component of cash and cash equivalents on the statement of cash flows in the relevant periods presented.

Accounts Receivable

The Company grants credit to various customers in the ordinary course of business. 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. Based on the borrowing rates currently available for loans with similar terms, the Company believes the fair value of its long-term notes payable approximates its carrying value. The estimated fair value of certain of the Company's common stock warrants is determined using the Black-Scholes pricing model as of September 30, 2018 and December 31, 2017 (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. The Company is paid directly by customers who use the products, distributors and third-party insurance payors.

In January 2018, the Company adopted the Revenue from Contracts with Customers Standard which supersedes 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 is 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 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 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 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 September 30, 2018 and December 31, 2017, $2.7 million and $2.0 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. Under the new guidance, 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. Historically, the allowance was recorded as a reduction of revenue and accounts receivable. The amount recorded on the Company's balance sheets for product return allowance was $0.2 million and $0.2 million at September 30, 2018 and December 31, 2017, 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 September 30, 2018 and December 31, 2017, the warranty reserve was $7.7 million and $5.6 million, respectively. The following table provides a reconciliation of the change in product warranty liabilities from December 31, 2017 through September 30, 2018 (in thousands):

Balance at December 31, 2017	$	5,640
Provision for warranties issued during the period		5,570
Settlements made during the period		(5,741)
Increases in warranty estimates		2,267
Balance at September 30, 2018	$	7,736
Current portion	$	4,137
Non-current portion		3,599
Total	$	7,736

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 2013 Stock Incentive Plan ("2013 Plan") and shares issued 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Warrants for common stock	710	-	710	-
Common stock options	5,155	8	3,031	3
ESPP	61	-	24	-
	5,926	8	3,765	3

Recent Accounting Pronouncements

In February 2016, the FASB issued final guidance for lease accounting. The new accounting standard 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 changes the definition of a lease and expands the disclosure requirements of lease arrangements. In July 2018, the FASB added a transition option for implementation that allows 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 of the new leases standard. The new accounting standard must be adopted using the modified retrospective approach and will be effective for the Company starting in the first quarter of fiscal 2019. Companies that elect the transition option will record a cumulative-effect adjustment to retained earnings in the period of adoption rather than the earliest period presented. The Company expects that the adoption of this standard will result in a material increase in assets and liabilities on its consolidated balance sheets and is in the process of analyzing its lease commitments, which consist primarily of operating leases for facilities, to determine the impact of the adoption of the standard on its financial statements.

In June 2016, the FASB issued an accounting standards update that changes the measurement and recognition of credit losses for most financial assets and certain other instruments. The new standard requires the use of forward-looking expected credit loss models based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount, which may result in earlier recognition of credit losses under the new standard. The 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 fiscal 2020, and is in the process of reviewing its credit loss models to assess the impact of the adoption of the standard on its financial statements.

In March 2018, the FASB issued Accounting Standards Update No. 2018-05, Income taxes (Topic 740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118 regarding Income Tax Accounting Implications of the Tax Cuts and Jobs Act. The Company recognized the income tax effects of the 2017 Tax Act in its 2017 financial statements for which the accounting under ASC Topic 740 is incomplete, but a reasonable estimate could be determined. The tax effects of certain provisions of the 2017 Tax Act, such as the deductibility of compensation in excess of $1 million for certain employees, and limitations on executive compensation, requires further analysis. The Company is in the process of assessing the impact of the adoption of the standard on its financial statements.

In August 2018, the FASB issued ASU 2018-15 that changes the accounting for implementation costs incurred in a cloud computing arrangement that is a service contract. ASU 2018-15 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 in 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 financial statements.

3. Short-Term Investments

The Company invests in investment securities, principally debt instruments of financial institutions and corporations with strong credit ratings. The following represents a summary of the estimated fair value of short-term investments as of September 30, 2018 and December 31, 2017 (in thousands):

At September 30, 2018	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Available-for-sale investment securities:					
Commercial paper	Less than 1	$ 65,654	$ 1	$ (14)	$ 65,641
U.S. Treasury securities	Less than 1	15,613	—	—	15,613
Total		$ 81,267	$ 1	$ (14)	$ 81,254

At December 31, 2017	Maturity (in years)	Amortized Cost	Unrealized Gain	Unrealized Loss	Estimated Fair Value
Trading securities:					
Mutual funds held for nonqualified deferred compensation plan participants		$ 459	$ 20	$ —	$ 479
Total		$ 459	$ 20	$ —	$ 479

4. Inventory

Inventory consisted of the following as of September 30, 2018 and December 31, 2017 (in thousands):

	September 30, 2018	December 31, 2017
Raw materials	$ 8,609	$ 10,328
Work-in-process	4,489	3,812
Finished goods	11,268	12,853
Total	$ 24,366	$ 26,993

5. Fair Value Measurements

Authoritative guidance on fair value measurements defines fair value, establishes a consistent framework for measuring fair value, and expands disclosures for each major asset and liability category measured at fair value on either a recurring or a nonrecurring basis. Fair value is intended to reflect an assumed exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as unadjusted quoted prices in active markets that are accessible at the measurement date for identical, unrestricted assets or liabilities.

Level 2: Inputs, other than quoted prices in active markets, that are observable either directly or indirectly for substantially the full term of the asset or liability.

Level 3: Unobservable inputs in which there is little or no market data and that are significant to the fair value of the assets or liabilities, which require the reporting entity to develop its own valuation techniques that require input assumptions.

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2018 and December 31, 2017, 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 September 30, 2018		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash equivalents (1)	$ 28,104	$ 28,104	$ —	$ —
Commercial paper	65,641	—	65,641	—
U.S. Treasury securities	15,613	15,613	—	—
Total assets	$ 109,358	$ 43,717	$ 65,641	$ —
Liabilities				
Common stock warrants	$ 20,643	$ —	$ —	$ 20,643
Total liabilities	$ 20,643	$ —	$ —	$ 20,643

		Fair Value Measurements at December 31, 2017		
		(Level 1)	(Level 2)	(Level 3)
Assets				
Cash equivalents (1)	$ 23,700	$ 23,700	$ —	$ —
Mutual funds held for nonqualified deferred compensation plan participants (2)	479	479	—	—
Total assets	$ 24,179	$ 24,179	$ —	$ —
Liabilities				
Common stock warrants	$ 5,432	$ —	$ —	$ 5,432
Deferred compensation (2)	479	479	—	-
Total liabilities	$ 5,911	$ 479	$ —	$ 5,432

(1) Generally, cash equivalents include money market funds and investments with a maturity of three months or less from the date of purchase. This asset is included as a component of cash and cash equivalents on the balance sheet, of which $10.0 million was classified as restricted cash – long-term as of December 31, 2017.

(2) The deferred compensation plan was directed by the Company and structured as a Rabbi Trust for the benefit of certain executives and non-employee directors. The investment assets of the Rabbi Trust were valued using quoted market prices multiplied by the number of shares held in each trust account. The related deferred compensation liability represents the fair value of the investment assets. The Company cancelled the deferred compensation plan in 2017 and all deferred compensation amounts were distributed to participants during the second quarter of 2018.

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 nine months ended September 30, 2018.

The Company's Level 3 liabilities at September 30, 2018 included the Series A warrants issued by the Company in connection with its public offering of common stock in October 2017. Level 3 liabilities at December 31, 2017 included the Series A and Series B warrants issued by the Company in connection with the October 2017 offering. 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 B warrants had a term of six months 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 and Series B warrants were initially valued in the aggregate amount of $6.5 million on the date of issuance utilizing a Black-Scholes pricing model. As of September 30, 2018, there were Series A warrants to purchase 516,030 shares of common stock outstanding and no Series B warrants outstanding (see Note 7, "Stockholders' Equity").

The Company reassesses the fair value of the outstanding Series A and Series B warrants at each reporting date utilizing a Black-Scholes pricing model. Inputs used in the pricing model include 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 September 30, 2018 and December 31, 2017 are presented below:

	Series A Warrants	
	September 30, 2018	December 31, 2017
Risk-free interest rate	2.9%	2.2%
Expected dividend yield	0.0%	0.0%
Expected volatility	77.6%	63.5%
Expected term (in years)	4.1	4.8

	Series B Warrants	
	September 30, 2018(1)	December 31, 2017
Risk-free interest rate	N/A	1.4%
Expected dividend yield	N/A	0.0%
Expected volatility	N/A	80.3%
Expected term (in years)	N/A	0.3

(1) As of September 30, 2018, there were no Series B warrants outstanding.

The following table presents a summary of changes in the fair value of the Company's Level 3 financial assets for the nine months ended September 30, 2018:

Balance at December 31, 2017	$	5,432
Increase in fair value included in change in fair value of common stock warrants		69,042
Decrease in fair value from warrants exercised during the period		(53,831)
Balance at September 30, 2018	$	20,643

During the nine months ended September 30, 2018, the Company issued 8,598,076 shares of common stock upon the exercise of Series A and Series B warrants and 13,450 Series B warrants expired unexercised. As a result, there were 516,030 Series A warrants to purchase common stock outstanding as of September 30, 2018.

6. Term Loan Agreement

In August 2018, the Company fully repaid the term loan made by CRG pursuant to the Term Loan Agreement. The term loan was collateralized by all assets of the Company. 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. As a result of the repayment, the Company did not have any borrowings outstanding under the Term Loan Agreement as of September 30, 2018. The Company had aggregate borrowings under the Term Loan Agreement of $82.7 million as of December 31, 2017. Notes payable-long term on the accompanying consolidated balance sheet reflected these aggregate borrowings, offset by a $6.2 million debt discount associated with the financing fees and certain debt issuance costs at December 31, 2017. Such discounts were amortized to interest expense over the term of the loan using the effective interest method. At the time of repayment, the remaining balance of $5.3 million was accelerated and recognized as a loss on extinguishment of debt in the consolidated statement of operations in the third quarter ended September 30, 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 (the "PIK Loan") to be added to the principal of the loan and subject to accruing interest. Interest-only payments were due quarterly on March 31, June 30, September 30 and December 31 of each year of the interest-only payment period, which would have ended on December 31, 2019. The principal balance was due in full at the end of the term of the loan, which was March 31, 2020 (the "Maturity Date"). The Company had elected to pay interest in cash at a rate of 11.5% per annum through September 30, 2015. From October 1, 2015 through December 31, 2017, the Company elected to pay interest in cash at a rate of 9.5% per annum and for a rate of 2.0% per annum to be added to the principal of the loan. As a result, $2.7 million was added to the principal of the loan during that time period (the "PIK Loans").

The Company entered into a series of amendments to the Term Loan Agreement in 2016, 2017 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. The Company treated the execution of each of the Third, Fourth and Fifth Amendments as a modification for accounting purposes. The present value of the future cash flows under these amendments did not exceed the present value of the future cash flows under the previous terms by more than 10%.

At December 31, 2017, the Company had accrued $4.1 million for the financing fee of 5%, which was subsequently increased to $5.0 million, or 6%, in February 2018. These fees were included in other long-term liabilities and as contra-debt in notes payable-long term on the accompanying consolidated balance sheet.

7. Stockholders' Equity

Public Offerings

In the first quarter of 2017, the Company completed a public offering of 1,850,000 shares of its common stock at a public offering price of $12.50 per share. The gross proceeds to the Company from the offering were $23.1 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company.

From July 2017 through September 2017, the Company sold 464,108 shares of its common stock under its "at-the-market" offering program at prices ranging from $5.64 to $10.54. The gross proceeds from the offering were $4.3 million, before deducting underwriting discounts and commissions and other offering expenses.

In the fourth quarter of 2017, the Company completed a public offering, pursuant to which it sold 4,630,000 shares of its common stock, Series A warrants to purchase up to 4,630,000 shares of common stock and Series B warrants to purchase up to 4,630,000 shares of common stock at a public offering price of $3.50 per share and accompanying warrants. The gross proceeds from the public offering were approximately $16.2 million, before deducting underwriting discounts and commissions and other offering expenses. As of September 30, 2018, the Company had issued 8,598,076 shares upon exercise of Series A and Series B warrants, which resulted in gross proceeds to the Company of $29.5 million. As of September 30, 2018, there were 516,030 Series A warrants outstanding and no Series B warrants outstanding. In April 2018, 13,450 Series B warrants expired unexercised.

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

In August 2018, the Company completed a public offering of 4,035,085 shares of its 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 September 30, 2018 (in thousands):

Shares underlying outstanding warrants	809
Shares underlying outstanding stock options	5,655
Shares authorized for future equity award grants	1,189
Shares authorized for issuance as ESPP awards	2,101
	9,754

In June 2018, the Company received approval from its stockholders to increase the number of shares of common stock reserved under the 2013 Plan by 5,500,000 shares. The Company issued 8,598,076 shares of its common stock upon the exercise of warrants, and 31,519 shares of its common stock upon the exercise of stock options during the nine months ended September 30, 2018. The Company did not issue any shares of its common stock upon the exercise of warrants, and issued 24,406 shares of its common stock upon the exercise of stock options during the year ended December 31, 2017.

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 began 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 will be November 15, 2018. As a result of the previous suspension of the ESPP, no shares of common stock were purchased under the ESPP during the nine months ended September 30, 2018. There were 38,929 shares of common stock purchased under the ESPP during the year ended December 31, 2017.

Stock-Based Compensation

In June 2018, the Company issued options to purchase 811,800 shares of common stock under the 2013 Plan, which were originally granted 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 common stock on the respective grant date, and generally vest 50% on the first anniversary of the grant date, 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 September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Weighted average grant date fair value (per share)	$ 21.77	$ 3.00	$ 12.35	$ 5.10
Risk-free interest rate	2.8%	2.0%	2.8%	1.9%
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	70.5%	60.3%	71.4%	60.0%
Expected term (in years)	6.1	6.1	5.7	6.1

	ESPP	
	Nine Months Ended September 30,	
	2018	2017(1)
Weighted average grant date fair value (per share)	$ 9.62	N/A
Risk-free interest rate	2.4%	N/A
Expected dividend yield	0.0%	N/A
Expected volatility	77.0%	N/A
Expected term (in years)	1.3	N/A

(1) There were no grants made pursuant to the ESPP during the nine months ended September 30, 2017.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Cost of sales	$ 784	$ 264	$ 1,129	$ 1,022
Selling, general & administrative	6,821	1,961	9,833	8,423
Research and development	1,932	167	2,465	1,057
Total	$ 9,537	$ 2,392	$ 13,427	$ 10,502

The total stock-based compensation expense capitalized as part of the cost of inventory was $0.7 million and $0.2 million as of September 30, 2018 and December 31, 2017, respectively.

8. Commitments and Contingencies

From time to time, the Company may be subject to legal proceedings, disputes and other claims arising in the ordinary course of business, including actions with respect to intellectual property, employment, product liability and contractual matters. In connection with these matters, the Company regularly assesses the probability and amount or range of possible loss based on the developments in these matters. A liability is recorded in the financial statements if it is determined that it is probable that a material loss has been incurred, and that the amount or range of the loss can be reasonably estimated. Because of uncertainties related to any pending actions, the Company is currently unable to predict their ultimate outcome, and, with respect to any legal proceeding or claim 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 September 30, 2018 and December 31, 2017, there were no legal proceedings, disputes or other 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, disputes and other 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 September 30, 2018, 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, 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 unique consumer-focused approach, and the incorporation of modern and innovative technology into our product offerings. Our manufacturing and sales activities primarily focus on our flagship product, the t:slim X2 Insulin Delivery System, or t:slim X2, which is based on our proprietary technology platform. The simple-to-use t:slim X2 is the smallest durable insulin pump available, and 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 began commercial sales in the United States of our first insulin pump, t:slim, in August 2012. Subsequently, we commercialized t:flex in May 2015, t:slim G4 in September 2015 and t:slim X2 in October 2016. The t:slim X2 technology platform now represents 100% of our new pump shipments, but we continue to provide ongoing service and support to existing t:slim, t:slim G4 and t:flex customers.

In June 2018, we received approval by the United States Food and Drug Administration (FDA) for t:slim X2 with Basal-IQ technology, our first-generation Automated Insulin Delivery (AID) algorithm. We commenced commercial sales of this product in the United States in August 2018. This system uses Dexcom G6 continuous glucose monitoring (CGM) sensor values to adjust the rate of insulin delivery to help minimize the frequency and/or duration of hypoglycemic events. In the second quarter of 2018, the FDA also created a new interoperability designation for integrated continuous glucose monitoring (iCGM) devices. Our t:slim X2 with Basal-IQ technology was the first insulin pump to receive approval for iCGM compatibility, which we expect will streamline the regulatory pathway for integration with future iCGM products approved by the FDA.

In August 2018, we commenced commercial sales in select international geographies of our t:slim X2 insulin pump, which is capable of displaying Dexcom's G5 Mobile CGM.

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.

Our insulin pumps are compatible with the Tandem Device Updater, a revolutionary new 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 customers 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 t:slim X2 customers two significant software updates including integration with the Dexcom G5 Mobile CGM system in September 2017 and an upgrade to our new Basal-IQ technology at no cost in August 2018. In the future, this tool has the potential to enable users to add other new features and functionality to their pumps independent of the typical four-year insurance pump reimbursement cycle.

Our innovative approach to product design and development is consumer-focused and based on our extensive market research, as we believe the user is the primary decision maker when purchasing an insulin pump. Our market research consists of interviews, focus groups and online surveys to understand what people with diabetes, their caregivers and healthcare providers are seeking in order to improve diabetes therapy management. We also apply the science of human factors to our design and development process, which seeks to optimize our devices, thereby allowing users to successfully operate them in their intended environment.

We developed our products to provide the specific features that people with insulin-dependent diabetes seek in a next-generation insulin pump. Our proprietary technology platform allows us to design the slimmest and smallest durable insulin pumps on the market, without sacrificing insulin capacity. Our platform features our patented Micro-Delivery technology, and a miniaturized pumping mechanism that draws insulin from a flexible bag within the pump's cartridge, rather than relying on a syringe and plunger mechanism. It also features an easy-to-navigate software architecture, and a vivid color touchscreen. In addition, the t:slim X2 features an advanced Bluetooth radio capable of communicating with multiple compatible devices, such as a CGM sensor, blood glucose meter or mobile device applications. Our platform has a micro-USB connection that supports a rechargeable battery and software updates through the Tandem Device Updater, as well as uploads to t:connect Diabetes Management Application, or t:connect. t:connect is our custom cloud-based data management application that provides customers and healthcare providers a fast, easy and visual way to display therapy management data from the pump and supported blood glucose meters. In April 2017, we launched the t:connect HCP Portal, which is designed to streamline healthcare providers' use of the original t:connect Application and improve office efficiency. Currently, t:connect and the Tandem Device Updater are available only 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. 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. 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 FDA. As we continue to develop differentiated products based on our proprietary technology platform, we intend to leverage a single sales, marketing and clinical organization in the United States, a shared manufacturing and supply chain infrastructure, and the expertise of our customer support services.

In the third quarter of 2018, we established a small group of sales and customer support employees to commercialize our products in Canada. In other select geographies outside the United States, 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 territories.

Products Under Development

Our products under development support our strategy of focusing on both consumer and clinical needs, and include 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 target people in differentiated segments of the insulin-dependent diabetes market including the following products under development:

- *t:slim X2 with Control IQ* – Our second-generation AID system is expected to integrate the t:slim X2 pump with the treat-to-range technology that we licensed from TypeZero Technologies LLC, as well as Dexcom's G6 CGM sensor. With TypeZero's technology, our product is intended to both increase and decrease basal insulin based on a user's predicted blood glucose levels, as well as deliver automated correction boluses. In conjunction with Dexcom and TypeZero, we have integrated our technologies into the U.S. portion of the Clinical Acceptance of the Artificial Pancreas (DCLP3) portion of the International Diabetes Closed Loop (IDCL) Trial, for which enrollment was completed in October 2018. This trial will utilize a t:slim X2 integrated with our implementation of TypeZero's inControl AID algorithms, which is designed to automatically adjust a person's insulin based on information from a Dexcom G6 CGM sensor. Under new guidelines with the FDA, we intend to file a 510(k) in the fourth quarter of 2018 in pursuit of a new insulin pump classification for the t:slim X2 pump referred to as iPump followed by an additional submission for the Control IQ algorithm using the results of the trial in the first half of 2019. We have also conducted and anticipate continuing to conduct targeted pediatric studies for a future regulatory submission.

- *t:sport Insulin Delivery System* – This product is our next generation hardware platform that is expected to be half the size of the t:slim platform and is being designed for people who seek even greater discretion and flexibility with the use of their insulin pump.

- *Connected (Mobile) Health Offerings* - We are currently developing a mobile application that is being designed to utilize the capability of the Bluetooth radio 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.

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. We consider the number of units shipped per quarter to be an important metric for managing our business, particularly the number of units shipped in the most recent four-year period due to typical four-year reimbursement cycles.

In the United States, we have shipped more than 70,000 pumps within the four-year period ended September 30, 2018. Pump shipments in the United States by fiscal quarter are as follows:

	Pump Units Shipped for Each of the Three Months Ended in Respective Years(1) - U.S.				
					Total
	March 31	June 30	September 30	December 31	Total
2012	-	9	204	844	1,057
2013	852	1,363	1,851	2,406	6,472
2014	1,723	2,235	2,935	3,929	10,822
2015	2,487	3,331	3,431	6,234	15,483
2016	4,042	4,582	3,896	4,418	16,938
2017	2,816	3,427	3,868	6,950	17,061
2018	4,444	5,447	7,379	N/A	17,270

(1) This table does not reflect returns or exchanges of pump products that occur in the ordinary course of business, nor does it reflect approximately 3,300 trade-ins fulfilled in 2016 and 2017 under the Technology Upgrade Program (discussed below) related to our commercial launch of t:slim X2.

International pump shipments, which began in the third quarter of 2018, by fiscal quarter are as follows:

	Pump Units Shipped for Each of the Three Months Ended in Respective Years - International				
					Total
	March 31	June 30	September 30	December 31	Total
2018	N/A	N/A	1,055	N/A	1,055

Technology Upgrade Program

Beginning in the third quarter of 2016 through the third quarter of 2017, we offered a Technology Upgrade Program under a variable pricing structure, as a pathway for certain existing customers to obtain the t:slim X2 insulin pump. Due to the high degree of accounting complexity, the program created unpredictable financial results under U.S. GAAP for the duration of the program. The accounting treatment for the program required us to defer up to 100% of sales at the time of pump shipment and recognize them in a subsequent period, either when the upgrade was fulfilled or at the expiration of the program. We recognized the deferred amount of sales and cost of sales at the earlier of when the obligations under the program were satisfied or upon the expiration of the program. If a customer elected to participate in the program, we recognized any upgrade fees that we received and the associated costs at the time of fulfilling the given obligation. The program expired on September 30, 2017 and, therefore, has no impact on our 2018 financial results.

Historical Financial Results

For the nine months ended September 30, 2018 and 2017, our sales were $107.6 million and $67.3 million, respectively. For the nine months ended September 30, 2017, this included incremental net sales of $4.8 million as a result of the Technology Upgrade Program. For the nine months ended September 30, 2018 and 2017, our net loss was $126.3 million and $61.6 million, respectively. Our accumulated deficit as of September 30, 2018 was $603.8 million.

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, and the commercial launch of products by us and our competitors.

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 actions relating to 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 Animas customers as their pumps come up for renewal, following the announcement by Johnson & Johnson that it discontinued the operations of Animas and exited the insulin pump business entirely;

- increased sales of infusion sets following the commercial launch of t:lock-compatible pump supplies in the third quarter of 2017;

- designation by UnitedHealthcare in July 2016 of one of our competitors as its preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18; and

- international expansion in select geographies, including Canada, in the second half of 2018.

For 2018, 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 international launch plans. We believe we can ultimately achieve profitability by driving incremental sales growth, 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.

Recent Developments

FDA Approval of t:slim X2 with Basal-IQ

In June 2018, the FDA approved our t:slim X2 Insulin Pump with Basal-IQ technology, a predictive low glucose suspend (PLGS) feature designed to help reduce the frequency and duration of low glucose events. We launched our new product in the third quarter of 2018 with Dexcom G6 CGM integration, which requires no fingersticks for calibration or diabetes treatment decisions and was the first CGM device to receive the iCGM designation from the FDA earlier this year.

International Expansion

In April 2018, we received CE mark approval and have entered into distribution agreements with independent distributors for markets in Australia, Italy, New Zealand, Scandinavia, South Africa, Spain and the United Kingdom. We began shipping into select geographies in the third quarter of 2018, where we initially intend to market our products primarily through third-party distributors. In Canada, we received regulatory approval in October 2018 and expect to begin shipping by the end of 2018, subject to the completion of various pre-commercialization activities.

Leverage from Technology Platform

We believe we can ultimately achieve profitability because our existing proprietary technology platform will allow us to maximize efficiencies in the development, production, sale and marketing of multiple products differentiated by software. By offering products that are all based on this proprietary technology platform, in combination with the flexibility provided by the Tandem Device Updater, we believe we can develop and bring to market products and functionality more rapidly, while significantly reducing our per-unit design and development costs. Due to shared product design features, our production system is adaptable to new products and we intend to leverage our shared manufacturing infrastructure to drive operational efficiencies. Further, we expect to continue to increase production volume and to reduce the per-unit production overhead cost for our pump products and their associated disposable cartridges over time. By expanding our product offerings to address the varying needs among people in different segments of the large and growing insulin-dependent diabetes market with continued software innovation and alternative hardware platforms such as t:sport, we believe we can increase the productivity of our sales, clinical, marketing, and customer support organizations, thereby improving our operating margin over the long term. However, it is possible that the launch of our t:sport platform in the future may reduce the total demand for our products based on our t:slim X2 platform. In that case, it is possible that the launch of our t:sport platform may temporarily negatively impact the gross margins for our products overall.

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 hardware platform in the United States in the third quarter of 2012 and continued to launch various iterations of that platform in the years following. In October 2016, we began shipping our t:slim X2 insulin pump, our next generation flagship product. The t:slim X2 hardware platform, which includes remote software update capabilities, now represents 100% of our new pump shipments. Accordingly, we have 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 such sales 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 Dexcom G5 Mobile CGM integration in select international geographies. With the exception of Canada where we intend to market with a direct sales force, we expect that most of our commercial sales outside the United States will initially be to independent distributors who will perform all sales, customer support and training in their respective territories. Historically, we have experienced consistent levels of reimbursement for our products in the United States, but 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, we have experienced, and expect to continue to experience in the United States, product shipments being weighted heavily towards the second half of the year, with the highest percentage of product shipments expected in the fourth quarter of the year due to the nature of the reimbursement environment. Consistent with prior results, we also expect product shipments from the fourth quarter to the following first quarter to decrease significantly.

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, reserves for expected warranty costs, freight, scrap and inventory excess and obsolescence. 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 products gain broader market acceptance and 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 we have more opportunities to spread our overhead costs 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. We also expect our warranty costs to decrease as we release 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 besides those associated with production volumes, such as the impact of changes in our stock price on non-cash stock-based compensation, changes in our warranty estimates or inventory obsolescence.

In general, we expect the gross margin on insulin pumps to be higher than the gross margin on pump-related supplies. Other factors impacting our overall gross margin may include the changing mix of products sold with different gross margins, 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, warranty and training costs, 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 administrative functions. In particular, our sales and clinical organization consisted of approximately 70 territories as of September 30, 2018 and our operations in Canada will be supported by a direct sales force of approximately 10 field representatives. 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. We may add a small number of domestic sales territories in the near term. 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. We expect our SG&A expenses, including the cost of our customer support infrastructure, to increase as our customer base grows in the United States and international geographies. Additionally, we realized a notable increase in non-cash stock-based compensation expense in the third quarter of 2018 from the recent appreciation of our stock price, which will expect will be sustained in future quarters as a result of the valuation of certain employee option grants. 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 due to the impact of the recent appreciation of our stock price.

Other Income and Expense

Our other income and expense primarily consists of changes in the fair value of the Series A and Series B warrants issued in our public offering of common stock in October 2017, as well as 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 coupon rate of 11.5% per annum (see the section below entitled “Indebtedness”). As a result, we recognized a loss on extinguishment of debt in the third quarter of 2018, but there will be no related interest expense or costs associated with the debt in future periods. We expect other income and expense to fluctuate from period to period due to revaluations of the outstanding Series A warrants, which expire in the fourth quarter of 2022.

Results of Operations

(in thousands, except percentages)	Three Months Ended September 30, 2018	Three Months Ended September 30, 2017	Nine Months Ended September 30, 2018	Nine Months Ended September 30, 2017
Sales:				
Domestic	$ 43,720	$ 27,003	$ 105,123	$ 67,306
International	2,544	-	2,544	-
Total Sales	$ 46,264	$ 27,003	$ 107,667	$ 67,306
Cost of sales	24,468	15,131	59,381	40,680
Gross profit	21,796	11,872	48,286	26,626
Gross margin	47%	44%	45%	40%
Operating expenses:				
Selling, general and administrative	29,506	20,125	73,048	65,077
Research and development	7,999	4,914	20,430	14,910
Total operating expenses	37,505	25,039	93,478	79,987
Operating loss	(15,709)	(13,167)	(45,192)	(53,361)
Other income (expense), net:				
Interest and other income	443	60	833	179
Interest and other expense	(1,401)	(2,928)	(7,585)	(8,445)
Loss on extinguishment of debt	(5,313)	-	(5,313)	-
Change in fair value of stock warrants	(12,265)	-	(69,042)	-
Total other expense, net	(18,536)	(2,868)	(81,107)	(8,266)
Net loss	$ (34,245)	$ (16,035)	$ (126,299)	$ (61,627)

Comparison of the Three Months Ended September 30, 2018 and 2017

Sales. For the three months ended September 30, 2018, sales were $46.2 million, which included $2.5 million of international sales that commenced this period. Sales were $27.0 million for the same period in 2017.

Domestic sales of insulin pumps were $28.7 million and $18.4 million, respectively, for the three months ended September 30, 2018 and 2017. For the three months ended September 30, 2018, domestic sales of pump-related supplies were $15.0 million, of which $10.3 million were sales of infusion sets and $4.6 million were sales of cartridges. For the three months ended September 30, 2017, sales of pump-related supplies were $8.7 million, of which $5.0 million were sales of infusion sets and $3.5 million were sales of cartridges. Sales of accessories were not significant in either of the reported periods. International sales primarily consisted of insulin pumps.

The increase in sales was primarily due to a 118% increase in worldwide pump shipments to 8,434 in the third quarter of 2018 compared to 3,868 in the third quarter of 2017, which were positively impacted by new product launches in August 2018 and August 2017 and the commencement of international sales in the three months ended September 30, 2018. Additionally, sales from pump-related supplies increased 77% due to the September 2017 launch of infusion set products using the t:lock Connector, as well as an overall increase in our installed base of customers reordering supplies. The ratio of the number of infusion sets shipped to the number of cartridges shipped increased to over 100% in the three months ended September 30, 2018 from 66% in the comparable quarter of the prior year.

Sales to domestic distributors accounted for 76% and 74% of our total domestic sales for the three months ended September 30, 2018 and 2017, 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. The percentage was particularly impacted in the three months ended September 30, 2018 by the mid-2017 launch of the t:lock Connector, which resulted in greater purchases of infusion sets by our independent distributors during the period as compared to the same period during the prior year. Sales to international distributors accounted for 100% of our total international sales.

Cost of Sales and Gross Profit. Our cost of sales for the three months ended September 30, 2018 was $24.5 million resulting in gross profit of $21.8 million, compared to $15.1 million cost of sales for the same period in 2017 resulting in gross profit of $11.9 million. The gross margin for the three months ended September 30, 2018 was 47% compared to 44% in the same period in 2017. The gross profit for the three months ended September 30, 2017 included a $2.6 million benefit from the Technology Upgrade Program in place at that time, which benefited the corresponding gross margin by 5 percentage points.

Excluding the impact of the Technology Upgrade Program, the increase in our gross profit for the three months ended September 30, 2018 was primarily the result of the increase in pump shipments. Gross profit and gross margin also increased as a result of per unit manufacturing cost improvements from higher sales volumes and overall manufacturing efficiencies, even taking into account the incremental costs associated with the doubling of our manufacturing capacity in our new Barnes Canyon facility, as well as the doubling of sales of our infusion sets. Additionally, we recognized a notable increase in non-cash stock-based compensation to $0.8 million in the three months ended September 30, 2018 from $0.3 million in the prior year, due to the impact of the recent stock appreciation of our stock price. As a whole, other non-manufacturing costs, which primarily consist of warranty, freight and training costs, also reflected improvement.

We expect the most significant factors impacting our gross margin will continue to be the percentage of our pump sales relative to total sales, as our pumps have higher gross margins than our pump-related supplies. We also expect the gross margin on our pump sales to improve as the volume of our pump sales increases. However, we are also continuing to experience an increasingly positive gross margin associated with the sale of our pump-related supplies as a whole, after first achieving a positive gross margin in the fourth quarter of 2016. We expect to continue to see improvements in the gross profit and gross margin associated with our pump-related supplies as we manufacture higher volumes of cartridges to support our growing installed base and continue to increase sales of infusion sets.

Selling, General and Administrative Expenses. SG&A expenses increased 47% to $29.5 million for the three months ended September 30, 2018 from $20.1 million for the same period in 2017. Employee-related expenses for our SG&A functions comprise the majority of SG&A expenses. The increase compared to 2017 was primarily the result of a $4.1 million increase in salaries, incentive compensation and other employee benefits as well as an increase of $4.9 million in non-cash stock-based compensation. The increase in stock-based compensation expense for the three months ended September 30, 2018 to $6.8 million is primarily due to the recent appreciation of our stock price. This higher level of expense is expected to continue in future quarters.

Research and Development Expenses. R&D expenses increased 63% to $8.0 million for the three months ended September 30, 2018 from $4.9 million for the same period in 2017. The increase in R&D expenses was primarily the result of an increase in non-cash stock-based compensation of $1.8 million, as well as an increase of $1.4 million in salaries, incentive compensation and other employee benefits. The increase in stock-based compensation expense for the three months ended September 30, 2018 to $1.9 million is primarily due to the recent valuation of certain employee stock option grants and the significant appreciation of our stock price. This higher level of expense is expected to continue in future quarters.

Other Income and Expense. Other expense for the three months ended September 30, 2018 and 2017 was $18.5 million and $2.9 million, respectively. Other expense for the three months ended September 30, 2018 was primarily comprised of a $12.3 million revaluation loss from the change in the fair value of the Series A warrants due to the significant appreciation of our stock price, as well as a $5.3 million loss on extinguishment of debt associated with the full repayment of our Term Loan Agreement in August 2018. Other expense for the three months ended September 30, 2017 was primarily comprised of interest expense associated with the Term Loan Agreement. Prior to the repayment, the outstanding principal balance under the Term Loan Agreement was $82.7 million. There will be no interest expense or other costs associated with the Term Loan Agreement in future periods.

Comparison of the Nine Months Ended September 30, 2018 and 2017

Sales. For the nine months ended September 30, 2018, sales were $107.6 million which included $2.5 million of international sales that commenced in the third quarter of 2018. Sales were $67.3 million for the same period in 2017, which included incremental net sales of $4.8 million as a result of the Technology Upgrade Program in place at that time.

Domestic sales of insulin pumps were $67.0 million and $44.3 million, respectively, for the nine months ended September 30, 2018 and 2017. For the nine months ended September 30, 2018, sales of pump-related supplies were $37.8 million, of which $25.7 million were sales of infusion sets and $11.8 million were sales of cartridges. For the nine months ended September 30, 2017, sales of pump-related supplies were $23.0 million, of which $13.0 million were sales of infusion sets and $9.7 million were sales of cartridges. Sales of accessories were not significant in either of the reported periods. International sales primarily consisted of insulin pumps.

The increase in sales was primarily due to an 81% increase in worldwide pump shipments to 18,325 in the first nine months of 2018 compared to 10,111 in the first nine months of 2017, which were positively impacted by the August 2018 launch of t:slim X2 with Basal-IQ technology and the August 2017 launch of t:slim X2 with G5. The ratio of the number of infusion sets shipped to the number of cartridges shipped increased to over 100% in the nine months ended September 30, 2018 from 60% in the same period in 2017.

Sales to domestic distributors accounted for 78% and 73% of our total domestic sales for the nine months ended September 30, 2018 and 2017, respectively, driven by the mid 2017 launch of the t:lock Connector. Sales to international distributors accounted for 100% of our total international sales.

Cost of Sales and Gross Profit. Our cost of sales for the nine months ended September 30, 2018 was $59.4 million resulting in gross profit of $48.3 million, compared to $40.7 million of cost of sales for the same period in 2017 resulting in gross profit of $26.6 million. The gross margin for the nine months ended September 30, 2018 was 45% compared to 40% in the same period in 2017. The gross profit for the three months ended September 30, 2017 included a $3.2 million benefit from the Technology Upgrade Program in place at that time, which benefited the corresponding gross margin by 3 percentage points.

Excluding the impact of the Technology Upgrade Program, the gross margin increased for the nine months ended September 30, 2018 compared to the same period in 2017 primarily as a result of an increase in pump shipments which have higher gross margins than pump-related supplies, as well as per unit cost improvements on all products, increased production volumes, and a decrease in other non-manufacturing costs.

Selling, General and Administrative Expenses. SG&A expenses increased 12% to $73.0 million for the nine months ended September 30, 2018 from $65.1 million for the same period in 2017. Employee-related expenses for our SG&A functions comprise the majority of the SG&A expenses. The increase in SG&A expenses was primarily due to an increase of $6.6 million in salaries, incentive compensation and other employee benefits, as well as an increase of $1.4 million in non-cash stock-based compensation.

Research and Development Expenses. R&D expenses increased 37% to $20.4 million for the nine months ended September 30, 2018 from $14.9 million for the same period in 2017. The increase in R&D expenses was primarily the result of employee-related expenses. This includes a $2.4 million increase in salaries, incentive compensation and other employee benefits and an increase of $1.4 million in non-cash stock-based compensation. Additionally, we recognized an increase of $2.2 million associated with clinical trial costs.

Other Income and Expense. Other expense for the nine months ended September 30, 2018 and 2017 was $81.1 million and $8.3 million, respectively. Other expense for the nine months ended September 30, 2018 was primarily comprised of a $69.0 million revaluation loss from the change in the fair value of the Series A and Series B warrants due to the significant appreciation in our stock price in recent months, $7.6 million of interest expense associated with the Term Loan Agreement, as well as a $5.3 million loss on extinguishment of debt associated with the full repayment of our Term Loan Agreement in August 2018. Other expense for the nine months ended September 30, 2017 was primarily comprised of interest expense associated with the Term Loan Agreement. Prior to the repayment, the outstanding principal balance under the Term Loan Agreement was $82.7 million. There will be no interest expense or other costs associated with the Term Loan Agreement in future periods.

Liquidity and Capital Resources

As of September 30, 2018, we had $113.6 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 placements and public offerings of equity securities, debt financing, and cash collected from product sales. Since the beginning of 2017, we completed the following financings:

- 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.

- 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 October 2017, we completed a registered public offering of common stock, pursuant to which we sold 4,630,000 shares of our common stock, Series A warrants to purchase up to 4,630,000 shares of our common stock and Series B warrants to purchase up to 4,630,000 shares of our common stock at a public offering price of $3.50 per share and accompanying warrants. The gross proceeds to us from this financing were approximately $16.2 million, before deducting underwriting discounts and commissions and other offering expenses payable by us. In the nine months ended September 30, 2018, we received proceeds of $29.5 million from the exercise of 8,730,520 outstanding Series A and Series B warrants. As of September 30, 2018, there were Series A warrants to purchase 516,030 shares outstanding and there were no Series B warrants outstanding.

- During the three months ended September 30, 2017, we sold 464,108 shares of common stock under our “at the market” program at prices ranging from $5.64 to $10.54. The gross proceeds to us from the offering were $4.3 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

- In March 2017, we completed a registered public offering of 1,850,000 shares of our common stock at a public offering price of $12.50 per share. The gross proceeds to us from the offering were approximately $23.1 million, before deducting underwriting discounts and commissions and other offering expenses payable by us.

Our historical cash outflows have primarily been associated with cash used for operating activities such as the development and commercialization of our products and expansion and support of our sales, marketing, clinical and customer support organizations, an increase in 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. 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 our recent financing transactions, the competitive environment in our industry, and uncertainties regarding the regulator environment.

The following table shows a summary of our cash flows for the nine months ended September 30, 2018 and 2017:

	Nine Months Ended September 30,	
(in thousands)	**2018**	**2017**
Net cash provided by (used in):		
Operating activities	$ (22,451)	$ (54,495)
Investing activities	(84,148)	4,201
Financing activities	115,227	25,695
Total	$ 8,628	$ (24,599)

Operating activities. Net cash used in operating activities was $22.5 million for the nine months ended September 30, 2018, compared to $54.5 million for the same period in 2017. 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 Series A and Series B warrants, loss on extinguishment of debt and increased stock-based compensation expense discussed above, as well as net changes in working capital. The net changes in working capital were primarily due to reductions in inventory levels based on continued high sales demand and a reduction of deferred revenue in 2017 associated with the end of the Technology Upgrade Program in place at that time.

Investing activities. Net cash used in investing activities was $84.1 million for the nine months ended September 30, 2018, which was primarily related to purchases of short-term investments of $100.6 million, offset by sales and maturities of $18.5 million of short-term investments. Net cash provided by investing activities was $4.2 million for the nine months ended September 30, 2017, which was primarily related to sales and maturities of $8.5 million of short-term investments, partially offset by the purchase of $4.3 million of property and equipment.

Financing activities. Net cash provided by financing activities was $115.2 million for the nine months ended September 30, 2018, which was primarily the result of net proceeds of approximately $172.9 million from the public offerings of our common stock in February 2018 and August 2018, as well as proceeds of $29.5 million from the exercise of Series A and Series B warrants issued in the public offering of common stock in October 2017. The majority of the August 2018 offering proceeds were used to fund the full repayment of our outstanding Term Loan Agreement, which was a cash usage of $87.7 million. Net cash provided by financing activities was $25.7 million for the nine months ended September 30, 2017, which was primarily the result of net proceeds of $25.1 million from public offerings of our common stock.

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 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 employee stock plans;
- fluctuations in gross margins and operating margins; and
- fluctuations in working capital.

Our primary short-term capital needs, which are subject to change, include expenditures related to:

- support of our commercialization efforts related to our current and future products;
- research and product development efforts, including clinical trial costs;
- acquisition of equipment and other fixed assets; 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. If 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.

Indebtedness

Term Loan Agreement

In August 2018, we fully repaid our term loan made by CRG pursuand 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 September 30, 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 in the third quarter ended September 30, 2018.

Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these 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 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 the Annual Report other than adoption of the new revenue recognition standard ("Revenue from Contracts with Customers Standard"). Refer to the disclosures in the Notes to Unaudited Condensed Consolidated Financial Statements.

Off-Balance Sheet Arrangements

As of September 30, 2018, 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, 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 September 30, 2018, this change would not have had a material effect on the fair value of our investment portfolio as of that date.

The interest rate under the Term Loan Agreement was fixed and not subject to changes in market interest rates. The outstanding balance associated with the Term Loan Agreement was fully repaid in August 2018.

Our operations are located in the United States, and nearly all of our sales since inception have been made in U.S. dollars. While we began commercialization of t:slim X2 in select geographies outside the U.S. in the third quarter of 2018, we expect the significant majority of our sales will continue to be made in U.S. dollars for the foreseeable future. Accordingly, we do not currently have or expect to have any material exposure to foreign currency rate fluctuations. From time to time, we may have foreign currency 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 risks. 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 September 30, 2018, 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 September 30, 2018.

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 September 30, 2018 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 and 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 and 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 II, Item 1A of the Quarterly Report for the period ended June 30, 2018.

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 September 30, 2018, we had an accumulated deficit of $603.8 million. To date, we have financed our operations primarily through public and private sales 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 next-generation flagship pump, 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. In addition, we commenced sales and shipments of our t:slim X2 with G5 integration in select markets outside the United States during the third quarter of 2018.

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, 2017 and 2016, our gross profit was $44.1 million and $23.6 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 at least the next two years.

To implement our business strategy and achieve 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. Our expenses may 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;
- 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 during 2016 that restricted 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, 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.

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, perceptions about the dilutive impact of our financing transactions, the current level of our indebtedness and debt service costs, 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. In addition, the retention of our customers may be 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. 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 plc, 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, in late 2017, Eli Lilly & Co. announced that it is developing an insulin pump with AID technology that it intends to launch in the next two to three years. 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, or cause consumers to delay the purchase of our products.*

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;

- the failure of our products to provide the features and functionality that people with insulin-dependent diabetes, their caregivers and healthcare providers are seeking in insulin pump products, and to incorporate those features into our products in a timely, cost-effective and user-friendly manner;

- 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;

- the introduction of competitive products, technologies or treatment techniques and the rate of their acceptance as compared to our insulin pump products;

- adverse regulatory or legal actions relating to our insulin pump products or similar products or technologies;

- discounts, rebates and other financial incentives that our competitors may offer for competitive products that make them more attractive than our products; 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, including by reducing raw material, labor, product-training, expected warranty and manufacturing overhead costs per unit.*

We believe our ability to reduce the per unit cost of our insulin pump products and related products will have a significant impact on our ability to achieve profitability. Our cost of sales includes raw material procurement costs, labor costs, product training expenses, warranty, scrap and inventory excess and obsolescence. It also includes manufacturing overhead costs, including expenses relating to quality assurance, inventory 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 improved pricing, 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. 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, effective July 1, 2016, UnitedHealthcare designated one of our competitors as their preferred, in-network durable medical equipment provider of insulin pumps for most customers over the age of 18. 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 176 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. Also, any negative perceptions among third-party payors regarding our financial stability, including our ability to continue to sell and service our products, may make it more difficult to enter into or renew reimbursement contracts with third-party payors. 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 rapidly 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. Unexpected turnover among our sales, marketing, clinical and customer service 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, 2017, sales to approximately 35 independent distributors represented approximately 75% 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 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 has also increased following our launch of the t:lock for our insulin cartridge, which may continue to result in greater sales of our infusion sets to distributors. 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. However, negative perceptions among independent distributors regarding our financial stability, and our ability to sustain our business operations on a long-term basis, may negatively impact the willingness of our distributors to continue to do business with us. None of our independent distributors in the United States 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. 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, 2017, our two largest independent distributors collectively comprised approximately 35.5% 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.

We also intend to market our products internationally primarily through independent distributors and expect we will be similarly dependent on these distributors when we commence international sales.

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 currently expect to rely 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. 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 IDCL Trial is 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 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 IDCL Trial that we intend to rely upon for the development of t:slim X2 with Control IQ. 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 changes specific to our business, such as the recent approval of t:slim X2 with Basal-IQ technology and our commencement of commercial sales in international markets during the third quarter of 2018, 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 emerging 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 and marketing and customer service 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 our stock price to decline. For example, any revenue growth in 2018 on a U.S. GAAP basis is expected to be lower than the rate of growth on a product volume basis. In addition, the complexities associated with the Program may cause investors to avoid investing in our common stock until our financial results and trends are more predictable, which may also 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. 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, 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.

We do not have long-term supply agreements with many of our suppliers and, in many cases, we make our purchases on a purchase order basis. Under most of our supply agreements, we 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 inventory 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 of products with t:lock, which 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. 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.

In addition, certain independent distributors may need to continue to purchase both styles of insulin cartridges and infusion sets from us to provide to their customers. We believe the transition period for our direct customers and distributors in the United States to utilize their inventory on hand before transitioning to t:lock is substantially complete. However, 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. Due to the variability in purchasing patterns, standard Luer-lok inventory 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 inventory 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.

We currently operate primarily at two locations in San Diego, California, and any disruption at these locations could adversely affect our business and operating results.*

Substantially all of our operations are conducted at two locations 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 inventory of component supplies and finished goods are stored at one of these locations. We also store finished goods at a third-party warehouse operator in Austin, 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 another catastrophic event, could damage or destroy our manufacturing equipment or our inventory 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 but 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 29, 2018, we closed the voluntary recall initiated on April 19, 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.

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 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 generations of Dexcom CGM technology with our insulin pump products. Our agreements with Dexcom currently run until June 2020 with automatic one-year renewals. Under certain circumstances, these agreements may be terminated by either party without cause or on short notice. Termination of any of our agreements with Dexcom could 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.

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. 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, 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. 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.

The failure of our or our service providers' information technology systems or our pumps' software 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 protecting the confidentiality 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 federal and state laws protecting the confidentiality and security of personal information, including certain patient health information, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services, or HHS, promulgated privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH. The privacy rule protects medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. The security rule protects protected health information, or PHI, stored electronically by requiring appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity and security of such PHI. If we, or any of our service providers, are found to be in violation of the promulgated privacy and security rules under HIPAA and HITECH, 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 may also face new risks relating to security laws and privacy rights as individual states adopt new laws and regulations on these topics and as we begin to commercialize our products outside the United States. For example, in the European Union, the General Data Protection Regulation, or GDPR, which came into force on May 25, 2018, introduces new data protection requirements in the European Union. As we expand internationally, our business will need to be adapted 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 the third quarter of 2018, we began commercialization of the t:slim X2 insulin pump in select geographies outside of the United States. We do not have experience commercializing our products outside of the United States and expect that we will be subject to additional risks related to entering into 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 the GDPR;
- reduced protection for our intellectual property rights in foreign countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- different reimbursement systems;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad or with U.S. regulations that would apply to activities in such foreign jurisdictions, such as the Foreign Corrupt Practices Act;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; and
- business interruptions resulting from geopolitical actions, including war and terrorism, 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.*

As of September 30, 2018, we had $113.6 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 commence commercial sales of our products outside the United States 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 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. 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 September 30, 2018, our patent portfolio consisted of approximately 68 issued U.S. patents and 49 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 17 U.S. trademark registrations and 17 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. Third parties also may 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 future 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 future 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, 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 increases.

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 could become the subject of 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 t:slim X2 with G5 in August 2017. More recently, we received approval of our PMA for t:slim X2 with Basal-IQ technology in June 2018. 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 a 510(k) may require a new 510(k). 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 we recently submitted a de novo 510(k) for our t:slim X2 insulin pump platform 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 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. This is not uncommon in our industry and we currently have ongoing voluntary recalls of products that we initiated during 2018. A government-mandated or voluntary recall by us, one of our distributors or any of our other third-party suppliers could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls or notices relating to any products that we distribute would divert managerial and financial resources, and have an adverse effect on our reputation, financial condition and operating results.

Further, under the FDA's Medical Device Reporting, or 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 and physician self-referral 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 federal "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 HITECH.

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 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 recently 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 over the past several 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, and perceptions about the dilutive impact of

our recent financing transactions (including the exercise of outstanding warrants);

- perceptions about our financial stability generally, and relative to our competitors, including our ability to sustain our business operations and achieve profitability;
- 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 on 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, 2017, we had federal net operating loss, or NOL, carryforwards of approximately $335.3 million, not considering the limitation discussed below. The federal tax loss carryforwards begin to expire in 2026, unless previously utilized. In general, if there is an “ownership change” with respect to our company, as defined under Section 382 of the Internal Revenue Code of 1986, as amended, or 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 completed an update of our Section 382 analysis subsequent to December 31, 2017, the recent offerings of our securities, may have caused or could cause 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. 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, or the Dodd-Frank 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. Recent legislation permits "emerging growth companies" to implement many of these requirements over a period of up to five years after becoming subject to the requirements. However, we expect we will cease to qualify as an "emerging growth company" on December 31, 2018, at which point we will become subject to the additional compliance and reporting requirements. 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.

We are an "emerging growth company" and we do not know whether the reduced disclosure requirements and relief from certain other significant obligations that are applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act, and we have taken advantage of, and intend to continue to take advantage of certain exemptions from various reporting and compliance requirements that apply to other public companies that are not "emerging growth companies." These exemptions include the following:

- not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act;
- less extensive disclosure obligations regarding executive compensation in our registration statements, periodic reports and proxy statements; and
- exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, which could result in a reduction in the price of our common stock or cause our stock price to be more volatile. We expect we will cease to qualify as an "emerging growth company" on December 31, 2018.

We are a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.*

We are a "smaller reporting company" under applicable SEC rules and regulations. Similar to an "emerging growth company", a "smaller reporting company" is subject to scaled reporting and compliance obligations as compared to other public companies. Specifically, "smaller reporting companies" are able to provide simplified executive compensation disclosures in their filings, are exempt from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, and have certain other reduced disclosure obligations in their SEC filings. Reduced disclosures in our SEC filings due to our status as a "smaller reporting company" may make it harder for investors to analyze our financial condition, operating results and prospects. If investors find our common stock less attractive as a result of our reduced disclosures, there may be a less active trading market for our common stock and our stock price may decline or be more volatile. In light of the increase in our stock price during 2018, we expect to cease to qualify as a "smaller reporting company" once our status is reassessed under applicable SEC rules.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. 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 the subsequent testing by our independent registered public accounting firm conducted in connection with Section 404(b) of the Sarbanes-Oxley Act after we no longer qualify as an "emerging growth company" or a "smaller reporting company," 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 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. However, for as long as we are an "emerging growth company" or a "smaller reporting company" under applicable SEC rules and regulations, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. 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 recently and in past years experienced significant stock price volatility. 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			Exhibit Number	Provided Herewith
		Form	File No.	Date of First Filing		
3.1	Amended and Restated Certificate of Incorporation as currently in effect.					X
3.2	Tandem Diabetes Care, Inc. Amended and Restated Bylaws as currently in effect.	S-1/A	333-191601	1-Nov-13	3.5	
10.1*	Tandem Diabetes Care, Inc. Amended And Restated 2013 Stock Incentive Plan	DEF 14A	001-36189	26-Apr-18	Appendix B	
10.2*	Amended And Restated 2013 Employee Stock Purchase Plan	DEF 14A	001-36189	26-Apr-18	Appendix C	
10.3*	Kim Blickenstaff Letter Agreement regarding employment terms	10-Q	001-36189	30-Jul-18	10.3	
10.4*	2018 Cash Bonus Plan for Executives	10-Q	001-36189	30-Jul-18	10.4	
10.5**	Development Agreement, dated June 4, 2015 by and between Tandem Diabetes, Care, Inc. and Dexcom, Inc.					X
31.1	Certification of Kim D. Blickenstaff, 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 Kim D. Blickenstaff, 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

* Indicates management contract or compensatory plan.
** Confidential treatment has been granted with respect to certain portions of this exhibit pursuant to an application for confidential treatment sent to the Securities and Exchange Commission. Such portions are omitted from this filing and have been filed separately with the Securities and Exchange Commission.
*** 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: November 1, 2018

By: /s/ Kim D. Blickenstaff
Kim D. Blickenstaff
President, Chief Executive Officer and Director
(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)

Exhibit 3.1

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
TANDEM DIABETES CARE, INC.

Kim D. Blickenstaff hereby certifies that:

ONE: He is the President and Chief Executive Officer of Tandem Diabetes Care, Inc., a Delaware corporation (the "Corporation").

TWO: The Certificate of Incorporation of said Corporation was originally filed with the Secretary of State of Delaware on January 7, 2008.

THREE: The Amended and Restated Certificate of Incorporation of this Corporation, as amended through October 9, 2017, is hereby amended and restated to read in full as follows:

*** * ***

ARTICLE 1 - NAME

The name of this Corporation is Tandem Diabetes Care, Inc.

ARTICLE 2 - REGISTERED OFFICE AND AGENT

The address of the registered office of the Corporation in the State of Delaware is 2711 Centerville Road, Suite 400, in the City of Wilmington, County of New Castle, 19808. The name of its registered agent at such address is Corporation Service Company.

ARTICLE 3 - PURPOSE

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware, as amended from time to time. The Corporation shall have perpetual existence.

ARTICLE 4 - CAPITAL STOCK

A. Classes of Stock. This Corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares of capital stock which this Corporation has authority to issue is Two Hundred Five Million (205,000,000) shares. Two Hundred Million (200,000,000) shares shall be designated Common Stock, $0.001 par value per share and Five Million (5,000,000) shares shall be designated Preferred Stock, $0.001 par value per share.

B. Preferred Stock. The Board of Directors is authorized, subject to limitations prescribed by law, to provide for the issuance of the shares of Preferred Stock in series, and by filing a certificate pursuant to the applicable law of the State of Delaware, 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, including, without limitation, the number of shares constituting that series and the distinctive designation of that series; the dividend rate, if any, on the shares of that series, whether dividends shall be cumulative, and, if so, from which date or dates, and the relative rights of priority, if any, of payment of dividends on shares of that series; whether that series shall have voting rights, in addition to the voting rights provided by law,

and if so, the terms of such voting rights; whether that series shall have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the Board of Directors shall determine; whether or not the shares of that series shall be redeemable, and, if so, the terms and conditions of such redemption, including the date upon or after which they shall be redeemable, and the amount per share payable in case of redemption, which amount may vary under different conditions and at different redemption dates; whether that series shall have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund; the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the Corporation, and the relative rights of priority, if any, of payment of shares of that series; and any other relative rights, preferences and limitations of that series. The Board of Directors is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

Except as otherwise required by law, holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon by law or pursuant to this Certificate of Incorporation (including any certificate of designation filed with respect to any series of Preferred Stock).

C. Reverse Stock Split. Effective immediately upon the filing of a Certificate of Amendment of Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware on October 9, 2017 (the "Effective Time"), each ten (10) shares of Common Stock then issued and outstanding, or held in the treasury of the Corporation, immediately prior to the Effective Time shall automatically be reclassified and converted into one (1) share of Common Stock, without any further action by the Corporation or the respective holders of such shares (the "Reverse Stock Split"). No fractional shares shall be issued in connection with the Reverse Stock Split. A holder of Common Stock who would otherwise be entitled to receive a fractional share as a result of the Reverse Stock Split will receive one whole share of Common Stock in lieu of such fractional share.

ARTICLE 5 - DIRECTORS AND STOCKHOLDERS

A. Board of Directors. The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors and elections of directors need not be by written ballot unless otherwise provided in the Bylaws. The number of directors of the Corporation shall be fixed from time to time by the Board of Directors either by a resolution or Bylaw adopted by the affirmative vote of a majority of the entire Board of Directors. Subject to the rights of the holders of any series of Preferred Stock to elect additional directors under specified circumstances, the directors shall be divided into three classes designated as Class I, Class II and Class III, respectively. The Board of Directors is authorized to assign members of the Board of Directors already in office to such classes at the time the classification becomes effective. At the first annual meeting of stockholders following the initial classification of the Board of Directors, the term of office of the Class I directors shall expire and Class I directors shall be elected for a full term of three years. At the second annual meeting of stockholders following such initial classification, the term of office of the Class II directors shall expire and Class II directors shall be elected for a full term of three years. At the third annual meeting of stockholders following such initial classification, the term of office of the Class III directors shall expire and Class III directors shall be elected for a full term of three years. At each succeeding annual meeting of stockholders, directors shall be elected for a full term of three years to succeed the directors of the class whose terms expire at such annual meeting. During such time or times that applicable law prohibits a classified Board of Directors as described in Section A of Article 5, all directors shall be elected at each annual meeting of stockholders to hold office until the next annual meeting.

Notwithstanding the foregoing provisions of this section, each director shall serve until his or her successor is duly elected and qualified or until his or her death, resignation or removal. No decrease in the number of directors constituting the Board of Directors shall shorten the term of any incumbent director.

Subject to the rights of any series of Preferred Stock that may be designated from time to time to elect additional

directors under specified circumstances, neither the Board of Directors nor any individual director may be removed without cause. Subject to any limitation imposed by applicable law, any individual director or directors may be removed with cause by the affirmative vote of the holders of a majority of the voting power of all of the then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class.

Subject to the rights of the holders of any series of Preferred Stock that may be designated from time to time, any vacancies on the Board of Directors resulting from death, resignation, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors, shall, unless the Board of Directors determines by resolution that any such vacancies or newly created directorships shall be filled by the stockholders, except as otherwise provided by law, be filled only by the affirmative vote of a majority of the directors then in office, even though less than a quorum of the Board of Directors, and not by the stockholders. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

B. Meetings of Stockholders. Meetings of the stockholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept (subject to any provision contained in the Delaware statutes) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or by the Bylaws of the Corporation.

C. Special Meetings of Stockholders. Except as otherwise required by statute and subject to the rights, if any, of the holders of any series of Preferred Stock, special meetings of the stockholders of the Corporation may be called only by the Board of Directors acting pursuant to a resolution approved by the affirmative vote of a majority of the Board of Directors then in office, and special meetings of stockholders may not be called by any other person or persons. Only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders of the Corporation.

D. Advance Notice Requirements. Advance notice of stockholder nominations for the election of directors and of business to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner and to the extent provided in the Bylaws of the Corporation.

E. Stockholder Action by Written Consent. Any action required or permitted to be taken by stockholders may be effected only at a duly called annual or special meeting of stockholders and may not be effected by a written consent or consents by stockholders in lieu of such a meeting.

ARTICLE 6 - LIMITATION OF DIRECTORS' LIABILITY

The liability of a director of the Corporation for monetary damages shall be eliminated to the fullest extent permitted by applicable law. If the Delaware General Corporation Law is amended to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated to the fullest extent permitted by the Delaware General Corporation Law, as so amended. Any repeal or modification of this Article 6 shall only be prospective and shall not affect the rights or increase the liability of any director under this Article 6 in effect at the time of the alleged occurrence of any action or omission to act giving rise to such liability.

ARTICLE 7 - INDEMNIFICATION

To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) its directors, officers, employees and agents (and any other persons to which applicable law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by such applicable law. If applicable law is amended after approval by the stockholders of this Article 7 to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director to the Corporation shall be eliminated or limited to the fullest extent

permitted by applicable law as so amended. Any repeal or modification of this Article 7 shall only be prospective and shall not affect the rights or limit the indemnification of any director, officer, employee or agent under this Article 7 in effect at the time of the alleged occurrence of any action or omission to act giving rise to such indemnification.

ARTICLE 8 - EXCLUSIVE JURISDICTION OF DELAWARE COURTS

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or the Corporation's Certificate of Incorporation or Bylaws, or (iv) any action asserting a claim against the Corporation governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of capital stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article 8.

ARTICLE 9 - AMENDMENT OF CERTIFICATE OF INCORPORATION

The Corporation reserves the right to amend or repeal any provision contained in this Certificate of Incorporation in the manner prescribed by the laws of the State of Delaware and all rights conferred upon stockholders are granted subject to this reservation; provided, however, that notwithstanding any other provision of this Certificate of Incorporation, or any provision of law which might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any particular class or series of the Corporation required by law or by this Certificate of Incorporation or any certificate of designation filed with respect to a series of Preferred Stock, the

affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class, shall be required to alter, amend or repeal Article 5, Article 6, Article 7, Article 8, Article 9 or Article 10 of this Certificate of Incorporation.

ARTICLE 10 - AMENDMENT OF BYLAWS

Subject to the rights of the holders of any series of Preferred Stock that may be designated from time to time, the Board of Directors is expressly empowered to adopt, amend or repeal the Bylaws of the Corporation. Any adoption, amendment or repeal of the Bylaws by the Board of Directors shall require the approval of a majority of the authorized number of directors. The stockholders shall also have power to adopt, amend or repeal the Bylaws, subject to any restrictions which may be set forth in this Certificate of Incorporation (including any certificate of designation that may be filed from time to time); provided, however, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by this Certificate of Incorporation, such action by stockholders shall require the affirmative vote of the holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then outstanding shares of capital stock of the Corporation entitled to vote generally in the election of directors, voting together as a single class.

*** * * ***

FOUR: This Amended and Restated Certificate of Incorporation has been duly adopted by the Corporation's Board of Directors and stockholders in accordance with the applicable provisions of Sections 228, 242 and 245 of the General Corporation Law of the State of Delaware.

[**Signature Page Follows**]

IN WITNESS WHEREOF, Tandem Diabetes Care, Inc. has caused this Amended and Restated Certificate of Incorporation to be executed by the undersigned, and the undersigned has executed this certificate and affirms the foregoing as true under penalty of perjury this day of October 9, 2017.

Tandem Diabetes Care, Inc.

By: /s/ Kim D. Blickenstaff
Kim D. Blickenstaff
President and Chief Executive Officer

DEVELOPMENT AGREEMENT

[***]: CONFIDENTIAL PORTIONS OMITTED AND FILED SEPARATELY WITH THE COMMISSION.

This Development Agreement (this "**Agreement**") is made and entered into on June 4, 2015 (the "**Effective Date**") by and between Tandem Diabetes Care, Inc., a Delaware corporation, having a principal place of business at 11045 Roselle St., San Diego, CA 92121 ("**Tandem**") and DexCom, Inc., a Delaware corporation, having a principal place of business at 6340 Sequence Drive, San Diego, CA 92121 ("**DexCom**").

BACKGROUND

A. DexCom is in the business of developing and commercializing continuous glucose monitoring systems, and is currently developing the DexCom G6 System (as defined below).

B. Tandem has developed, and is developing, current and next generations of insulin infusion pump systems.

C. The parties believe it is in each of their best interests to enable Tandem to adapt the Tandem Display Device (defined below) to identify, receive, and display information from the DexCom G6 System, which is adapted to communicate information on a one-way basis between a DexCom Sensor (defined below) via the DexCom BT CGM Transmitter (defined below) to an external receiver or other display, such as the Tandem Display Device.

The parties therefore agree as follows:

I. Definitions

1.1. "**Affiliates**" means any corporation or other entity that is directly or indirectly controlling, controlled by or under common control with a party. For the purpose of this definition, "control" means the direct or indirect ownership of more than fifty percent (50%) of the capital stock of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, interests entitled to vote in the election of the corresponding managing authority).

1.2. **"Communication Protocol"** will have the meaning given to that term in Section 2.2 below.

1.3. "**DexCom BT CGM Transmitter**" means the transmitter component of the DexCom G6 System that is configured to transmit information from a DexCom Sensor via Bluetooth to any receiver adapted to identify, receive, and display such information, and is also controlled from an authenticated receiver, such as the DexCom Receiver, and the DexCom CGM Smartphone App.

1.4. "**DexCom CGM-Enabled Tandem Display Device**" means a Tandem Display Device comprising a receiver or other component of the Tandem Insulin Infusion Pump

configured to identify, receive, interpret, process and/or display DexCom Sensor Information from a DexCom BT CGM Transmitter and control the DexCom BT CGM Transmitter. A DexCom CGM-Enabled Tandem Display Device will be independently developed by Tandem pursuant to Section 2.1 and is not, and will not be, a component of a DexCom G6 System.

1.5. **DexCom CGM Smartphone App**" means the smartphone application component of the DexCom G6 System that identifies, receives, deciphers and displays information transmitted by a DexCom BT CGM Transmitter from a DexCom Sensor, and also enables control of the DexCom BT CGM Transmitter by receiving and transmitting data to the DexCom G6 System, such as configuration settings and calibration values.

1.6. "**DexCom G6 System**" means DexCom's sixth generation continuous glucose monitoring system comprised of the following components, all designed, developed and manufactured by DexCom: a DexCom Sensor, a DexCom BT CGM Transmitter, DexCom Sensor Information, the Communication Protocol, a DexCom Receiver, and the DexCom CGM Smartphone App.

1.7. "**DexCom Receiver**" means a component of the DexCom G6 System that identifies, receives, deciphers and displays information transmitted by a DexCom BT CGM Transmitter from a DexCom Sensor, and also enables control of the DexCom Transmitter by receiving and transmitting data to the DexCom G6 System, such as configuration settings and calibration values.

1.8. "**DexCom Sensor**" means the component of the DexCom G6 System comprising a continuous glucose monitoring electrode sensor, adapted to (i) penetrate the patient's skin to come into contact with the patient's interstitial fluid, (ii) measure interstitial fluid glucose level, and (iii) be operably coupled to a DexCom BT CGM Transmitter to communicate the blood glucose value as measured by the DexCom Sensor to a separate receiver.

1.9. "**DexCom Sensor Information**" consists of a DexCom BT CGM Transmitter interface spec that specifies contents of the transmitter broadcast message and the available control functions (the "**Specification**"). The transmitter broadcast message will contains items such as estimated glucose value, device display time stamp information, the trend arrow and calibration confidence intervals as stored in the DexCom BT CGM Transmitter. The control functions provide the commands required to start session, stop session and calibrate. Any additional sensor information to be shared must be agreed in writing by both parties or shall be the result of DexCom's updating of the Specification, which shall be permitted without requiring compliance with Section 10.7. The term "DexCom Sensor Information" shall in no way be construed to include the Raw Data.

1.10. "**Effective Date**" is the date set forth in the preamble above.

1.11. "**Integrated System**" shall mean a Tandem System that implements the Communication Protocol and is capable, among other things, of receiving and displaying continuous glucose monitoring data generated by the DexCom G6 System.

1.12. "**Intellectual Property Rights**" means (collectively): copyright rights (including, without limitation, the exclusive right to use, reproduce, modify, distribute, publicly display and publicly perform the copyrighted work), trademark rights (including, without limitation trade names, trademarks, service marks, and trade dress), patent rights (including, without limitation, the exclusive right to make, have made, import, use, sell and offer to sell), trade secrets, rights of publicity, authors' and moral rights, goodwill and all other intellectual and industrial property rights as may exist now and/or hereafter come into existence and all renewals, reissues and extensions thereof, regardless of whether such rights arise under the laws of the United States or any other U.S. state or other country or jurisdiction.

1.13. "**Raw Data**" means any raw data used by the DexCom G6 System or any other data generated or stored by the DexCom G6 System that is not included in the definition of DexCom Sensor Information.

1.14. "**Tandem Display Device**" means a device used in connection with, or component of the, Tandem Insulin Infusion Pump that communicates with and controls the Tandem Insulin Infusion Pump and which also stores and processes data related to the Tandem System.

1.15. "**Tandem Insulin Infusion Pump**" means a subcutaneous infusion pump for insulin delivery, either alone or together with other medicaments.

1.16. "**Tandem System**" means a subcutaneous infusion system comprised of the following components: a Tandem Insulin Infusion Pump and a Tandem Display Device.

II. Development & Regulatory

(a) Tandem Responsibilities. At Tandem's sole cost, Tandem intends to develop a version of the Tandem System comprising a DexCom CGM-Enabled Tandem Display Device. Tandem shall be solely responsible for all design, development, regulatory and commercialization activities associated with such DexCom CGM-Enabled Tandem Display Device. Tandem shall ensure that any DexCom CGM-Enabled Tandem Device shall not interfere with the ability of the DexCom BT CGM Transmitter to remain paired and communicate with the DexCom CGM Smartphone App at all times, notwithstanding any pairing with the Tandem System.

(b) DexCom Responsibilities. At DexCom's sole cost, DexCom intends to develop a DexCom G6 System. DexCom shall be solely responsible for all design, development, regulatory and commercialization activities associated with such DexCom G6 System. Upon completion of such development, DexCom will provide Tandem with a communication protocol that permits a DexCom CGM-Enabled Tandem Display Device to identify, receive and display DexCom Sensor Information and to control the DexCom

BT CGM Transmitter (the "**Communication Protocol**"). Upon request, DexCom agrees to provide commercially reasonable assistance in response to questions from Tandem to facilitate Tandem's implementation of the Communication Protocol. In addition, if reasonably necessary for Tandem to secure regulatory approval for the commercialization of a Tandem System, or a component thereof, DexCom agrees to permit Tandem to reference DexCom's own regulatory filings for the DexCom G6 System.

(c) Costs. Each party shall bear its own costs.

III. Ownership & License

(a) Ownership. The parties do not intend for there to be any "joint inventions" under this Agreement and, except as set forth in Section 3.2, this Agreement does not comprise an assignment or license of any intellectual property, trade secrets or confidential information by either party to the other. DexCom (and/or its Affiliates) will own and retain their Intellectual Property Rights. Tandem (and/or its Affiliates) will own and retain their Intellectual Property Rights.

(b) License. DexCom hereby grants Tandem a royalty-free, worldwide, non-exclusive license to (i) use the Communication Protocol for the purpose of developing and commercializing a DexCom CGM-Enabled Tandem Display Device, including the right to make, have made, use, sell, offer to sell, have sold and import the DexCom CGM-Enabled Tandem Display Device; and (ii) use the trademarks, trade names and other marketing names used by DexCom for the DexCom G6 System solely in connection with Tandem's advertising, promotion, marketing and sale of the Tandem System, and in related brochures and other materials, in full accordance with all guidelines and instructions as DexCom may deliver to Tandem from time to time in DexCom's sole discretion.

(c) Limitations on Use. Tandem agrees not to distribute, license, sublicense or otherwise transfer the Communication Protocol to any third party. Tandem shall have no right under this Agreement to in any way distribute the Communication Protocol, or to intercept, propagate, reverse engineer, disassemble, de-encrypt, or derive the source code for the software or bios included in any DexCom G6 System, or any component thereof. Tandem is not granted any right to the Raw Data received or generated by any DexCom G6 System and/or used by it to produce output such as timestamps, measurements or other data, and will not try to derive, de-encrypt or intercept any of such Raw Data. Tandem shall not access or use any information within the DexCom G6 System other than the information contained in the Specification. Tandem shall be prohibited from using the Communication Protocol for any purposes other than as set forth in this Agreement. DexCom shall not access or use any information within the Tandem System other than as set forth in this Agreement.

(d) No Other Restrictions. For the avoidance of doubt, except as expressly agreed by the parties in writing, (i) DexCom will not be restricted from distributing, licensing,

transferring, or otherwise exploiting the DexCom G6 System or any component thereof, or any Intellectual Property Rights therein, and (ii) Tandem will not be restricted from distributing, licensing, transferring, or otherwise exploiting the Tandem System or any component thereof, or any Tandem Intellectual Property Rights therein.

IV. Commercialization

(a) DexCom shall have sole discretion to decide whether to complete development of and commercialize the DexCom G6 System and shall be under no obligation to complete such development or commercialization as a result of this Agreement.

(b) Tandem shall have sole discretion to decide whether to complete development of and commercialize a version of the Tandem System comprising a DexCom CGM-Enabled Tandem Display Device and shall be under no obligation to complete such development or commercialization as a result of this Agreement. Tandem and DexCom will use commercially reasonable efforts to develop a mutually acceptable written plan to provide training and customer and technical support for any mutual customers prior to Tandem's submission of any application to regulatory authorities to secure regulatory approval for the commercialization of a DexCom CGM-Enabled Tandem Display Device.

(c) If DexCom and Tandem, respectively, complete the development and commercialization of (i) the DexCom G6 System, and (ii) a DexCom CGM-Enabled Tandem Display Device, then the parties will use commercially reasonable efforts to develop a plan to cooperate on marketing such products to their respective customers.

(d) Tandem hereby acknowledges that DexCom may discontinue its support of the DexCom G6 System [***]. DexCom agrees to[***]. Tandem further acknowledges that DexCom has no obligation to[***].

V. Representations and Warranties

(a) By Tandem. Tandem warrants and represents to DexCom that (i) Tandem has the full right and authority to enter into this Agreement and grant the rights granted herein; (ii) Tandem has not previously granted and will not grant any right in conflict with any of the rights granted herein; (iii) to Tandem's knowledge on the Effective Date, there is no existing or threatened action, suit or claim pending against it with respect to its right to enter into and perform any of its obligations under this Agreement.

(b) By DexCom. DexCom warrants and represents to Tandem that (i) DexCom has the full right and authority to enter into this Agreement and grant the rights granted herein; (ii) DexCom has not previously granted and will not grant any right in conflict with any of the rights granted herein; (iii) to DexCom's knowledge on the Effective Date, there is no existing or threatened action, suit or claim pending against it with respect to its right to enter into and perform its obligations under this Agreement.

(c) Disclaimer of Warranties. EXCEPT AS EXPRESSLY SET FORTH IN THIS SECTION 5, EACH OF TANDEM AND DEXCOM MAKES NO REPRESENTATIONS OR WARRANTIES UNDER THIS AGREEMENT, AND EXPRESSLY DISCLAIMS ANY WARRANTIES EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY, AND NON-INFRINGEMENT.

VI. Confidentiality

(a) Confidential Information. Except as expressly provided in this Agreement, during the Term and for[***], any party receiving Confidential Information, as defined below (the "**Receiving Party**"), will not publish or otherwise disclose and will not use such Confidential Information for any purpose other than carrying out Receiving Party's obligations under this Agreement. For purposes of this Agreement, "**Confidential Information**" means any information furnished by a party (the "**Disclosing Party**") pursuant to this Agreement which is confidential or proprietary to the Disclosing Party, including, without limitation, the Specifications. Notwithstanding the foregoing, Confidential Information will not include information that, in each case as demonstrated by the Receiving Party with reliable written documentation:

A. **was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure;**

B. **was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving party;**

C. **became generally available to the public or otherwise part of the public domain after its disclosure hereunder and other than through any act or omission of the Receiving Party in breach of this Agreement; or**

D. **was subsequently lawfully disclosed to the Receiving Party by a person without breaching a duty of confidentiality or developed by the Receiving Party without use of, reliance on, or reference to any information or materials disclosed by the Disclosing Party.**

(b) Permitted Disclosures. Notwithstanding Section 6.1, a Receiving Party may use or disclose Confidential Information solely to the extent such use or disclosure is reasonably necessary in complying with an order of a court of law, prosecuting or defending litigation, complying with applicable governmental regulations, submitting information to tax or other governmental authorities, or conducting clinical trials, provided that if a Receiving Party is required to make any such disclosure of Confidential Information, it will give the other party reasonable advanced notice of the disclosure, and use its reasonable efforts to secure confidential treatment of the information prior to its disclosure (whether through protective orders or otherwise).

(c) Return of Confidential Information. Within 30 days after the effective date of any termination of this Agreement, except to the extent reasonably necessary for a party to exercise any rights that expressly survive the termination of the Agreement, each party will return to the other party (where practicable), or at the Receiving Party's option, destroy and provide written certification of the destruction of, all tangible materials that contain the Disclosing Party's Confidential Information.

(d) Confidentiality of Agreement; No Press Release. Except to the extent required to comply with applicable law, and subject to the requirements of Section 6.2, neither party will make any disclosure to any third party, and no press release will issue, relating to the existence of this Agreement, any term hereof, or any transaction contemplated herein without prior written agreement of the other party.

VII. Indemnification and Defense of Infringement

(a) DexCom will defend and indemnify Tandem, its Affiliates, and each of its directors, officers, employees, agents, successors and assigns (collectively, "**Tandem Indemnitees**"), against all third-party claims, suits and proceedings, and will hold the Tandem Indemnitees harmless against all judgments, settlements, costs, liabilities and expenses (including without limitation, reasonable attorneys' fees and litigation costs) (collectively, "**Losses**") payable to third parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) DexCom's breach of the[***],(ii) the [***], or (iii) physical injury (including death) and/or property damage[***], excluding[***].

(b) Tandem will defend and indemnify DexCom, its Affiliates, and each of its directors, officers, employees, agents, successors and assigns (collectively, "**DexCom Indemnitees**"), against all third-party claims, suits and proceedings, and will hold the DexCom Indemnitees harmless against all Losses payable to third parties in connection with such claims, suits and proceedings, to the extent arising from or occurring as a result of: (i) Tandem's breach of the[***], (ii) the[***], or (iii) physical injury (including death) and/or property damage[***], excluding[***].

(c) If the manufacture or use of the Integrated System results in a claim, suit or proceeding in which DexCom and Tandem are both entitled to indemnification by the other party pursuant to Sections 7.1 and 7.2, then the parties will discuss in good faith their cooperation in connection with such matter, and shall discuss in good faith an equitable allocation of each party's indemnification obligations under this Section 7.

(d) If the manufacture or use of the Integrated System results in a third-party claim, suit, allegation, action or proceeding against Tandem or DexCom alleging infringement of a claim of a patent or alleges infringement or misappropriation of some other intellectual property right of such third party and neither DexCom nor Tandem is entitled to indemnification pursuant to Sections 7.1 and 7.2 (an "**Integrated System Infringement Action**"), such party will promptly notify the other party in writing. The parties will

[***] and [***] of any Integrated System Infringement Action. The parties will [***] concerning any Integrated System Infringement Action and, in the [***] that the[***], the parties[***].

(e) Any party seeking indemnification hereunder (the "**Indemnitee**") will promptly notify the indemnifying party (the "**Indemnitor**") of any claim, loss, or expense likely to lead to a claim for indemnification, along with all material related information. The Indemnitor will[***], except that[***]. The Indemnitee may[***]. The Indemnitee will[***]. The Indemnitee may[***]. In addition, the Indemnitee may[***].

(f) Notwithstanding the foregoing, an Indemnitor under this Section 7 has no obligation for any Losses to the extent resulting from (i)[***], or (ii)[***].

VIII. Term and Termination

(a) Term. The initial term of this Agreement will commence on the Effective Date and will continue for five (5) years thereafter (the "**Initial Term**"). Subsequent to the Initial Term, the term of this Agreement shall automatically renew and be extended for additional one (1) year periods, unless either party notifies the other at least ninety (90) days prior to the expiration of the then current term (the total period during which this Agreement is effective being the "**Term**").

(b) Termination With Cause or Due to Bankruptcy. Either DexCom or Tandem may terminate this Agreement by written notice if the other materially breaches or defaults in the performance of any of its material obligations hereunder, and such default continues for [***] after the non-breaching party provides written notice of the breach to the breaching party. Either party may terminate this Agreement immediately if the other party: (i) liquidates or dissolves, or (ii) becomes subject to any bankruptcy or insolvency proceeding under federal or state law that is not dismissed within[***].

(c) Effect of Termination.

A. **Accrued Rights and Obligations. Termination of this Agreement will not relieve either party for liabilities or obligations incurred pursuant to the terms and conditions of this Agreement prior to termination.**

B. **Survival. In addition, Articles 1, 3.1, 3.3, 3.4, 4.4, 5, 6, 7, 8, 9 and 10 will survive expiration or termination of this Agreement. Further, Section 3.2 will survive expiration or termination of this Agreement to the extent reasonably necessary for Tandem to satisfy ongoing warranty obligations and to provide ongoing service and support to any customer who originally acquired a DexCom CGM-Enabled Tandem Display Device during the Term of this Agreement.**

IX. Limitation of Liability

EXCEPT WITH RESPECT TO A BREACH OF AN OBLIGATION UNDER SECTION 6 OR 10.7, OR CLAIMS REQUIRING INDEMNIFICATION PURSUANT TO SECTIONS 7.1, 7.2, 7.3 OR 7.4, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER OR ANY OTHER ENTITY FOR COSTS OF PROCUREMENT OF SUBSTITUTE GOODS, LOST PROFITS, OR ANY OTHER SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES, HOWEVER CAUSED AND UNDER ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE. THESE LIMITATIONS SHALL APPLY WHETHER OR NOT THE BREACHING PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY PROVIDED HEREIN.

IF EITHER PARTY TERMINATES THIS AGREEMENT IN ACCORDANCE WITH ANY OF ITS PROVISIONS, NEITHER PARTY SHALL BE LIABLE TO THE OTHER, BECAUSE OF SUCH TERMINATION, FOR COMPENSATION, REIMBURSEMENT OR DAMAGES ON ACCOUNT OF THE LOSS OF PROSPECTIVE PROFITS OR ANTICIPATED SALES OR ON ACCOUNT OF EXPENDITURES, INVENTORY, INVESTMENTS, LEASES OR COMMITMENTS IN CONNECTION WITH THE BUSINESS OR GOODWILL OF TANDEM OR DEXCOM.

X. Miscellaneous

(a) Subcontractors. Either party may subcontract the performance of its obligations under this Agreement to third parties, provided that such third parties are bound by terms and conditions consistent with this Agreement, including restrictions with respect to the protection and use of Confidential Information which are no less stringent than those set forth in this Agreement and each party shall be fully responsible for the performance of its subcontractor(s).

(b) Force Majeure. Nonperformance of any party (except for payment obligations) will be excused to the extent that performance is rendered impossible by strike, fire, earthquake, flood, governmental acts or orders or restrictions, or any other reason where failure to perform is beyond the reasonable control and not caused by the gross negligence or willful misconduct of the nonperforming party.

(c) No Implied Waivers; Rights Cumulative. No failure on the part of DexCom or Tandem to exercise and no delay in exercising any right under this Agreement, or provided by statute or at law or in equity or otherwise, will impair, prejudice or constitute a waiver of any such right, nor will any partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right.

(d) Independent Contractors. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute DexCom or Tandem as partners in the legal sense. No party hereto will have any express or implied right or authority to assume or create any

obligations on behalf of or in the name of any other party or to bind any other party to any contract, agreement or undertaking with any third party.

(e) Notices. All notices, requests and other communications hereunder will be in writing and will be personally delivered or sent by registered or certified mail, return receipt requested, postage prepaid, in each case to the respective address specified below, or such other address as may be specified in writing to the other parties hereto:

Tandem:	Tandem Diabetes Care 11045 Roselle St. San Diego, CA 92121 Attn: Chief Executive Officer with copy to: General Counsel
DexCom:	DexCom, Inc. 6340 Sequence Drive San Diego, CA 92121 Attn: Legal Department

(f) Assignment. This Agreement will not be assignable by either party to any third party without the written consent of the other party hereto; provided that either party may assign this Agreement to a third party acquiring all or substantially all of the business or assets of such party, including by way of merger, sale of assets, consolidation, change of control or operation of law upon written notice to the other party to this Agreement; provided further however, that Tandem shall make no such assignment to a competitor of DexCom without DexCom's written consent, which determination and consent shall be made by DexCom in its sole discretion.

(g) Standstill. Except as permitted by the last sentence of this Section 10.7, during the Term of this Agreement and for a period of twelve (12) months thereafter, without the prior written consent of the Board of Directors of Tandem, DexCom and its officers, directors and Affiliates, will not directly or indirectly in any manner: (i) acquire, announce an intention to acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, gift or otherwise, any direct or indirect beneficial ownership (within the meaning of Rule 13d-3 under the Securities Exchange Act of 1934 (the "**Exchange Act**")) or interest in any securities or direct or indirect rights, warrants or options to acquire, or securities convertible into or exchangeable for, any securities of Tandem (ii) make, or in any way participate in, directly or indirectly, alone or in concert with others, any "solicitation" of "proxies" to vote (as such terms are used in the proxy rules of the SEC promulgated pursuant to Section 14 of the Exchange Act) any securities of Tandem with respect to any business combination, restructuring, recapitalization or similar transaction; (iii) form, join or in any way participate in a "group" within the meaning of Section 13(d)(3) of the Exchange Act with respect to any voting securities of Tandem; (iv) acquire, announce an intention to acquire, or agree to acquire, directly or indirectly, alone or in concert with others, by purchase, exchange or otherwise, (a) any of the assets, tangible or intangible, of Tandem or (b) direct or indirect rights, warrants or options to acquire any assets of Tandem, other than in the ordinary course of business; (v) enter into

any arrangement or understanding with, or otherwise assist or encourage, others to do any of the actions restricted or prohibited under clauses (i), (ii), (iii) or (iv) of this Section 10.7; (vi) otherwise act in concert with others, to seek to offer to Tandem or any of its stockholders any business combination, restructuring, recapitalization or similar transaction to or with Tandem, or (vii) take any action to control the management, Board of Directors or policies of Tandem. Notwithstanding the above, cumulative acquisitions by DexCom, including any Affiliate of DexCom, of less than one percent (1%) of Tandem's outstanding common shares shall not be deemed a breach of this provision.

(h) Modifications. No amendment or modification of any provision of this Agreement will be effective unless in writing signed by all parties hereto. No provision of this Agreement will be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by all parties.

(i) Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, all other provisions hereof will remain in full force and effect in such jurisdiction and will be liberally construed in order to carry out the intentions of the parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability will not affect the validity, legality or enforceability of such provision in any other jurisdiction.

(j) Governing Law. This Agreement and any dispute arising from the performance or breach hereof will be governed by and construed and enforced in accordance with, the laws of the State of Delaware without regard for conflicts of laws principles.

(k) Counterparts. This Agreement may be executed in two or more counterparts, each of which will be deemed an original, and all of which together, will constitute one and the same instrument.

(l) Headings. Headings used herein are for convenience only and will not in any way affect the construction of or be taken into consideration in interpreting this Agreement.

(m) Entire Agreement. This Agreement, including the Attachments attached hereto, constitutes the entire agreement with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, whether written or oral, between DexCom and Tandem with respect to such subject matter. For the avoidance of doubt, DexCom and Tandem acknowledge and agree that this Agreement does not terminate, amend or otherwise modify either (i) the Amended and Restated Development and Commercialization Agreement between the parties dated as of January 4, 2013 or (ii) the G5 Development Agreement between the parties entered into concurrently with this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be signed by duly authorized officers or representatives as of the date first above written.

DexCom, Inc.
By: /s/ Kevin Sun for Jess Roper
Jess Roper
Title: Senior Vice President and Chief Financial Officer

Date: June 4, 2015

Tandem Diabetes Care, Inc.
By: /s/ Kim D. Blickenstaff
Print Name: Kim D. Blickenstaff
Title: President & Chief Executive Officer

Date: June 4, 2015

Exhibit 31.1

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

I, Kim D. Blickenstaff, 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/ Kim D. Blickenstaff
Kim D. Blickenstaff
President, Chief Executive Officer and Director

Dated: November 1, 2018

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 preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

Tandem Diabetes Care, Inc.

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

Dated: November 1, 2018

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 September 30, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kim D. Blickenstaff, 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.

Date: November 1, 2018

/s/ Kim D. Blickenstaff
Kim D. Blickenstaff
President and 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 September 30, 2018, 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.

Date: November 1, 2018

/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.